

**Attachment 3 Contains Proprietary Information to be
Withheld from Public Disclosure Pursuant to 10 CFR 2.390**

PSEG Nuclear LLC
P.O. Box 236, Hancocks Bridge, NJ 08038-0236



SEP 23 2016

10 CFR 50.90

LR-N16-0165
LAR H15-01

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

Hope Creek Generating Station
Renewed Facility Operating License No. NPF-57
NRC Docket No. 50-354

Subject: **RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION REGARDING
DIGITAL POWER RANGE NEUTRON MONITORING (PRNM) SYSTEM
UPGRADE (CAC NO. MF6768)**

- References
1. PSEG letter to NRC, "License Amendment Request - Digital Power Range Neutron Monitoring (PRNM) System Upgrade," dated September 21, 2015 (ADAMS Accession Nos. ML15265A224 and ML15265A225)
 2. NRC letter to PSEG, "Hope Creek Generating Station – Request for Additional Information Regarding Digital Power Range Neutron Monitoring System Upgrade," dated August 17, 2016 (ADAMS Accession No. ML16217A430)

In the Reference 1 letter, PSEG Nuclear LLC (PSEG) submitted a license amendment request for Hope Creek Generating Station (HCGS). The proposed amendment would revise the HCGS Technical Specifications to reflect the installation of the General Electric-Hitachi (GEH) digital Nuclear Measurement Analysis and Control (NUMAC) Power Range Neutron Monitoring (PRNM) system. Reference 1 provided the Phase 1 information in accordance with Digital I&C ISG-06 Licensing Process.

In the Reference 2 letter, the U.S. Nuclear Regulatory Commission staff provided PSEG a Request for Additional Information (RAI) to support the NRC staff's detailed technical review of Reference 1. The requested information is provided in Attachment 1 (Non-Proprietary) and Attachment 3 (Proprietary).

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Attachment 3 contains proprietary information as defined by 10 CFR 2.390. GEH, as the owner of the proprietary information, has executed an affidavit (provided in Attachment 2) identifying that the proprietary information has been handled and classified as proprietary, is customarily held in confidence, and has been withheld from public disclosure. GEH requests that the proprietary information in Attachment 3 be withheld from public disclosure, in accordance with the requirements of 10 CFR 2.390(a)(4).

PSEG has determined that the information provided in this submittal does not alter the conclusions reached in the 10 CFR 50.92 no significant hazards determination previously submitted. In addition, the information provided in this submittal does not affect the bases for concluding that neither an environmental impact statement nor an environmental assessment needs to be prepared in connection with the proposed amendment.

No new regulatory commitments are established by this submittal. If you have any questions or require additional information, please do not hesitate to contact Mr. Brian Thomas at (856) 339-2022.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on Sept 23rd, 2016
(Date)

Respectfully,



Paul Davison
Site Vice President
Hope Creek Generating Station

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Attachments

1. Response to Request for Additional Information Regarding Digital PRNM Upgrade – Non-Proprietary (GEH Reference GEH-KTO-182455-183 Enclosure 2)
2. GEH Affidavit supporting the withholding of information in Attachment 3 from public disclosure
3. Response to Request for Additional Information Regarding Digital PRNM Upgrade – Proprietary (GEH Reference GEH-KTO-182455-183 Enclosure 1)

cc: Mr. D. Dorman, Administrator, Region I, NRC
Ms. C. Parker, Project Manager, NRC
NRC Senior Resident Inspector, Hope Creek
Mr. P. Mulligan, Chief, NJBNE
Mr. L. Marabella, Corporate Commitment Tracking Coordinator
Mr. T. MacEwen, Hope Creek Commitment Tracking Coordinator

**Response to Request for Additional Information Regarding Digital PRNM Upgrade
Non-Proprietary**

(GEH Reference GEH-KTO-182455-183 Enclosure 2)

This is the non-proprietary version of Attachment 3 of this letter which has the proprietary information removed. Portions of the document that have been removed are indicated by white space inside open and closed bracket as shown here [[]].

EICB-RAI-1

(Open Item 6) PRNM System Management Plan (LAR Appendix E)

- a. Section 2.3, "Management Objectives and Priorities – Oversight," describes how project management will be performed. This section refers to critical-to-quality features to be part of the management process; however, this plan does not define these features. Since these features are part of project oversight, please describe these features, and identify in which document(s) they will be recorded in.
- b. Section 2.4.1, "Secured Development Environment," describes the secure development environment. This section states the controls employed in the system development should be in accordance with GEH established procedures, consistent with guidance provided in Regulatory Guide (RG) 1.152, "Criteria for Use of Computers in Safety Systems of Nuclear Power Plants." In order to complete its assessment of the criteria of RG 1.152, the NRC staff needs to review these documents. Please provide additional information including a description of the GEH procedures to be followed for secure development environment or make these procedures available for NRC audit.
- c. Section 3.1, "Project Quality Metrics – Measurement," describes the need to establish project quality metrics; however, this section does not identify the project quality metrics used to track progress and determine appropriateness of the software development process.

Appendix K of the LAR, "Design Analysis Report: Methodology Modifications," refers to two sections in the Systems Independent Verification and Validation Plan (SyIVVP) (LAR Appendix D) to confirm Branch Technical Position (BTP) 7-14, Section B.3.1.10.2, which includes measurement criteria. Section 4.2 of the SyIVVP describes how metrics are used to assess design review objectives, but it does not identify the metrics. Section 4.4.4 of the SyIVVP discusses recording of quality metrics but fails to identify the metrics used for Nuclear Measurement Analysis and Control (NUMAC) system development.

In order for the NRC staff to complete its assessment of BTP 7-14, Section B.3.1.10.2 criteria, information on application-specific metrics will need to be reviewed. Please provide additional information on HCGS project quality metrics used to determine the effectiveness of the HCGS PRNM development verification and validation (V&V) effort.

