wyle laboratories

October 18, 2012

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

cc: Richard A. Rasmussen, Chief
Electrical Vendor Branch
Div. of Construction Inspection & Operational Programs
Office of New Reactors

Subject: Reply to a Notice of Nonconformance

Reference NRC Inspection Report No. 99900905/2012-201
Nonconformance 99900905/2012-201-01 thru-04

Dear Sir/Madam:

Wyle Laboratories, Huntsville, AL has reviewed nonconformance 99900905/2012-201-01 thru -04 and is enclosing responses to each nonconformance.

Should there be any questions or need for additional information, Wyle will be pleased to provide the same. I may be contacted by phone at (256) 716-4483, or by email at raul.terceno@wyle.com .

Sincerely yours,

WYLE LABORATORIES, INC

R Terceno

Raul Terceno
Manager, Quality Assurance

Attachment: Response to Notice of Nonconformance

Distribution: Tom Brewington
Keith Wilson

IE09
NRO

RESPONSES TO NRC NOTICE OF NONCONFORMANCE
Inspection Report 99900905/2012-201, dated 9/7/12

10/18/12

A. Nonconformance 99900905/2012-201-01, Item 1.

All test requirements contained in the Westinghouse Electric Company Qualification plan were satisfied. Specifically, Wyle failed to identify a discrepancy between the Westinghouse Qualification Plan and the Wyle Qualification Plan associated with the time required to test the squib valves for sealing capability. The Westinghouse Qualification Plan, APP-PV70-VPH-001 specified testing of the sealing capability of the AP1000 squib valves for 15 minutes, while the Wyle Qualification Plan specified testing the sealing capability for 5 minutes;

(1) The reason for the noncompliance, or if contested, the basis for disputing the noncompliance.

After a detailed review of all documentation, Wyle disputes that this is a nonconformance for the following reasons:

a) The latest Purchase Order Change Notice #3 dated April 12, 2012, specifies the following references:
   i) APP-GM-VP-010 (time not specified)
   ii) APP-GW-G1-002 (no less than 5 minutes)
   iii) ASME QME-1-2007 (no less than 5 minutes)

b) APP-PV70-VPH-001, in draft form, was transmitted to Wyle engineers on May 30, 2012 for comment only. The draft specification changed the leakage time to 15 minutes. The final Westinghouse signed APP PV70 VPH 001 document has not been amended to the QME-1 purchase order issued to Wyle.

c) The test procedure WLP57622-02 was issued on April 12, 2012 based on Westinghouse's latest purchase order change notice #3.

d) The leakage check was performed on May 18, 2012. The test procedure used for the leakage test followed the requirements of "no less than 5 minutes" as stated in the Westinghouse purchase order references. The purchase order did not reference any document that called for the 15 minute leakage test.

(2) The corrective steps that have been taken and the results achieved.

Not Applicable. No actions are being taken by Wyle to address this issue.

(3) The corrective steps that have been taken to avoid noncompliance.

APP-PV70-VPH-001 Draft 2 was sent to Wyle for review on May 30, 2012. When the completed Westinghouse signed APP PV70 VPH 001 document is amended to the Westinghouse QME purchase order, the test procedure will be amended if required.

(4) The date when your corrective action will be completed.

Not Applicable. No timeline is required for this.

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10/18/12

A. Nonconformance 99900905/2012-201-01, Item 2.

The test program designed for the QME 1 qualification of testing of 8-inch globe valves was not sufficient to ensure that valve would perform satisfactorily in service. Specifically, the Wyle Qualification Plan for 8-inch globe valves specifies partial stroke segments to be used during steam or water flow tests without justification that this test method demonstrates valve performance consistent with a continuous valve stroke.

(1) The reason for the noncompliance, or if contested, the basis for disputing the noncompliance.

The root cause for this non-compliance is that the valve maximum flow rates and stroke times exceeded the test system capacity. Wyle based the use of partial strokes on the following technical provisions and assumptions, which were not stated in the Qualification Plan:

a) Test and analysis data from GL89-10 showed that for a typical gate or globe valve, the maximum internal stresses and resulting maximum thrust occurred in the last 30% of a closing stroke.
b) Test and analysis data from GL89-10 showed that the flow rate is important in determination of maximum thrust loads during line break conditions.
c) Analysis results for an H pattern globe valve show that the primary forces on the valve act directly in line with the stem, thus limiting the impact of frictional loads on the thrust requirements.
d) The available test data from GL89-10 was mainly focused on unbalanced globe valves. The valve in question is a "balanced" design, so verification of no unexpected loads at positions above 30% open was determined to be required, thus leading to the series of partial strokes approach.
e) There was a similar designed valve in this test program that was tested for a full stroke for comparison.

(2) The corrective steps that have been taken and the results achieved.

Analysis of the valve test data is proceeding at this time:

a) A first round of analysis showed no significant loads beyond 35% open, which was as expected.
b) A check based on testing of a similar designed valve with a full stroke shall be made in the test report to add clarity that unexpected thrust increases were not experienced for this valve.
c) The valve is being inspected. Other similar valves have shown no signs of galling or other damage which would indicate overstressing of the valve internals which would have led to an accumulation of damage during the valve stroke.

