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1801 Route 51
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U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

June 4, 2012

REPLY TO A NOTICE OF NONCONFORMANCE

Docket No.: 99901412 Inspection Report No.: 99901412/2012-201

Nonconformances: 99901412/2012-201-02 through 99901412/2012-201-06

To Whom It May Concern:

Attached please find our replies to each of the subject nonconformances. For each nonconformance, provided are:

- Reason for the Nonconformance,
- Corrective Steps That Have Been Taken and the Results Achieved,
- Corrective Steps That Will Be Taken, and
- Date When Corrective Action Will Be Completed.

Please don't hesitate to contact me if you have any questions or need further information.

Sincerely,

Gary Felicetti

Gary Felicetti
QA Manager
1801 Route 51
Pittsburgh, PA 15025
412.387.1017

Cc: Chief, Mechanical Vendor Branch
Division of Construction Inspection and Operational Programs
Office of New Reactors
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attachments: Attachment 1: Nonconformance 99901412/2012-201-02
Attachment 2: Nonconformance 99901412/2012-201-03
Attachment 3: Nonconformance 99901412/2012-201-04
Attachment 4: Nonconformance 99901412/2012-201-05
Attachment 5: Nonconformance 99901412/2012-201-06

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Attachment 1

REPLY TO A NOTICE OF NONCONFORMANCE

Nonconformance 99901412/2012-201-02

Provided below please find our reply to the subject nonconformance, summarized as follows:

As of March 23, 2012, Clark failed to ensure that adequate test instrumentation was used in safety-related testing. Specifically:

1. *Clark used three accelerometers over a range for which they were not calibrated. During vibrational aging of the actuator (test specimen), Clark used three accelerometers that were calibrated over a range of 25 Hz to 500 Hz (whereas the test procedure required a frequency sweep from 5 Hz to 100 Hz).*
2. *Clark used uncalibrated torque wrenches to torque seismic fixture bolts and wedge bolts for the LV-1 low voltage penetration seismic testing.*

Reason for the Nonconformance

1. The piezoelectric accelerometers in question were used at a frequency (5 Hz) that was below their lowest calibration checkpoint but, because of the accelerometers' physical characteristics, still within their range of acceptable accuracy. (This was verified during their subsequent recalibration, as described below.)
2. As detailed in Nonconformance 99901412/2012-201-03, Clark had internally calibrated its torque wrenches using a torque calibrator that could not be accurately read to the required tolerances. Therefore, the calibration status of all of Clark's torque wrenches was in question (rather than being uncalibrated, per se).

Corrective Steps That Have Been Taken and the Results Achieved

1. As detailed in the Clark reply to Nonconformance 99901412/2012-201-04, we sent our accelerometer standard to Bruel & Kjaer (B&K) to be recalibrated. The calibration checkpoints for the standard ranged from 5 Hz to 5000 Hz. Our ISL Work Instruction 0766, "Calibration of Piezoelectric Accelerometers, Universal" was modified (Revision 5 dated April 23, 2012) to specify calibration checkpoints ranging from 5 Hz to 2000 Hz for our internal calibration of our working piezoelectric accelerometers. We dedicated the accelerometer standard upon its return from B&K then used it to internally recalibrate all of our working accelerometers, including the piezoelectrics. These internal recalibrations were completed on May 30, 2012. None of our working accelerometers were found to be out of tolerance at any calibration checkpoint. Therefore, there was no impact on past customer testing.
2. As detailed in the Clark reply to Nonconformance 99901412/2012-201-03, all of our torque wrenches were immediately removed from service. Brand new torque wrenches were purchased, calibrated by Exelon, and placed into service. We also decided that, going forward, none of our torque wrenches will be calibrated internally; they will all continue to be calibrated by Exelon. Our work instruction for the internal calibration of torque wrenches was removed from our QMS active directory.

   The original torque wrenches were sent for recalibration to Exelon. Because Exelon determined that some of the wrenches exceeded typical tolerance limits, by April 18, 2012 Clark evaluated the corresponding impact on all nuclear safety-related orders in which those wrenches had been used. (See details in the Clark reply to Nonconformance 99901412/2012-201-03.) Based on that evaluation, no reporting in accordance with 10 CFR Part 21 is applicable.

Corrective Steps That Will Be Taken

1. All necessary corrective steps have been taken, as described above.
2. All necessary corrective steps have been taken, as described above.

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Attachment 1

REPLY TO A NOTICE OF NONCONFORMANCE

Nonconformance 99901412/2012-201-02

Date When Corrective Action Will Be Completed

1. The Corrective Action was completed as of May 30, 2012, as described above.
2. The Corrective Action was completed as of April 18, 2012, as described above.