Response:

- a. The System Management Plan (SyMP), Appendix E of the phase one submittal NEDC-33864P (Reference 1-1), contains non-commercial information, complementary to what is contained in the HCGS Power Range Neutron Monitor (PRNM) upgrade Project Work Plan (PWP). The SyMP does not contain project-specific Critical to Quality (CTQ) features, which are in Appendix C of the PWP. Those CTQs are:
 - GEH (internal) CTQs:
 - a. No non-compliance condition report initiated on the project. Comply with GEH policies and procedures, including the requirements described in the project planning documents.

- b. Adhere to GEH policies of Integrity, Safety culture principles, Quality and Outputs (ISQO).
 - c. Meet customer's expectations, achieve Transactional Net Promoter Score (T-NPS) greater or equal to 8.
 - d. Utilize Human Performance (HU) tools.
 - e. Execute the project in accordance with the Project schedule and meet the established Engineering Deliverables (ED) and Customer Deliverables (CD) promise dates.
 - f. Report or escalate to the Engineering Manager and/or Project Manager (PM) any issues related to integrity and safety using the issue resolution process. Safety means both occupational safety and the requirements that will impact the safety functions and operation of the system being design and developed.
- Customer CTQs
 - a. Meet project milestones specified in the contract.
 - b. Timely escalate issues to PM using the escalation process.
- b. A collection of administrative procedures covers specific topics related to the secure development environment:
- Asset Identification
 - Secure Development Network
 - Physical Security
 - Malicious Code Protection
 - Patch Management
 - Server and Computer Hardening
 - Threat Analysis
 - Software Usage
 - Electronic Access Control
 - Log Management
 - Personnel Security and Segregation of Duties
 - Production Deployment
 - Product Handling and Delivery
 - Incident Response
 - Contingency Planning
 - Security Control Review
 - Changes to Physical, Logical, or Programmatic Controls
- c. The software development process includes a series of technical design reviews and baseline reviews. At the end of each of these reviews, a review report and a scorecard will be issued by the review chair. The review report summarizes the results of the review. The scorecard evaluates the content of the review material and the performance of the design team based on pre-established criteria also known as metrics (e.g., "Did the design team

resolve action items assigned at previous reviews, or are acceptable plans in place?”). A successful review will require a passing grade of 75%. However, any grade below 90% would result in action items to correct the deficiency in the design or in the compliance with the design process. Condition reports will be issued in accordance with GEH problem reporting procedure should a design fail any of the reviews.

Reference

- 1-1 GE Hitachi Nuclear Energy, “Hope Creek Generating Station NUMAC PRNM Upgrade,” NEDC-33864P, Revision 0, September 2015 (ADAMS Accession No. ML15265A225).

EICB-RAI-2

(Open Item 7) PRNM Systems Engineering Development Plan (LAR Appendix B)

a. Section 4.2, "Technical Design Review," of Appendix B describes an independent review team to perform the technical design review. Section 2.3 of Appendix K implies that these reviews are performed by a team independent of the design team. However, Section 2.4.1 of Appendix K states the verification of the design documents is performed by the design team prior to Independent Verification and Validation Plan activities. Please provide clarification of what group (in the GEH organization) performs these independent reviews.

b. BTP 7-14, Section B.3.1.10.2 procedures state the Software Verification and Validation Plan should describe how anomalies are identified and reported. To complete the safety evaluation, the NRC staff needs to assess the adequacy of the processes used to identify, document, and address deficiencies found during system design and development.

Section 4.5, "Configuration Control," of Appendix B describes three different forms of documenting deficiencies, or discrepancies, to be tracked. Section 7.0, "NUMAC Problem Reports," states "most problems identified during product development are generally handled through the engineering change order," processes. The specific criteria for determining which of the three discrepancy resolution processes to be invoked, however, is unclear. It is also unclear if the three processes can be invoked concurrently or if only one would be invoked for a single issue. Please provide additional information on methods used to identify and track problems that are identified during technical design reviews. This information should include a description of the process for approving resolution of these problems.

c. BTP 7-14, Section B.3.1.2.3, provides guidance for reviewing software tools used during system development. Additional guidance for the use of software tools is provided in Section 5.3.2 of Institute of Electrical and Electronics Engineers (IEEE) Standard 7-4.3.2, "IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations." Section 5.0 of the Systems Engineering Development Plan describes the use of development tools; however, it does not identify the tools used for HCGS application development. Section 4.3 states the baseline review team would also review and approve development tools. Please provide additional information regarding the specific software development tools used for the development of the HCGS PRNMS.

d. Section 6.0, "Secure Development and Operational Environment," of Appendix B, describes the secure development and operational environment. This section states access to the NUMAC lab is controlled and monitored. However, it does not provide details on how these activities are performed. Please provide additional information on these activities, including a description of all activities performed to establish and maintain the secure NUMAC application development environment. This information should also include a description of access control measures for the secure server in which the NUMAC application code is stored.

Response:

- a. When the design team prepares and releases design artifacts, GEH procedures require the design team to perform verification of documents prior to the document release. The released document is then provided to the Independent Verification and Validation (IVV) team who conducts the independent verification in accordance with the System Independent Verification and Validation Plan (SyIVVP). Conducting the IVV activities defined in the SyIVVP (Reference 2-1, Appendix D, Section 3.0) constitutes the technical design review, which is performed by the IVV team and is supervised by the Chief Engineers Office.
- b. During design and development of the Power Range Neutron Monitoring (PRNM) system for PSEG, the IVV team would review and provide comments about design artifacts at each phase. The comments and resolutions are archived in the design records in accordance with GEH procedures. The comments, resolutions and any open items are also reported and tracked in Appendix A of the SyIVVP task report or the System Safety Analysis (SySA) task report for each phase as discussed in Section 4.4 of the System Engineering Development Plan (SyEDP), SyIVVP, and System Quality Assurance Plan (SyQAP). The System Verification Engineer and the System Safety Analysis Engineer are responsible for documenting results of reviews including anomalies in their respective task reports.

