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10 CFR 50.4
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ATTN: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: UniStar Nuclear Energy, NRC Docket No. 52-016
Response to Request for Additional Information for the
Calvert Cliffs Nuclear Power Plant, Unit 3,
RAI No. 319, Human Factors Engineering

Reference: Surinder Arora (NRC) to Paul Infanger (UniStar Nuclear Energy), "FINAL RAI
319 COLP 6037," dated September 19, 2011.

The purpose of this letter is to respond to the request for additional information (RAI) identified in the NRC e-mail correspondence to UniStar Nuclear Energy, dated September 19, 2011 (Reference). This RAI addresses Human Factors Engineering, as discussed in Section 18.7, 18.8, and 18.12 of the Final Safety Analysis Report (FSAR), as submitted in Part 2 of the Calvert Cliffs Nuclear Power Plant (CCNPP) Unit 3 Combined License Application (COLA), Revision 7.

The enclosure provides our response to RAI No. 319 Question 18-2, and includes revised COLA content. A Licensing Basis Document Change Request has been initiated to incorporate these changes into a future revision of the COLA.

Our response does not include any new regulatory commitments. This letter does not contain any sensitive or proprietary information.

DOG
NRC


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If there are any questions regarding this transmittal, please contact me at (410) 369-1905, or Mr. Wayne A. Massie at (410) 369-1910.

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

Executed on October 18, 2011


for Greg Gibson

Enclosure: Response to NRC Request for Additional Information RAI No. 319, Question 18-2, Human Factors Engineering, Calvert Cliffs Nuclear Power Plant, Unit 3

cc: Surinder Arora, NRC Project Manager, U.S. EPR Projects Branch
Laura Quinn, NRC Environmental Project Manager, U.S. EPR COL Application
Getachew Tesfaye, NRC Project Manager, U.S. EPR DC Application (w/o enclosure)
Charles Casto, Deputy Regional Administrator, NRC Region II (w/o enclosure)
Silas Kennedy, U.S. NRC Resident Inspector, CCNPP, Units 1 and 2
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GTG/FRP/mdf

Enclosure

**Response to NRC Request for Additional Information
RAI No. 319, Question 18-2,
Human Factors Engineering,
Calvert Cliffs Nuclear Power Plant, Unit 3**

RAI No. 319

Question 18-2

Regulatory guidance: 52.79(c) (1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the design approval, *provided, however,* that the final safety analysis report must either include or incorporate by reference the standard design approval final safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design approval.

Evaluation: CCNPP FSAR, Revision 7 contains information that is inconsistent with U.S. EPR FSAR, Revision 3. For example:

1. CCNPP Section 18.7 adds supplemental information on Minimum Inventory. However, the EPR FSAR explains that minimum inventory is no longer singled out since the task analysis identifies a complete inventory. Since an ITAAC tracks this work, and ITAAC are the COLA's responsibility, plant specific inventory is within the scope of the ITAAC. This seems to be a less confusing path than adding a list to the CCNPP FSAR. Also it is not clear why wind and temperature data would be plant specific (perhaps it is because the elevations have been specifically designated). If the minimum inventory information is retained, it also raises the question of whether it is a complete list. For example, there is no indication of switchyard status. Typically, the control room would have switchyard breaker and disconnect indications as well as normal electrical power feed into the plant.
2. CCNPP Section 18.8 references section 18.8.2 of the EPR FSAR. This creates circular referencing. It is preferred that the CCNPP FSAR just reference Chapter 13 similar to what is done in CCNPP FSAR, Section 18.9. An alternative would be to directly address the COL information item by describing the HFE principles that will be applied to procedures (for example, the typical guidance incorporated in a writer's guide).
3. CCNPP Section 18.12 references a COL item which no longer exists in EPR FSAR, Revision 3. But more importantly, it appears the EPR DCD is being used as a template with new information provided and EPR FSAR information deleted to establish a site specific version. A quick comparison between the EPR and CCNPP documents indicates that the CCNPP document would probably stand on its own if evaluated against NUREG-0711 but it has some significant differences from what is in the EPR FSAR which is what will be approved. Some of these differences represent deviations, and as such, need a basis.