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Attachment 2

REPLY TO A NOTICE OF NONCONFORMANCE

Nonconformance 99901412/2012-201-03

Provided below please find our reply to the subject nonconformance, summarized as follows:

As of March 23, 2012, Clark failed to ensure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality were properly calibrated. Specifically:

1. *Clark failed to use appropriate calibration equipment to calibrate its torque wrenches. To calibrate torque wrenches with McBee (internal I.D.) numbers 4085 and 4091 Clark used a torque calibrator that had a range of 0 ft-lbs to 600 ft-lbs, marked in increments of 10 ft-lbs. The torque calibrator could not be accurately read to the tolerance required by the procedure (+/- 3 percent over a range of 20 ft-lbs to 600 ft-lbs per ISL Work Instruction 1816, "Calibration of Torque Calibrators/Torque Wrenches, Universal," Revision 4).*
2. *Clark failed to appropriately calibrate torque wrench McBee number 4091. It had a calibration tag that required 30 ft-lbs to be subtracted from the setpoint. ISL Work Instruction 1816 did not specify this special requirement. Clark did not evaluate if the special calibration requirement was appropriate over the entire range of the torque wrench calibration.*

Reason for the Nonconformance

1. Clark's self-imposed torque tolerance limits for its internal calibrations of torque wrenches were unnecessarily tight (as compared to typical limits of +/- 6 percent) and beyond the readable accuracy of its analog torque calibrator at low nominal torque values.
2. The calibration technician who was not consistently following this procedure (and two other procedures, as detailed in the Clark reply to Nonconformance 99901412/2012-201-05) felt that he could vary from them without a significant effect on accuracy and without informing responsible management.

Corrective Steps That Have Been Taken and the Results Achieved

1. All eight of our torque wrenches were immediately removed from service. Four brand new torque wrenches were purchased. The new wrenches were calibrated by an outside calibration service provider on our Approved Supplier list which has a 10 CFR Part 21/Part 50 Appendix B quality program (Exelon), then placed into service. We also decided that, going forward, none of our torque wrenches will be calibrated internally; they will all continue to be calibrated by Exelon. ISL Work Instruction 1816 was removed from our QMS active directory.

   The eight original torque wrenches were sent for recalibration to Exelon, where it was determined that some of the wrenches exceeded typical +/- 6 percent tolerances on the positive and/or negative sides. By April 18, 2012, Clark identified and reviewed all nuclear safety-related orders in which those wrenches had been used. The worst case involved the possible application of an actual torque value approximately 10% over the specified value (i.e., about 4% over the typical maximum tolerance). That customer was notified. There was no record indicating that anything unusual had occurred during that customer's testing at Clark. Since Clark uses torque wrenches only to secure a test specimen onto a test fixture for seismic and/or vibration testing, only significant levels of under- or over-torque (+/- 20 percent vs. the specified value, or worse) would have any effect during testing (which would be seen during the testing). Significant under-torque would lead to the specimen violently shaking, causing the test data to spike and the test technician to immediately cease testing until determination of the cause. Significant over-torque would lead to the fastener being stressed beyond its capacity, when shearing would occur and require replacement.

   Based on the above, we conclude that no reporting in accordance with 10 CFR Part 21 is applicable.

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Attachment 2

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Nonconformance 99901412/2012-201-03

2. The calibration technician who was not consistently following this procedure (and two other procedures, as detailed in the Clark reply to Nonconformance 99901412/2012-201-05) was terminated with qualifications revoked on March 23, 2012.

   As described above, by April 18, 2012 Clark identified and reviewed all nuclear safety-related orders in which our eight original torque wrenches had been used. Based on the analyses described above, we conclude that no reporting in accordance with 10 CFR Part 21 is applicable.

Corrective Steps That Will Be Taken

1. All necessary corrective steps have been taken, as described above.
2. All necessary corrective steps have been taken, as described above.

Date When Corrective Action Will Be Completed

1. The Corrective Action was completed as of April 18, 2012, as described above.
2. The Corrective Action was completed as of April 18, 2012, as described above.

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Attachment 3

REPLY TO A NOTICE OF NONCONFORMANCE

Nonconformance 99901412/2012-201-04

Provided below please find our reply to the subject nonconformance, summarized as follows:

As of March 23, 2012, Clark failed to review the suitability of the application of commercially calibrated measuring and test equipment (M&TE) for use in activities affecting quality as part of a commercial-grade item dedication. Specifically, Clark issued five purchase orders for commercial calibration services for M&TE and subsequently used the commercially procured M&TE in safety-related applications without dedicating the commercial-grade item.