During IVV team testing, when anomalies are observed, they are recorded in the control copy of the test datasheets. The anomalies and the resolutions, which may include changes or corrections to the design, are discussed in the test reports. An independent engineer is responsible to verify that the content of test report is consistent with the test data sheets. The technical design reviews and baseline reviews will confirm that the acceptance of the resolution and the closure of the anomalies or open items. Resolution of all anomalies and closure of all open items is required before the system can be delivered to PSEG.

After GEH delivers the system to PSEG, if an anomaly is discovered it would be tracked in the GEH corrective action program.

PSEG will continue oversight and audit activities during the design, development, V&V, and testing of the PRNM system. PSEG's IT-AA-101, Digital Technology Systems Quality Assurance (DTSQA) procedure, and CC-AA-103-1007, Critical Software Package Creation and Maintenance, will disposition any anomalies identified. This will include, as appropriate, resolution in the PSEG Corrective Action Program (CAP) and in the Engineer of Choice (EOC) CAP (for the vendor performing the design change package for the PRNM upgrade – Sargent and Lundy). During the installation and acceptance testing, and after installation, both the PSEG CAP and EOC CAP will be used to identify, document, track and resolve anomalies.

- c. The SyQAP functional configuration audit checklist (NUMAC SyQAP, Section 4.4.1) lists tools that were approved for the associated baseline. A SyQAP functional configuration audit checklist is developed for each baseline. Tools are approved for use via the baseline

review process for application to a specific project. Tools were used for the HCGS PRNM system development.

The HCGS PRNM system has similar hardware and software designs as previously approved PRNM projects (e.g., Grand Gulf Nuclear Station and Columbia Generating Station). Therefore, the software tools for the HCGS PRNM are the same as those previously described for Columbia Generating Station in Section 4.4.6 (Reference 2-2).

- d. GEH has a procedure for controlling access to the NUMAC lab and for access control of the secure server; see additional information in the EICB-RAI-1b response.

References

- 2-1. GE Hitachi Nuclear Energy, "Hope Creek Generating Station NUMAC PRNM Upgrade," NEDC-33864P, Revision 0, September 2015 (ADAMS Accession No. ML15265A225).
- 2-2. GE Hitachi Nuclear Energy, "Digital I&C-ISG-06 Compliance for Columbia Generating Station NUMAC Power Range Neutron Monitoring Retrofit Plus Option III Stability Trip Function," NEDC-33685P, Revision 2, December 2012 (ADAMS Accession No. ML13015A272).

EICB-RAI-3

(Open Item 8) NUMAC Systems Quality Assurance Plan (SyQAP) (LAR Appendix C)

- a. The SyQAP plan does not cover all the activities identified in Section B.3.1.3 of BTP 7-14. Specifically, the SyQAP does not describe the corrective action program (Anomaly Reporting and Resolution), provide a description of quality assurance procedures, or identify indicators to determine software quality (measurement). Please provide additional information for NUMAC software quality assurance activities to address the Criteria B.3.1.3 of BTP 7-14.
- b. Section 3.0 of the SyQAP states, “[a]n unresolved configuration anomaly is grounds for failure of a baseline review.” The NRC staff needs to understand how these anomalies are identified, recorded, and tracked to completion, including who is responsible for approving resolution of these issues. Please provide additional information on how unresolved configuration anomalies are addressed and documented.

Response:

- a. The Nuclear Measurement Analysis and Control (NUMAC) plans in Reference 3-2 augment and supplement the GEH Quality Assurance (QA) program (Reference 3-1). As stated in Section 1.0 of the NUMAC System Quality Assurance Plan (SyQAP), the GEH QA program encompasses quality assurance related activities such as audits, supplier control, and archiving of quality records. Although not explicitly mentioned, the corrective action program is a component of the GEH QA program. Additional information on measurement of the software process is provided in the response to EICB-RAI-1c. Additional information on how anomalies are identified, documented, tracked and resolved is provided in the response to EICB-RAI-2b.
- b. Open items are listed in the system QA configuration audit checklist and tracked in the system configuration management task report (SyEDP Section 4.4.2). The checklist and task report are part of the baseline review records. These records are approved by the baseline review team, which is chaired by the Chief Consulting Engineer. Additional information on how anomalies are identified, documented, tracked and resolved is provided in the response to EICB-RAI-2b.

References

- 3-1 GE Hitachi Nuclear Energy, “GE Hitachi Nuclear Energy Quality Assurance Program Description, NEDO-11209-A, Revision 13, August 4, 2016 (ADAMS Accession No. ML16217A239).
- 3-2 GE Hitachi Nuclear Energy, “Hope Creek Generating Station NUMAC PRNM Upgrade,” NEDC-33864P, Revision 0, September 2015 (ADAMS Accession No. ML15265A225).

EICB-RAI-4

(Open Item 9) Software Integration Plan (SIntP)

BTP 7-14, Section B.3.1.4.2, identifies the implementation characteristics required for an SIntP. This section requires description of the software integration activities. GEH did not submit a separate SIntP; however, Appendix K of the LAR identified the NUMAC documents to address the requirements for this plan. GEH references System Engineering Development Plan (SyEDP) for this, but SyEDP does not provide sufficient information about the software integration processes to support the NRC review. Please provide additional information on software integration activities performed to address the criteria of BTP 7-14, Section B.3.1.4.2.

Response:

As discussed in NEDC-33864P Appendix A (Reference 4-1), the microprocessor-based Nuclear Measurement Analysis and Control (NUMAC) instruments consist of a chassis and a complement of modules, which may include embedded software. Software integration is accomplished by compiling individual software components into executable applications that are specific to each programmable entity in the modules, integrating those modules into the instruments in which they run, and finally integrating the instruments within the system to perform the system functions. For GEH, software integration is performed by the design team and their activities are described in the SyEDP. At completion of design team activities, software and hardware are provided to the independent verification and validation team who perform independent integration and system testing in a phased approach as detailed in the Systems Independent Verification and Validation Plan (SyIVVP).