Information Request: Update the CCNPP FSAR to address EPR FSAR, Revision 3 with specific attention to the examples described above.

Response

Question Part 1:

The Calvert Cliffs Unit 3 (CCNPP Unit 3) FSAR Section 18.7 will be revised, as identified COLA Impact section below, to remove the supplemental information on Minimum Inventory. The Design Features section of the U.S. EPR FSAR Tier 1 Section 3.4, indicates that the selection of the minimum inventory is performed in accordance with the U.S. EPR Human System Interface Design Implementation Plan. U.S. EPR FSAR Tier 1 Section 3.4 provides Table 3.4-1 which lists the Human Factors Engineering (HFE) Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC). The selection of the minimum inventory of main control room and remote shutdown station fixed alarms, displays, and controls is addressed by HFE ITAAC Table 3.4-1 (commitment wording No. 8). Therefore, plant specific minimum inventory is within the scope of the ITAAC.

Question Part 2:

FSAR Section 18.8 will be revised, as identified COLA Impact section below, to reference Section 13.5. Section 13.5 is the correct reference and FSAR Section 18.8 will reference Chapter 13 in a manner similar to what is done in FSAR Section 18.9. FSAR Section 13.5 has been revised to include mention of a Writer's Guide which will ensure that procedures comply with HFE principles.

Question Part 3:

The reference to COL Item 18.12-1, which no longer exists, has been deleted from FSAR Table 1.8-2 and COLA Part 10. FSAR Section 18.12 has been revised as identified in the COLA Impact section below to be site specific. Table 13.4-1 has been revised to include the Human Performance Monitoring (HPM) Program under the License Condition for COL Item 13.4-1. COLA Part 7, Departures and Exemption Requests, Section 1.1.X has been added to provide the associated departure justification. The departure justification provides an evaluation of the site specific HPM Program against NUREG-0711.

COLA Impact

FSAR Table 1.8-2 will be revised as follows:

Table 1.8-2 – FSAR Sections that Address COL Items

Item No.	Description	Section
...		
18.9-1	A COL applicant that references the U.S. EPR design certification will describe how HFE principles and criteria are incorporated into the development of training program scope, structure, and methodology.	18.9
18.12-1	A COL applicant that references the U.S. EPR design certification will implement a human performance monitoring program similar to that which is described in this section.	18.12
19.0-1	A COL applicant that references the U.S. EPR design certification will either confirm that the PRA in the design certification bounds the site specific design information and any design changes or departures, or update the PRA to reflect the site-specific design information and any design changes or departures.	19.0
...		

FSAR Table 13.4-1 will be revised as follows:

Table 13.4-1—{Operational Programs Required by NRC Regulations and Program Implementation}

Item	Program Title	Source	FSAR	Implementation	
		(Required By)	Section	Milestones	Requirements
19	Initial Test Program	10 CFR 50.34; 10 CFR 52.79(a)(28)	14.2 Note 1	Prior to conduct of activities described in the Initial Test Program	License Condition
20	Human Performance Monitoring (HPM)	10 CFR 50.34(f); 10 CFR 52.47(a)(1)(ii)	18.12	Prior to authorization to load fuel per 10 CFR 52.103(g)	License Condition

FSAR Section 13.5 will be revised as follows:

13.5 PLANT PROCEDURES

This section of the U.S. EPR FSAR is incorporated by reference with the following supplements.

The U.S. EPR FSAR includes the following COL Item in Section 13.5:

A COL applicant that references the U.S. EPR design certification will provide site-specific information for administrative, operating, emergency, maintenance and other operating procedures.