Reason for the Nonconformance
Only three of the five referenced purchase orders applied to the Clark Dynamics facility. Of those three, one was issued to an outside calibration lab which had a 10 CFR Part 21/Part 50 Appendix B quality program at the time, and another was for the calibration of an instrument which is neither a measuring device nor used in nuclear-related jobs. The remaining purchase order was issued to Bruel & Kjaer (B&K) for the calibration of an accelerometer standard. B&K is a commercial calibration service accredited by A2LA to ISO/IEC 17025, but does not have a 10 CFR Part 21/Part 50 Appendix B quality program. We internally calibrated working accelerometers based on the standard calibrated by B&K.

The root cause of this nonconformance was Clark's misinterpretation of part of the requirement. Outside calibration services had been approved based on the service supplier's current ISO/IEC 17025:2005 accreditation and corresponding scope of services. All calibration service suppliers were accredited by an accreditation body recognized by the ILAC Mutual Recognition Agreement. The calibration certificates for all instruments/standards were reviewed and approved by our QA Manager prior to placing the instruments into service. We were missing a formal dedication process which documents the QA Manager's review and approval of the instruments' critical characteristics, versus corresponding acceptance criteria, prior to placing them into service.

Corrective Steps That Have Been Taken and the Results Achieved
We sent the accelerometer standard back to B&K for recalibration. Our internal calibration procedure QAP 07.06.01, "Calibration Procedure," was modified (Revision 3 dated April 4, 2012) to incorporate a formal dedication process for any instruments, to be used in safety-related applications, that are calibrated by an outside commercial calibration service which does not have a 10 CFR Part 21/Part 50 Appendix B quality program. We used the modified procedure to dedicate the recalibrated standard upon its return from B&K on April 20, 2012. We then used the dedicated standard to internally recalibrate our working accelerometers. These internal recalibrations were completed on May 30, 2012. None of the working accelerometers were found to be out of tolerance at any calibration checkpoint. Therefore, there was no impact on past customer testing.

Corrective Steps That Will Be Taken
All necessary corrective steps have been taken, as described above.

Date When Corrective Action Will Be Completed
The Corrective Action was completed as of May 30, 2012, as described above.

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Attachment 4

REPLY TO A NOTICE OF NONCONFORMANCE

Nonconformance 99901412/2012-201-05

Provided below please find our reply to the subject nonconformance, summarized as follows:

As of March 23, 2012, Clark failed to develop a documented procedure for an activity affecting quality. Specifically:

1. *Clark failed to develop a procedure that prescribes which information is required to be included in the logbook for testing. This includes information relating to the identification, description, and quantity of test specimens, test setup and interfaces, list of all measuring equipment used and calibration dates, test data and results, and test deviations and anomalies.*

As of March 23, 2012, Clark failed to accomplish activities affecting quality in accordance with documented procedures. Specifically:

2. *Clark did not appropriately document the M&TE used during the seismic qualification testing of the MV-1 medium voltage and the LV-1 low voltage electrical penetration in accordance with Section 4.2 "Test Instrument Lists" of Test Procedure K-403869-PSWI-001, and Test Procedure K-403869-PSWI-002, respectively.*
3. *Clark used various time periods for the calibration of its timing devices, which had not been calculated in accordance with ISL Work Instruction 2575. Clark needed to determine the accuracy of the timing device based on the manufacturer's documentation, which Clark could not locate in its files.*
4. *Clark failed to document the post-calibration information for a waveform synthesizer, a weight handler, and several accelerometers, working weights, and torque wrenches on form QAF 07.06.01 as required by procedure QAP 07.06.01.*
5. *Clark failed to calibrate its accelerometers to a minimum of seven points and complete the appropriate M&TE records.*

Reason for the Nonconformance

1. Clark had not historically used a documented procedure for the creation of logbooks, since our testing projects often varied significantly in both subject and scope. However, as our business has grown, we see the need to document and standardize the common requirements for the content of our logbooks.
2. Seismic testing of both the LV-1 and MV-1 test specimens was conducted as a single job, with a single list of M&TE in a single logbook, as originally specified by the customer. After the testing was completed, the customer requested that we provide the test data for each specimen separately. Clark "split" the single logbook into two parts, including the list of M&TE in the LV-1 portion without replicating it in the MV-1 portion.
3. The calibration technician who was not consistently following this procedure (and the procedure referenced in issue (5) below) felt that he could vary from them without a significant effect on accuracy and without informing responsible management.
4. The subject calibration records were paper-based, with a calibration form that had been in place for years. The fields on that form meant for recording the pre-calibration and post-calibration conditions were entitled "Pre-Cal Test" and "Calibration," respectively, which was sometimes confusing to our calibration technicians. As a result, these fields were not consistently completed.
5. The piezoelectric accelerometers in question had not been calibrated in accordance with our ISL Work Instruction 0766. The calibration technician who was not consistently following this procedure (and the procedure referenced in issue (3) above) felt that he could vary from them without a significant effect on accuracy and without informing responsible management.