Management Characteristics of the SIntP:

- Purpose – Objectives and scope of a software integration plan are included within the SyEDP lifecycle process. As part of the design phase of the SyEDP, planning is performed and software design specifications are developed which describe major modules, their functions and how the software tasks fit together. In the implementation phase, code is assembled into modules and tested as described in SyEDP Section 3.4.5.2.2, Software Module Testing. After module testing, software is integrated with the hardware and tested as described in SyEDP Section 3.4.5.2.4, Integration Testing.
- Organization – Design team organization is discussed in SyEDP Section 2.2. Scheduling and resource allocation is described in SyEDP Section 3.1.1, Project Planning.
- Responsibilities - Design team responsibilities are discussed in SyEDP Section 2.1

Implementation Characteristics of the SIntP:

- Measurement - The software development process includes a series of technical design reviews and baseline reviews. At the end of each of these reviews, a review report and a scorecard will be issued by the review chair. The review report summarizes the results of the review. The scorecard evaluates the content of the review material and the performance of the design team based on pre-established criteria also known as metrics. Per SyEDP

Section 3.4, integration testing is part of the implementation phase (Baseline 4) baseline and technical review.

- Procedures – As indicated in SyEDP Sections 3.4.5.2.2 and 3.4.5.2.4, results, methods, and extent of testing are recorded during the testing and are included in a test item transmittal report.

Resource Characteristics of the SIntP:

- Methods/tools - SyEDP Sections 3.4.5.2.2 and 3.4.5.2.4 discuss the general methods employed for testing and types of tools used. Section 5.0 of the SyEDP describes the use of tool evaluation reports and method for approval of development tools which includes tools used for module and integration testing.

Reference

- 4-1 GE Hitachi Nuclear Energy, "Hope Creek Generating Station NUMAC PRNM Upgrade," NEDC-33864P, Revision 0, September 2015 (ADAMS Accession No. ML15265A225).

EICB-RAI-5

(Open Item 11) NUMAC SyIVVP (LAR Appendix D)

Appendix K of the LAR refers to the SyIVVP Section 4.0, "Baseline Process," to confirm BTP 7-14, Item B.3.1.10.1 criteria for assessment of risk. It is not clear to the NRC staff how the baseline process will be used to identify and manage risks associated with the V&V process. Please provide additional information on the processes and methods employed by the baseline review team for assessing project risk to safety associated with each software item and V&V task in relation to the criteria of BTP 7-14, Section B.3.1.10.1, "Risks."

Response:

Project risk management is performed during the system life cycle development phases in accordance with the GEH Quality Assurance Program (Reference 5-1). Systems Independent Verification and Validation Plan (SyIVVP) Section 4.2 (Reference 5-2) describes technical reviews. Although not stated in the SyIVVP, the GEH procedure for technical design reviews requires risk management. SyIVVP Section 4.3 describes baseline reviews, which are a process check to ensure the project plans are being followed.

References

- 5-1 GE Hitachi Nuclear Energy, "GE Hitachi Nuclear Energy Quality Assurance Program Description," NEDO-11209-A, Revision 13, August 4, 2016 (ADAMS Accession No. ML16217A239).
- 5-2 GE Hitachi Nuclear Energy, "Hope Creek Generating Station NUMAC PRNM Upgrade," NEDC-33864P, Revision 0, September 2015 (ADAMS Accession No. ML15265A225).

EICB-RAI-6

(Open Item 12) Software Configuration Management Plan (SCMP)

LAR Appendix K refers to the SyEDP (Appendix B) for the information required in BTP 7-14, Section B.3.1.11.2 criteria for software configuration management. The information identified in the SyEDP addresses configuration of documents; however, other types of configuration items (e.g., data files, tables, software libraries, support software, software tools, etc.) are not addressed. Please provide additional information to demonstrate compliance with the criteria in BTP 7-14, Section B.3.1.11.2 for the other configuration items.

Response:

System Engineering Development Plan (SyEDP) Section 3.4 (Reference 6-1) specifies configuration management of source code and Section 5 specifies configuration management of firmware. Tools are controlled at the baseline in which they are introduced. Configuration status accounting includes all the configurable items.

Reference

- 6-1 GE Hitachi Nuclear Energy, "Hope Creek Generating Station NUMAC PRNM Upgrade," NEDC-33864P, Revision 0, September 2015 (ADAMS Accession No. ML15265A225).

EICB-RAI-7

(Open Item 16) System Requirements

LAR Appendix F defines generic system requirements for a NUMAC PRNM system for a boiling water reactor nuclear power plant. It is not clear if these requirements reflect the specific system to be installed in HCGS. It is also unclear to the NRC staff if the requirements identified in Appendix F include the plant-specific requirements for the modified components described in Appendix J. Please provide additional information to ensure that all HCGS plant-specific PRNM system specifications meet the criteria in BTP 7-14, Section B.3.3.1.

Response:

The HCGS system requirements specification (NEDC-33864P Appendix F, Reference 7-1) is plant-specific. The following discussion elaborates on how the topics from Appendix J are addressed in the HCGS specifications.

Licensing Topical Report (LTR, Reference 7-2) Deviations

1. Average Power Range Monitor (APRM) Upscale / Oscillation Power Range Monitor (OPRM) Upscale / APRM Inop. Appendix F1, Section 6.1 reflects this LTR deviation.

NOTE: Appendix J reference document 001N5636 is included in Appendix A immediately following the EICB-RAI-7 response. This topic was discussed during previous Power Range Neutron Monitoring (PRNM) projects. Please see Enclosure 1 (Appendix A) of ML12040A073 submitted for Columbia Generating Station.

2. Time to Calculate Flow-Biased Trip Setpoint. This clarifies a statement in the LTR but does not affect the NUMAC PRNM design.

NOTE: Appendix J reference document 001N5637 is included in Appendix A immediately following the EICB-RAI-7 response. This topic was discussed during a previous PRNM project. Please see Enclosure 1 (Appendix A) of ML12040A073 submitted for Columbia Generating Station.

3. Abnormal Conditions Leading to Inoperative Status. Appendix F2, Section 4.3.4.9 reflects this LTR deviation.

NOTE: Appendix J reference document 001N5635 is included in Appendix A immediately following the EICB-RAI-7 response. This topic was discussed during a previous PRNM project. Please see Enclosure 1 (Appendix A) of ML12040A073 submitted for Columbia Generating Station.

