U.S. Nuclear Regulatory Commission Attn: Document Control Desk Washington, DC 2055-001 cc: Juan Peralta, Chief
Quality and Vendor Branch 1
Div. of Construction Inspection & Operational Programs
Office of New Reactors

Subject: Reply to a Notice of Nonconformance

Reference NRC Inspection Report No. 99900905/2009-201 Nonconformance 99900905/2009-201-01.

Dear Sir/Madam:

Wyle Laboratories, Huntsville, AL has reviewed nonconformance 99900905/2009-201-01 and recognizes that engineering analysis records for Notification of Out-of Tolerance Conditions, using Form WH-1140, Rev. Feb '05 did not adequately portray engineering activities undertaken to meet the guidelines given on Quality Directive XII-1, Rev. O.

Form WH-1140 required the project engineer to review all tests conducted since the last calibration of the instrument to determine if any test, as outlined on the Job History Tracking Report, was affected.

The engineering review would be evidenced by a statement explaining the relevance or lack of "As Found" Out-of Tolerance condition. The engineer's signature would indicate a review of all tests was performed. QA would review and/or discuss the results prior to closure.

It is apparent that the degree of detail recorded on the WH-1140 form(s) varied from instance to instance, and between various engineers. In fact, the brevity of some engineering responses could be considered inadequate, and would typically have required further investigation by Wyle QA or others reviewing the results. This investigation would have been documented in each case as a means of substantiating the conclusions.

In order to establish greater consistency in documenting the engineering review process for Out-of Tolerance Conditions, Wyle has instituted measures expected to improve controls and transparency of the process.

These measures can be summarized as follows:

- QD XII-1, Rev. P, assigns the applicable Engineering Dept. Manager responsibility for the coordination and review of the of Out-of-Tolerance Conditions, QD XII-1, Rev. P, page 12 attached.
- Form WH-1140, Rev. June '09 (attached) has been reformatted to support QD XII-1, Rev. P changes.
- The updated computerized Job History Tracking Report template, attached, prompts the project engineer to sign-off and date the review performed on each job listed on the report.
- Wyle QA requested that engineering document the review of the Out-of Tolerance Record, Control No. 16-008. Email summary attached.

Wyle Corrective Action Request, CAR 09-009, has been issued by Wyle Laboratories to address (a) causes and/or reason for the stated nonconformance, (b) the interim corrective steps taken, (c) the results achieved, (d) the steps that will be taken to avoid further noncompliances, (e) the date when the corrective actions will be completed.

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

Raul Terceno

Manager, Quality Assurance and Safety.

Attachments:

- Corrective Action Request, CAR 09-009.
- QD XII-1, Rev. P, page 12.
- Computerized Job History Tracking Report, typical.
- Form WH-1140, Rev June '09
- Engineering review of Out-of Tolerance Record 16-008

Distribution: Tom Brewington

Bruce Bateman Keith Wilson