This COL Item is addressed as follows:

This section of the FSAR describes the administrative and operating procedures that the operating organization (plant staff) uses to ensure that routine operating, off-normal, and emergency activities are conducted in a safe manner. Activities affecting quality shall be prescribed by and conducted in accordance with approved procedures.

Procedures are developed consistent with guidance in the U.S. EPR FSAR Section 48.8.A detailed Writer's Guide will be developed which ensures each procedure is sufficiently detailed, consistently formatted and complies with Human Factors Engineering principles. The typical guidance incorporated into the Writer's Guide will include but not be limited to:

- Rigorous application of HFE guidelines to procedures associated with plant operations and testing:
 - Generic Technical Guidelines (GTG) for emergency operating procedures.
 - Plant and system operations (including startup, power, and shutdown operations).
 - Abnormal and emergency operations.
 - Alarm response.
 - Equipment testing.
- Consistency in organization, style, and content.
- Consistency with terminology, abbreviations, and the use of component coding.
- Technically accurate, comprehensive, explicit, easy to use, and validated by task analysis (i.e., the user can comply with the requirements of each step).

FSAR Section 18.7 will be revised as follows:

18.7 HUMAN SYSTEM INTERFACE DESIGN

This section of the U.S. EPR FSAR is incorporated by reference ~~{with the following supplements}~~.

Table 18.7-1—{Minimum Inventory of Main Control Room Fixed Alarms, Displays, and Controls}

Description	Alarm	Display	Control
ESWS Cooling Tower Basin Level	X	X	X
Meteorological Monitoring System Wind Speed—10 meters		X	
Meteorological Monitoring System Wind Speed—60 meters		X	
Meteorological Monitoring System Wind Direction—10 meters		X	
Meteorological Monitoring System Wind Direction—60 meters		X	
Meteorological Monitoring System Vertical Temperature Difference—between 10 and 60 meters		X	

Table 18.7-2—{Minimum Inventory of Remote Shutdown Station Fixed Alarms, Displays, and Controls}

Description	Alarm	Display	Control
ESWS Cooling Tower Basin Level	X	X	X
Meteorological Monitoring System Wind Speed—10 meters		X	
Meteorological Monitoring System Wind Speed—60 meters		X	
Meteorological Monitoring System Wind Direction—10 meters		X	
Meteorological Monitoring System Wind Direction—60 meters		X	
Meteorological Monitoring System Vertical Temperature Difference—between 10 and 60 meters		X	

FSAR Section 18.8 will be revised as follows:

18.8 PROCEDURE DEVELOPMENT

This section of the U.S. EPR FSAR is incorporated by reference with the following supplement.

The U.S. EPR FSAR includes the following COL Item in Section 18.8:

A COL applicant that references the U.S. EPR design certification will describe how HFE principles and criteria are incorporated into the development program for site procedures.

This COL Item is addressed as follows:

Plant specific procedures are developed consistent with the guidance of the operational guidelines described in Section 13.518.8.2 of the U.S. EPR FSAR.

FSAR Section 18.12 will be revised as follows:

18.12 HUMAN PERFORMANCE MONITORING

~~The U.S. EPR FSAR includes the following COL Item in Section 18.12:~~

~~A COL applicant that references the U.S. EPR design certification will implement an HPM program similar to that which is described in this section.~~

~~This COL Item is addressed as follows:~~

~~{The following site-specific information represents a Departure to the U.S. EPR conceptual Human Performance Monitoring (HPM) description is replaced with site-specific information as follows:~~

Monitoring human performance is performed throughout the life of the plant so that:

- ◆ The results of the integrated system validation are maintained.
- ◆ Operator performance does not degrade over time.
- ◆ Issues discovered by operating and maintenance personnel are noted, tracked, and corrected before plant safety is compromised.
- ◆ Changes made to the design do not result in a degradation of human performance.