4. OPRM Pre-Trip Alarms. Appendix F1, Section 4.3.1.2 reflects this LTR deviation.

NOTE: Appendix J reference document 001N5641 is included in Appendix A immediately following the EICB-RAI-7 response. This topic was discussed during a previous

PRNM project. Please see Appendix A (page A-5) of ML101790437 submitted for Grand Gulf Nuclear Station, which is a Detect and Suppress Solution – Confirmation Density (DSS-CD) plant like HCGS.

5. Increased Instrument Security. Appendix F1 Section 4.1 (traceable item 436R) provides the higher level requirement that the system provides a means to adjust user-configurable parameters, and Appendix F2 Section 4.4.14 (traceable item 2345R) incorporates the same feature at the instrument level. That the HCGS design implements increased security relative to previous applications may be seen by comparing it to a previous application. Please see Section 4.4.8 of 25A5916, APRM Performance Specification for Columbia Generating Station (NEDC-33685P Reference 64 and included in NEDC-33685P Appendix A) - ML13015A272 submitted for Columbia Generating Station. That design includes an “OPER-SET” function, a function that enables the user to adjust a small number of select parameters after entering a password but without placing the instrument in INOP. PSEG elected to not include this feature at HCGS.

NOTE: Appendix J reference document 001N5640 is included in Appendix A immediately following the EICB-RAI-7 response.

6. PRNM System Input Power Source. This deviation does not affect the PRNM design. Appendix F1 Section 7.5 reflects the type of input power as described in the HCGS License Amendment Request (LAR) Attachment 1 Section 4.1.1 page 28 of 46, which deviates from what is described in the LTR.

NOTE: Appendix J Reference document 002N3909 is included in Appendix A immediately following the EICB-RAI-7 response.

Differences from the Columbia Generating Station PRNM:

1. OPRM Solution. Appendix F1 Sections 4.1 (traceable item 225) and 4.3 reflect this difference.
2. Relay Logic Module. The new part is incorporated in schematics and bills of material, which was placed in the reading room portal. The design function is not changed and therefore does not affect Appendix F.
3. APRM High Voltage Power Supply. Appendix F2 Section 4.4.2 (traceable item 2322) reflects this difference (Note that Appendix F2 Table 4.3-1 erroneously points to Section 3.3.1 versus 4.4.2 for ‘Manual LPRM I/V curve request’).
4. Display of Calibration Constants for Local Power Range Monitor (LPRM) Detector and Flow Signals. Appendix F2 Section 4.4.5 (traceable item 2287) reflects this difference.
5. Instrument Front Panel Display. The new part is incorporated in schematics and bills of material, which were placed in the reading room portal. The design function is not changed and therefore does not affect Appendix F.

References

- 7-1 GE Hitachi Nuclear Energy, "Hope Creek Generating Station NUMAC PRNM Upgrade," NEDC-33864P, Revision 0, September 2015 (ADAMS Accession No. ML15265A225).
- 7-2 (a) GE Nuclear Energy, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," NEDC-32410P-A Volume 1, October 1995.

(b) GE Nuclear Energy, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," NEDC-32410P-A Volume 2 -- Appendices, October 1995.

(c) GE Nuclear Energy, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," NEDC-32410P-A, Supplement 1, November 1997.

APPENDIX A – EICB-RAI-7 SUPPLEMENTAL INFORMATION

001N5635, PRNM Abnormal Conditions Leading to Inoperative Status

001N5636, PRNM APRM Upscale / OPRM Upscale / APRM Inop Function Logic

001N5637, PRNM Time to Calculate Flow-biased Trip Setpoint

001N5640, PRNM Increased Instrument Security

001N5641, PRNM OPRM Amplitude and Growth Based Pre-Trip Alarms

002N3909, PRNM System Input Power Source

INFORMATION NOTICE

This is a non-proprietary version of 001N5635, Rev. 0, which has the proprietary information removed. Portions of the document that have been removed are indicated by white space inside open and closed bracket as shown here [[]].

Abnormal Conditions Leading to Inoperative Status

[[

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The way the system is designed meets the Technical Specification Requirements. Specifically, if the channel is found to be inoperative, a limiting condition for operation (LCO) exists, and the Technical Specifications allow time to correct the problem or to place the channel in INOP. Therefore, it is not necessary to cause an immediate, automatic trip if a module is determined to be missing from the chassis. [[

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Reference 1 Section 3.2.10.1 discusses the purpose of the APRM INOP trip, and provides insight. Quoting in part from that section “[[

]]”

If the system were designed as described in Reference 1 Section 5.3.8.2 and [[

]] This is well beyond the intent of the APRM INOP trip, and is not required by the Technical Specifications. Similar reasoning applies to the RBM. Therefore, the present design is acceptable.

References

1. NEDC-32410P-A Volume 1, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," October, 1995.
2. NEDC-32410P-A Volume 2 - Appendices, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," October, 1995.
3. NEDC-32410P-A Supplement 1, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," November, 1997.

APRM Upscale / OPRM Upscale / APRM Inop Function Logic

Licensing Topical Report NEDC-32410P-A Supplement 1 (Reference 3) Section 8.4.1.3 describes the logic wherein the OPRM Upscale function is voted separately from the APRM Inop function. That is, an APRM Inop in one APRM channel and an OPRM Upscale in another will result in two half-trips in each of the 2-out-of-4 voter channels, but no RPS trips.

Designed this way, when an APRM chassis keylock switch is placed in the "INOP" position, the APRM upscale trip signal sent to the 2-out-of-4 voter channels is set to trip. However, the OPRM trip output from that chassis continues to be processed normally. Typically this logic is of no consequence because if an APRM chassis (affecting both the APRM and OPRM channels) is declared inoperable, the APRM bypass can be used to bypass both the APRM and OPRM trips from that channel, which in turn modifies the logic in the 2-out-of-4 voter to be a 2-out-of-3 vote of both the APRM and OPRM trips from the remaining 3 channels. However, if the need to declare a second APRM/OPRM channel inoperable arises when another APRM/OPRM channel is already bypassed (and cannot be returned to service within the allowed out of service time), it is necessary to place the APRM and OPRM outputs from the second channel in the tripped condition to satisfy Technical Specification requirements. If the APRM channel is still sufficiently functional to process trip outputs, placing the keylock switch in the INOP position will force a trip for the APRM channel, but not for the OPRM channel. Other action, such as disconnecting a fiber-optic cable to the 2-out-of-4 voters or removing power from the APRM chassis, is necessary to satisfy the requirement to place the OPRM channel in the tripped condition.