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Attachment 4

REPLY TO A NOTICE OF NONCONFORMANCE

Nonconformance 99901412/2012-201-05

Corrective Steps That Have Been Taken and the Results Achieved

1. We developed QAP 9 "Log Book Procedure" (Revision 0 dated April 9, 2012), which specifies the minimum requirements for the content of our logbooks. Our logbook is a bound book issued to test technicians that contains all of the documents required to comply with the customer purchase order and the subsequent verification of testing activities. These documents include, but are not limited to:
   - customer-supplied drawing(s), if any,
   - test plan,
   - blank test diary (for the documentation of daily activities including test setup and interface information, tests conducted, any test deviations or anomalies, etc.),
   - blank Equipment List (for recording M&TE ID numbers and calibration due dates),
   - Clark Testing quotation, and
   - Clark Testing Router that describes testing sequence, customer hold points, etcetera.

   Each logbook is uniquely identified, reviewed, and approved prior to its use in testing. Training was conducted for all appropriate employees on April 10, 2012.

   (Note: as detailed in the Clark reply to Nonconformance 99901412/2012-201-06, QAP 9 has since been modified (Revision 1 dated May 24, 2012) to include a sample form for use in documenting all RIM test frequencies.)
2. As described above QAP 9 now specifies the minimum requirements for the content of logbooks, including a list of M&TE ID numbers and calibration due dates. Going forward, our test technicians will create a complete list of M&TE for each testing project. QAP 9 also requires that, after testing is complete, our engineers check each logbook for all required information including a complete list of M&TE.
3. The calibration technician who was not consistently following this procedure (and the procedure referenced in issue (5) below) was terminated with qualifications revoked on March 23, 2012.

   All three of our stopwatches were immediately removed from service. Three brand new stopwatches were purchased, calibrated by Exelon, and placed into service. We also decided that, going forward, none of our stopwatches will be calibrated internally; they will all continue to be calibrated by Exelon. Our ISL Work Instruction 2575 was removed from our QMS active directory.

   The original stopwatches were sent for recalibration to Exelon. On April 17, 2012, the recalibrated stopwatches were returned. All three had been found to be within acceptable tolerances. Therefore, no customer test reports were compromised.
4. At the time of the inspection, we were in the process of implementing a change to a computerized (electronic-based) calibration records system. The electronic calibration form replaces the former "Pre-Cal Test" and "Calibration" field titles with "Pre-Cal/As Found" and "As Left," respectively. Our current calibration technician was reminded that these fields on the electronic calibration form must be completed for internal calibrations. For calibrations performed by an outside service, the calibration record must indicate the source of the calibration.

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REPLY TO A NOTICE OF NONCONFORMANCE

Nonconformance 99901412/2012-201-05

As detailed in the Clark reply to Nonconformance 99901412/2012-201-04, we sent our accelerometer standard to Bruel & Kjaer (B&K) to be recalibrated. We dedicated the standard upon its return from B&K then used it to internally recalibrate all of our working accelerometers, including the piezoresistive accelerometers referenced here. These internal recalibrations were completed on May 30, 2012. None of our working accelerometers were found to be out of tolerance at any calibration checkpoint. Therefore, there was no impact on past customer testing.

As detailed in the Clark reply to Nonconformance 99901412/2012-201-03, all of our torque wrenches were immediately removed from service. Brand new torque wrenches were purchased, calibrated by Exelon, and placed into service. We also decided that, going forward, none of our torque wrenches will be calibrated internally; they will all continue to be calibrated by Exelon.

The original torque wrenches were sent for recalibration to Exelon. Because Exelon determined that some of the wrenches exceeded typical tolerance limits, by April 18, 2012 Clark evaluated the corresponding impact on all nuclear safety-related orders in which those wrenches had been used. (See details in the Clark reply to Nonconformance 99901412/2012-201-03.) Based on that evaluation, no reporting in accordance with 10 CFR Part 21 is applicable.