(3) The corrective steps that have been taken to avoid noncompliance.

In the future, any use of partial strokes in Wyle qualification plans will more clearly state the underlying assumptions leading to the conclusion that partial strokes are acceptable. In this manner, all parties reviewing the Wyle qualification plan can be aware of the underlying assumptions and determine if a change in test methods may be required.

A. Nonconformance 99900905/2012-201-01, Item 2. (Continued)

(4) The date when your corrective action will be completed.

The analysis of the test data will be complete by January 2013 for the valves that had full stroke and the valves that used partial strokes. The inspection of the valve internals for the 8" valve specifically mentioned in this response will be completed by November 2012 and will be presented in the test report.

RESPONSE TO NRC NOTICE OF NONCONFORMANCE
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B. Nonconformance 99900905/2012-201-02

Wyle failed to implement measures to assure that products were appropriately procured and examined upon receipt as required. Specifically, Wyle Purchase Order (PO)HSV0031500, dated April 5, 2004, used to procure the DaSiSP 2002 program used for safety-related testing was not developed , reviewed, or approved by the Wyle QA organization, nor was it examined by the QA organization upon delivery.

Reason for the noncompliance:

When using an "Overhead" account to purchase an item to be used in support of customer testing activities, the PO requisition must select a "Direct" account approval code in order for the requisition to be forwarded to the QA Department for review/approval. The original DADiSP2002 Software purchase requisition did not use the "Direct" account approval code and consequently the requisition went directly to Purchasing not to QA. Delivery of the software was made directly to the originating engineering Dept. QA was not notified of delivery because no QA Requirements were issued with the purchase order.

Investigation indicates that the originator of the requisition was not adequately familiarized with the use of the "Direct" account approval coding when the DADiSP2002 software was purchased, and made an assumption that the requisition was being automatically routed to QA for review.

Corrective steps taken, and the results achieved:

Refresher training in the use of the Wyle's electronic CostPoint purchasing module, to include the proper selection of "Direct" approval routing codes on overhead account purchases, was organized by the Wyle Purchasing Dept. and completed on September 5, 2012 with all personnel authorized to originate Purchase Order Requisitions in attendance. Attendance Record is attached.

Corrective steps that will be taken to avoid noncompliance(s):

Personnel authorized to enter and approve Purchase Requisitions had the refresher training which included training in the use the use of the "Direct" approval code for routing to QA Dept. All purchases for safety-related customer services, to include software, are to be routed through Wyle QA.

A new form (WH-1642) was developed and released for use by all Wyle functions to determine potential safety-related applications of software and establish a plan for dedicating the software, if required. All Wyle functions have been made aware that Form WH-1642 is to be used in all software purchases for evaluation of potential safety-related applications.

A technical evaluation of the DADiSP 2002 program will be performed to verify the adequacy of the software to serve its intended function.

Date when corrective actions will be completed:

The new Form, WH-1642, was completed/released in Sept. 2012. See attached.

The refresher training was completed on September 5, 2012. Attendance has been recorded.

The technical evaluation for DADiSP 2002 will be completed by October 30, 2012.

wyle laboratories	SOFTWARE TECHNICAL EVALUATION	Date: Click here to enter a date.

SOFTWARE SUMMARY

Software Name and Version: Click here to enter text.

Software Function: Click here to enter text.

SAFETY RELATED FUNCTION

Software Safety-Related Use: Data Collection ☐ Data Presentation ☐ Data Analysis ☐ Other ☐

Will the software output be verified with each use? Yes ☐ No ☐

SOFTWARE PROCUREMENT

Procure Software As:

- **☐ Developed under 10CFR50, App. B program**
- **☐ Commercial without dedication**
  - **Requires outputs to be verified for each use.**
- **☐ Commercial with dedication**
  - **Perform Failure Mode and Effects Analysis (FMEA)**
  - **Identify Critical Characteristics**
  - **Develop Dedication Plan**
  - **Identify PO Requirements**

Comments: Click here to enter text.

APPROVALS

Initiated By: _____ **Date:** _____

Department Manager: _____ **Date:** _____

Software Engineer: _____ **Date:** _____

Quality Assurance: _____ **Date:** _____

WH-1642 SEP '12

RESPONSE TO NRC NOTICE OF NONCONFORMANCE
Inspection Report 99900905/2012-201, dated 9/7/12

B. Nonconformance 99900905/2012-201-02

Note: COSTPOINT/QA Training Record is provided as a separate attachment

04-05-12

Sign Up Sheet

COSTPOINT / QA TRAINING

Patricia Phillips

[illegible]

Phil McManigan

[illegible] Lee

[illegible]

[illegible] Parrott

[illegible]

Lyn Rothe

Paul Terceru

Natalie [illegible]

Lori Duncan

[illegible] Walton

Tom Brewington

Davin Lee

E. REILLY SCHUM E.R.S.

John Hardy [illegible]