The automatic APRM Inop trip is intended to provide a trip when the APRM channel is known to be incapable of providing a trip based on normal functions. This trip occurs immediately even though the Technical Specification requirements allow a period of time for action. The automatic trip is provided to assure that conditions that may disable the APRM trip function do not go undetected. Since the OPRM trip function is implemented in the same equipment as the APRM trip function, conditions that could disable the APRM trip function would likely disable the OPRM trip function as well.

Instead of performing as described in the LTR, the OPRM Upscale function is combined with the APRM Inop function as the OPRM channel input to be voted. That is, an APRM Inop in one APRM channel and an OPRM Upscale in another will result in RPS trip outputs from all four 2-out-of-4 voter channels. Again this logic is typically of no consequence because if an APRM chassis (affecting both the APRM and OPRM channels) is declared inoperable, the APRM bypass can be used to bypass both the APRM and OPRM trips from that channel, which in turn modifies the logic in the 2-out-of-4 voter to be a 2-out-of-3 vote of both the APRM and OPRM trips from the remaining 3 channels. This design allows using the APRM chassis keylock switch to place APRM and OPRM outputs from a second channel in the tripped condition when another APRM/OPRM channel is already bypassed (and cannot be returned to service within the allowed out of service time) without having to resort to other actions such as disconnecting a fiber-optic cable to the 2-out-of-4 voters or removing power from the APRM chassis.

Non-Proprietary Information - Class I (Public)
PRNM APRM Upscale / OPRM Upscale / APRM Inop Function Logic

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Therefore, the Supplement 1 (Reference 3) Bases are changed as follows.

1. Page H-12: change the second paragraph as shown below.

The APRM System is divided into four APRM channels and four 2-out-of-4 voter channels. Each APRM channel provides inputs to each of the four voter channels. The four voter channels are divided into two groups of two each, with each group of two providing inputs to one RPS trip system. The system is designed to allow one APRM channel, but no voter channels, to be bypassed. A trip from any one unbypassed APRM will result in a "half-trip" in all four of the voter channels, but no trip inputs to either RPS trip system. ~~APRM trip Functions 2.a, 2.b, 2.c, and 2.d are voted independently from OPRM Upscale Function 2.f. Therefore, any Function 2.a, 2.b, 2.c, or 2.d trip from any two unbypassed APRM channels will result in a full trip in each of the four voter channels, which in turn results in two trip inputs into each RPS trip system logic channel (A1, A2, B1, and B2). Similarly, a Function 2.f trip from any two unbypassed APRM channels will result in a full trip from each of the four voter channels.~~ Three of the four APRM channels and all four of the voter channels are required to be OPERABLE to ensure that no single failure will preclude a scram on a valid signal. In addition, to provide adequate coverage of the entire core, consistent with the design bases for the APRM Functions 2.a, 2.b, and 2.c, at least [20] LPRM inputs, with at least [three] LPRM inputs from each of the four axial levels at which the LPRMs are located, must be operable for each APRM channel. For the OPRM Upscale, Function 2.f, LPRMs are assigned to "cells" of [4] detectors. A minimum of [later] cells, each with a minimum of [2] LPRMs, must be OPERABLE for the OPRM Upscale Function 2.f to be OPERABLE.

Replaced deleted text with the following:

Since APRM trip Functions 2.a, 2.b, 2.c and 2.f are implemented in the same hardware, these trip Functions are combined with APRM Inop trip Function 2.d. Any Function 2.a, 2.b, 2.c or 2.d trip from any two unbypassed APRM channels will result in a full trip in each of the four voter channels, which in turn results in two trip inputs into each RPS trip system logic channel (A1, A2, B1, and B2). Similarly, any Function 2.d or 2.f trip from any two unbypassed APRM channels will result in a full trip from each of the four voter channels.

2. Page H-13: For Function 2.e, change the 1st sentence of the 3rd paragraph to the following. "The 2-Out-Of-4 Voter Function votes APRM Functions 2.a, 2.b, and 2.c independently of Function 2.f."

Non-Proprietary Information - Class I (Public)
PRNM APRM Upscale / OPRM Upscale / APRM Inop Function Logic

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References

1. NEDC-32410P-A Volume 1, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," October, 1995.
2. NEDC-32410P-A Volume 2 -- Appendices, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," October, 1995.
3. NEDC-32410P-A Supplement 1, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," November, 1997.

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Time to Calculate Flow-biased Trip Setpoint

Licensing Topical Report NEDC-32410P-A Volume 1 (Reference 1) Section 3.3.2 describes the processing time for calculating flow-biased setpoints as follows.

“[[

]]”

The Average Power Range Monitor (APRM) Simulated Thermal Power (STP) high trip is the only trip function with a setpoint that is calculated based on recirculation flow. [[

]] The flow transmitters, which are unaffected by a PRNM retrofit, also perform signal processing and their filters have time constants that are adjustable from 0.2 and 2 seconds. Allowing 5 constants to settle on a new value, the response time for the transmitters takes between 1 and 10 seconds. Thus, the response of the recirculation flow system alone exceeds what is described in Reference 1. When combined with the PRNM response, the total time could be as high as just over 10 seconds. For the reasons discussed below, this is inconsequential.

Most importantly, the Safety Analysis does not take credit for the STP high trip in any of the design basis events. Therefore, the conclusions of the Safety Analysis are not called into question in any way.