The weight handler and working weights referenced here were used only for internally calibrating our torque wrenches. As described above we decided that, going forward, our torque wrenches will no longer be calibrated internally. As a result, we discarded the weight handler and designated the working weights as out of service.

We also concluded that the subject waveform synthesizer is actually a "source" (i.e., not used as a measuring device). Therefore, the waveform synthesizer need not be calibrated and was removed from our calibration system.

5. The calibration technician who was not consistently following this procedure (and the procedure referenced in issue (3) above) was terminated with qualifications revoked on March 23, 2012.

   As detailed in the Clark reply to Nonconformance 99901412/2012-201-04, we sent our accelerometer standard to Bruel & Kjaer (B&K) to be recalibrated. We dedicated the standard upon its return from B&K then used it to internally recalibrate all of our working accelerometers, including the piezoelectrics. The piezoelectrics were internally recalibrated using at least seven calibration checkpoints. These internal recalibrations were completed on May 30, 2012. None of our working accelerometers were found to be out of tolerance at any calibration checkpoint. Therefore, there was no impact on past customer testing.

Corrective Steps That Will Be Taken

1. All necessary corrective steps have been taken, as described above.
2. All necessary corrective steps have been taken, as described above.
3. All necessary corrective steps have been taken, as described above.
4. All necessary corrective steps have been taken, as described above.
5. All necessary corrective steps have been taken, as described above.

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Attachment 4

REPLY TO A NOTICE OF NONCONFORMANCE

Nonconformance 99901412/2012-201-05

Date When Corrective Action Will Be Completed

1. The Corrective Action was completed as of April 10, 2012, as described above.
2. The Corrective Action was completed as of April 10, 2012, as described above.
3. The Corrective Action was completed as of April 17, 2012, as described above.
4. The Corrective Action was completed as of May 30, 2012, as described above.
5. The Corrective Action was completed as of May 30, 2012, as described above.

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Attachment 5

REPLY TO A NOTICE OF NONCONFORMANCE

Nonconformance 99901412/2012-201-06

Provided below please find our reply to the subject nonconformance, summarized as follows:

As of March 23, 2012, Clark failed to control the issuance of documents that prescribe activities affecting quality and failed to ensure that those documents are distributed to and used at the location where the prescribed activity is performed. Specifically:

1. *Several uncontrolled prior revision calibration procedures were found in the calibration laboratory.*
2. *A test engineer performed the test setup for the seismic qualification of the LV-1 electrical penetration with an uncontrolled work instruction that was not reviewed for adequacy and approved for release by authorized personnel.*

Reason for the Nonconformance

1. A hardcopy book of calibration instructions, "ISL Work Instructions," was found; the instructions had recently (~two weeks prior) been converted to online (electronic) versions. The hardcopy and electronic versions of each instruction had identical calibration guidance, but the electronic version included a Clark Testing logo. Clark's QA Manager had inadvertently removed and destroyed only 3 of the 4 hardcopy books upon release of the electronic versions, even though our Master List had indicated that there were a total of 4 hardcopy books in the Calibration Lab.
2. The subject seismic qualification testing was conducted in accordance with a controlled and approved test procedure. The RIM (Required Input Motion) portion of the testing was set up (as is typical) to incorporate a few test frequencies, based on the results of the test specimen resonance searches, in addition to those pre-specified in the test procedure. The test procedure was consistent with this approach. These additional frequencies were listed on a separate sheet of paper that did not bear evidence of approval.

Corrective Steps That Have Been Taken and the Results Achieved

1. The remaining hardcopy book was immediately removed. The Calibration Lab was also searched for any other similar documents, but none were found. As a result, hardcopy versions of our ISL Work Instructions have been made unavailable and are no longer permitted. The calibration technician was reminded that the online ISL Work Instructions are the official, controlled versions and the only versions to be used.
2. Clark's procedure for providing all of the necessary documents to test personnel, QAP 9 "Log Book Procedure," has been modified (Revision 1 dated May 24, 2012) to include a sample form for use in documenting all RIM test frequencies. Going forward, such a form will be included in the logbooks for seismic RIM testing orders. All of our logbooks are reviewed and approved for release before testing begins, then reviewed again after the testing has been completed. As a result, the use of any additional frequencies during RIM testing will be documented in a controlled manner and subsequently reviewed. Training was conducted for all appropriate employees on May 24, 2012.

Corrective Steps That Will Be Taken

1. All necessary corrective steps have been taken, as described above.
2. All necessary corrective steps have been taken, as described above.

Date When Corrective Action Will Be Completed

1. The Corrective Action was completed as of March 23, 2012, as described above.
2. The Corrective Action was completed as of May 24, 2012, as described above.