Cheryl Baldwin

MICKEY MOUSE

Serge M'Sadoques

[illegible]

[illegible]

[illegible] PATRICK [illegible]

TOM BOONARKAT Tom [illegible]

John Wood John Wood

Sandra Daniel

David Bell

[illegible] (Greg Ilason)

Kim Bray Kim Bray

Virgil Patterson

Trainer Jon Rosenblum Jonathan Rosenblum

This document FOR REF. ONLY NOT FOR public posting on NRC SITE. Thank you. Wyle Laboratories

RESPONSE TO NRC NOTICE OF NONCONFORMANCE
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C. Nonconformance 99900905/2012-201-03

Wyle failed to provide for verifying or checking for adequacy calculations within DaDiSP software used for safety-related testing at the laboratory. Specifically, two calculations: (1) used to adjust baseline pressure to account for test configuration, and (2) used to perform curve smoothing of the raw test data within the DaDiSP program on safety-related testing activities were not checked for accuracy by an alternate (method(s), nor documented as required.

Reason for the noncompliance:

Engineering checked the adequacy of calculations provided by DADiSP2002, but in so doing failed to recognize the potential safety-related applications, and did not record the results in a manner that is verifiable.

Corrective steps taken, and the results achieved:

The Wyle software coordinator has reviewed Wyle software being used in safety-related applications and is compiling/examining software verification records to ensure that all software verification information has been properly documented.

A new form (WH-1641) was developed and released for use by all Wyle functions to document the formula, its safety related function, where it is used in a report, and method for validation. Each completed form is to be reviewed by an independent checker.

Corrective steps that will be taken to avoid noncompliance(s):

Quality Directive, QD III-3, Software Development and Configuration Control, is being updated to mandate the use of Form WH-1641 to document all formulas used in software, and to provide for its safety related function.

The original copy of the completed Form WH-1641 along with supporting data is to be recorded and stored in the Software Configuration Control Library; a copy will be stored with the job file.

Date when corrective actions will be completed:

The new form, WH-1641, was developed/released in September 2012. See attached.

The Quality Directive, III-3 will be revised no later than October 30, 2012.

wyle laboratories	SOFTWARE CALCULATION VALIDATION	**Date:** Click here to enter a date.

Customer: Click here to enter text. **Job Number:** Click here to enter text.

SOFTWARE SUMMARY	PLATFORM
Software Name: Click here to enter text.	**Operating System:** Click here to enter text.
Software Version: Click here to enter text.	**Processor:** Click here to enter text.

CALCULATION SUMMARY

Enter the formula used:

Click here to enter text.

Provide a brief description of the calculation performed:

Click here to enter text.

VALIDATION SUMMARY

Provide a description of the method used to validate the software output. Attach supporting documents if necessary:

Click here to enter text.

APPROVALS

Initiated By: _____ **Date:** _____

Checked By: _____ **Date:** _____

WH-1641 SEP '12

D. Nonconformance 99900905/2012-201-04

Wyle failed to implement measures to verify or check the adequacy of the design. Specifically, Wyle Qualification Plans for calculating the valve factors and stem friction coefficients for motor operated valves did not include provisions to account for tolerances associated with instrument uncertainties. Consideration of such instrument uncertainties is necessary to ensure that the testing will envelope the most adverse design conditions.

(1) The reason for the noncompliance, or if contested, the basis for disputing the noncompliance.

Wyle does not agree this nonconformance is part of Criterion III. Wyle is not responsible "to verify or check the adequacy of the design" for valves per QME-1. Wyle is not performing the final actual sizing and setup (design) of the valve assemblies. Wyle is responsible for collecting test data in accordance with the guidance of QME-1 and passing that data to the valve vendor to support their efforts to verify the adequacy of the design. Wyle does understand the nonconformance, although we disagree with this being a "design verification step".

In the Wyle Qualification Plan, the section stated says "The following formulas will be used for the analysis of the test data." Since the analysis of data is after the collection of test data, Wyle believed that it was clear that the consideration of the impact of instrumentation accuracies is after collection of the test data, and therefore is part of the Test Report scope and not the Qualification Plan scope.

However, there was an acceptance criterion in the Plan that the Valve Factors had to be stable. A clear statement on the impact of instrumentation accuracies on this acceptance criteria should have been stated (since it was looking for a trend in the data, instrumentation accuracies would have no impact).

(2) The corrective steps that have been taken and the results achieved.

For this test program, there are no corrective steps that can be taken. The testing has been completed and the analysis of the results is being performed at this time.

(3) The corrective steps that have been taken to avoid noncompliance.

For future test plans, Wyle will be clearer when calculation methods are discussed in the test plan to state clearly:

a) The Impact of instrumentation accuracy must be considered in the report for all calculated analysis results.
b) For any acceptance criteria based on the calculation results, the impact of instrumentation accuracies must be stated and considered.

Nonconformance 99900905/2012-201-04 (cont'd)

(4) The date when your corrective action will be completed.

The test reports are expected to be complete by January 2013, and these reports will consider the impact of instrumentation accuracies on the calculation results which was not covered in the qualification plan.