The Safety Analysis mentions the flow-biased STP trip in the context of protection against transients such as the Loss of Feedwater Heating *where thermal power increases slowly*. In this type of scenario, the thermal power and flow rates change gradually, over tens of seconds. Even if the longest setpoint calculation time is assumed, the setpoint will track closely with the ideal value (i.e., the value based on actual flow rate). Furthermore, when the initial condition is at or near rated power, the STP trip setpoint does not even vary with flow because it is clamped.

In summary, due to processing in the recirculation flow transmitters, the time for the recirculation flow system to calculate the APRM STP trip setpoint is longer than what is stated in Reference 1. However, the performance does not present any safety risks, and is acceptable.

Non-Proprietary Information - Class I (Public)
PRNM Time to Calculate Flow-biased Trip Setpoint

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References

1. NEDC-32410P-A Volume 1, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," October, 1995.
2. NEDC-32410P-A Volume 2 – Appendices, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," October, 1995.
3. NEDC-32410P-A Supplement 1, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," November, 1997.

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PRNM Increased Instrument Security

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Increased Instrument Security

Licensing Topical Report NEDC-32410P-A Volume 1 (Reference 1) Section 5.3.13 describes the three different levels of security provided as part of the NUMAC APRM design. One level involves a password only, one level involves a keylock switch only, and the third level involves a combination of both a password and a keylock switch.

One of these three levels is applied to activities that lead to changes in plant parameters or instrument mode. Section 5.3.13 explains which security levels are applied to specific activities. Additionally, Section 5.3.3.2 names the activities that can be performed with just a password.

For some activities that require just a password according to the Reference 1, a higher level of security has been voluntarily applied. Instead of requiring just a password, performing the selected activities will involve the combination of both a password and the keylock switch. The specific activities affected are changing or accepting a new APRM gain, authorizing single recirculation loop setpoints, and assigning transient test outputs.

This deviation from the LTR is justified because it is conservative relative to what is described in the LTR.

References

1. NEDC-32410P-A Volume 1, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," October, 1995.
2. NEDC-32410P-A Volume 2 -- Appendices, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," October, 1995.
3. NEDC-32410P-A Supplement 1, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," November, 1997.

Non-Proprietary Information - Class I (Public)
PRNM OPRM Amplitude and Growth Based Pre-Trip Alarms

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OPRM Amplitude and Growth Based Pre-Trip Alarms

LTR NEDC-32410P-A (Reference 1) paragraph 3.3.3.1.2 states that [[

]]

References

1. NEDC-32410P-A Volume 1, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," October, 1995.
2. NEDC-32410P-A Volume 2 -- Appendices, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," October, 1995.
3. NEDC-32410P-A Supplement 1, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip Function," November, 1997.
4. NEDO-31960-A, "BWR Owners' Group Long-Term Stability Solutions Licensing Methodology," November 1995.
5. NEDO-31960-A Supplement 1, "BWR Owners' Group Long-Term Stability Solutions Licensing Methodology," November 1995.
6. NEDO-32465-A, "Reactor Stability Detect and Suppress Solutions Licensing Basis Methodology for Reload Applications," August 1996.

Non-Proprietary Information - Class I (Public)
PRNM System Input Power Source

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PRNM System Input Power Source

Licensing Topical Report NEDC-32410P-A Volume 1 (Reference 1), Sections 5.3.5.6 and 5.3.8.1, describe the input power source for PRNM system as RPS power. The replacement PRNM system utilizes the same power sources as the existing PRM system. For some plants, the PRM system is powered from a source other than the RPS buses. The acceptability of these other power sources is already documented and approved as part of the plant's existing licensing basis. The discussion on effects of failure in Sections 5.3.5.6 and 5.3.8.1 of reference 1 is still applicable when the PRNM system is powered by these other power sources. The existing plant basis for use of these other power sources is still applicable for the replacement PRNM system.

References

1. NEDC-32410P-A, "Nuclear Measurement Analysis and Control Power Range Neutron Monitor (NUMAC PRNM) Retrofit Plus Option III Stability Trip function," Volumes 1 and 2, October, 1995.

EICB-RAI-8

(Open Item 28)

LAR Section 4.1.1 states that, “[a]ll interfaces with external systems are maintained electrically equivalent using interface subassemblies with exception of the interface to the plant computer and plant operator's panel.” As written, this statement implies that plant computer and operator's panel interfaces do not maintain electrical compatibility between the PRNM system and these systems. The NRC staff needs to understand the nature of this exception in order to determine if these interfaces are compliant with independence criteria of IEEE Standard 603-1991, “IEEE Standard Criteria for Safety Systems for Nuclear Generating Stations,” as incorporated by Title 10 of the *Code of Federal Regulation* Section 55a, “Codes and standards,” paragraph (h). Please provide additional information describing this exception, as well as a justification for why this exception is acceptable from a system functional and independence perspective.

Response:

The statement was not meant to imply that any of the PRNM system interfaces do not maintain electrical compatibility. This statement indicates that all interfaces other than those mentioned are electrically equivalent to the existing system, as discussed in the PRNM LTR Section 2.1.2.

The plant computer interface is modified by deleting the existing physical I/O and implementing a data link.

The plant operator's panel interface is modified by the addition of Operator Display Assemblies.

Hope Creek's proposed design conforms to descriptions of these interfaces in the PRNM LTR. The system compliance with electrical independence is addressed in Appendix L of NEDC-33864P.

SRXB-RAI-1

(Open Item 22) Diversity and Defense in Depth Analysis (LAR Appendix I)

Appendix-I, "Diversity and Defense in Depth Analysis," provides information to reach the conclusion that the instrumentation and controls are sufficiently robust against software common cause failure. For Section 4.1.2, "Instability," provide the TRACG transient results plots (please include all relevant sensitivity parameters) for the limiting cases to demonstrate that the Safety Limit Minimum Critical Power Ratio (SLMCPR) is not exceeded for these events.

Response:

[[

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[[

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Figure 1-1: [[]]

[[

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Figure 1-2: [[]]

SRXB-RAI-2

(Open Item 25) Thermal Hydraulic Stability (LAR Appendix T)

Appendix-T, "HCGS Thermal Hydraulic Stability, DSS-CD Evaluation," describes the long-term thermal hydraulic stability solution. The TRACG confirmatory best-estimate Minimum Critical Power Ratio margins to the SLMCPR were calculated and are summarized in Appendix-T, Table 2-2. Submit the detailed plots (please include all relevant sensitivity parameters) that include the important parameters for the most limiting case to demonstrate that the SLMCPR is not exceeded.

Response:

[[

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[[

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Figure 2-1: [[

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AFFIDAVIT

I, **Lisa K. Schichlein**, state as follows:

- (1) I am a Senior Project Manager, NPP/Services Licensing, Regulatory Affairs, GE-Hitachi Nuclear Energy Americas LLC (GEH), and have been delegated the function of reviewing the information described in paragraph (2) which is sought to be withheld, and have been authorized to apply for its withholding.
- (2) The information sought to be withheld is contained in Enclosure 1 of GEH letter GEH-KT0-182455-183, "GEH Responses to Hope Creek NUMAC PRNM Phase 1 RAIs," dated September 14, 2016. The GEH proprietary information in Enclosure 1, which is entitled "GEH Responses to Hope Creek PRNMS RAIs," is identified by a dotted underline inside double square brackets. ~~[[This sentence is an example.⁽³⁾]]~~ In each case, the superscript notation ⁽³⁾ refers to Paragraph (3) of this affidavit, which provides the basis for the proprietary determination.
- (3) In making this application for withholding of proprietary information of which it is the owner or licensee, GEH relies upon the exemption from disclosure set forth in the *Freedom of Information Act* ("FOIA"), 5 U.S.C. Sec. 552(b)(4), and the *Trade Secrets Act*, 18 U.S.C. Sec. 1905, and NRC regulations 10 CFR 9.17(a)(4), and 2.390(a)(4) for trade secrets (Exemption 4). The material for which exemption from disclosure is here sought also qualifies under the narrower definition of trade secret, within the meanings assigned to those terms for purposes of FOIA Exemption 4 in, respectively, Critical Mass Energy Project v. Nuclear Regulatory Commission, 975 F.2d 871 (D.C. Cir. 1992), and Public Citizen Health Research Group v. FDA, 704 F.2d 1280 (D.C. Cir. 1983).
- (4) The information sought to be withheld is considered to be proprietary for the reasons set forth in paragraphs (4)a. and (4)b. Some examples of categories of information that fit into the definition of proprietary information are:
 - a. Information that discloses a process, method, or apparatus, including supporting data and analyses, where prevention of its use by GEH's competitors without license from GEH constitutes a competitive economic advantage over other companies;
 - b. Information that, if used by a competitor, would reduce their expenditure of resources or improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product;
 - c. ~~Information that reveals aspects of past, present, or future GEH customer-funded development plans and programs, resulting in potential products to GEH;~~
 - d. Information that discloses trade secret or potentially patentable subject matter for which it may be desirable to obtain patent protection.
- (5) To address 10 CFR 2.390(b)(4), the information sought to be withheld is being submitted to NRC in confidence. The information is of a sort customarily held in confidence by GEH,

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and is in fact so held. The information sought to be withheld has, to the best of my knowledge and belief, consistently been held in confidence by GEH, not been disclosed publicly, and not been made available in public sources. All disclosures to third parties, including any required transmittals to the NRC, have been made, or must be made, pursuant to regulatory provisions or proprietary or confidentiality agreements that provide for maintaining the information in confidence. The initial designation of this information as proprietary information, and the subsequent steps taken to prevent its unauthorized disclosure, are as set forth in the following paragraphs (6) and (7).

- (6) Initial approval of proprietary treatment of a document is made by the manager of the originating component, who is the person most likely to be acquainted with the value and sensitivity of the information in relation to industry knowledge, or who is the person most likely to be subject to the terms under which it was licensed to GEH.
- (7) The procedure for approval of external release of such a document typically requires review by the staff manager, project manager, principal scientist, or other equivalent authority for technical content, competitive effect, and determination of the accuracy of the proprietary designation. Disclosures outside GEH are limited to regulatory bodies, customers, and potential customers, and their agents, suppliers, and licensees, and others with a legitimate need for the information, and then only in accordance with appropriate regulatory provisions or proprietary or confidentiality agreements.
- (8) The information identified in paragraph (2), above, is classified as proprietary because it contains detailed GEH design information of the instrumentation and control equipment used in the design and analysis of Nuclear Measurement Analysis and Control digital instrumentation systems by GEH. Development of these methods, techniques, and information and their application for the design, modification, and analyses methodologies and processes was achieved at a significant cost to GEH.

The development of the evaluation processes along with the interpretation and application of the analytical results is derived from extensive experience databases that constitute a major GEH asset.

- (9) Public disclosure of the information sought to be withheld is likely to cause substantial harm to GEH's competitive position and foreclose or reduce the availability of profit-making opportunities. The information is part of GEH's comprehensive BWR safety and technology base, and its commercial value extends beyond the original development cost. The value of the technology base goes beyond the extensive physical database and analytical methodology and includes development of the expertise to determine and apply the appropriate evaluation process. In addition, the technology base includes the value derived from providing analyses done with NRC-approved methods.

The research, development, engineering, analytical and NRC review costs comprise a substantial investment of time and money by GEH. The precise value of the expertise to devise an evaluation process and apply the correct analytical methodology is difficult to quantify, but it clearly is substantial. GEH's competitive advantage will be lost if its

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competitors are able to use the results of the GEH experience to normalize or verify their own process or if they are able to claim an equivalent understanding by demonstrating that they can arrive at the same or similar conclusions.

The value of this information to GEH would be lost if the information were disclosed to the public. Making such information available to competitors without their having been required to undertake a similar expenditure of resources would unfairly provide competitors with a windfall, and deprive GEH of the opportunity to exercise its competitive advantage to seek an adequate return on its large investment in developing and obtaining these very valuable analytical tools.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 14th day of September 2016.



Lisa K. Schichlein
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Regulatory Affairs
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