18.12.1 Objectives and Scope

The objectives for HPM are:

- ◆ To confirm that the design can be effectively used by personnel.
- ◆ To confirm that human actions (HAs) are accomplished within an acceptable time and meet performance criteria.
- ◆ To confirm that design changes do not adversely affect personnel performance.
- ◆ To confirm that the acceptable level of performance established during the integrated system validation remains valid.
- ◆ To confirm that the acceptable level of performance established during the integrated system verification is maintained.
- ◆ Monitoring is done for HAs commensurate with their safety significance.

- ◆ To detect degrading human performance before plant safety is compromised.
- ◆ To confirm identified errors in the design are resolved in a timely manner.

To verify that the objectives are met, HPM is conducted in areas of the plant requiring HAS, including:

- ◆ Main Control Room (MCR).
- ◆ Remote Shutdown Station (RSS).
- ◆ Technical Support Center (TSC).
- ◆ Local Control Stations (LCSs) important to plant safety.
- ◆ Emergency Operations Facility (EOF).
- ◆ Operational Support Center(OSC).

Operation, testing, and maintenance actions during each plant mode are also monitored for human performance.

The HPM program establishes the requirements and interfaces for continuous improvement of human performance. The goal of the program is to reduce human errors that lead to plant events by promoting fundamental behaviors that support safe, reliable, and event free operation by:

- ◆ Establishing a strategic approach and expectations to improving human performance.
- ◆ Establishing processes to maintain and improve human performance.
- ◆ Promote behaviors to identify and eliminate error-likely situations.

The program elements include:

- ◆ Identification, evaluation, and performance of risk-significant activities using appropriate human performance tools.
- ◆ Provision of human performance tools to site personnel and promoting their use through training and procedures.
- ◆ Provision of a variety of defense-in-depth measures (such as pre-job briefs, just-in-time training, contingency planning, etc.) to reduce the probability of error and mitigate its effects should an error occur.
- ◆ The use of subordinate and peer coaching to reinforce desired behaviors.

- ◆ Assessment and trending of human performance through the use of field observations and assessments.
- ◆ Provision of feedback on suggestions for improvement.

18.12.2 Methodology

HPM is performed by observing personnel activities (i.e., during training and operation), interviews, self-initiated feedback, and walkthroughs. The use of a corrective action program combined with tracking issues allows design errors, design issues, operator workarounds, operator burdens, or inefficiencies to be captured and addressed. Programs such as the design change control process, operator focus index, performance indicators, and corrective action program are in place to prevent degradation of human performance. The combination of these tools creates a strategy that meets the intent of HPM as described in NUREG-0711 (NRC, 2004).

18.12.2.1 Corrective Action Program and Issue Tracking

The UniStar Nuclear Quality Assurance Program Description (UNE, 2007) describes the corrective action program used so that issues are documented, reviewed, addressed, tracked, and trended.

Plant personnel are encouraged to report errors, deficiencies, workarounds, and design inefficiencies, to ensure that issues are captured. Personnel performing evaluations of recommended dispositions shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

For significant conditions adverse to quality, the cause of the condition is determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality is documented and reported to appropriate levels of management. Follow-up action is taken to verify implementation of the corrective action.

Trend evaluation is performed in a manner and at a frequency that provides for prompt identification of adverse quality trends. Identified adverse trends are handled in accordance with the corrective action program described in the UniStar Nuclear Quality Assurance Program (UNE, 2007), and reported to the appropriate level of management.

Industry and self-identified operating experience results contribute to enhancing human performance and preventing potential reduction in human performance. Self-identified human performance operating experience will be documented, reviewed, addressed, tracked, and trended through the corrective action program. The industry operating experience issues are screened for human performance and analyzed for applicability to CCNPP Unit 3. Preventive measures are taken for those issues that could potentially adversely impact human performance.

18.12.2.2 Monitoring and Trending

HAs and the level of performance are monitored during simulator-training and during actual plant conditions, when feasible. The data from monitoring is evaluated and the results are entered into the corrective action program for analysis and trending. The results of the trends are used to monitor for any change, positive and negative, in human performance. If the trend shows that performance has degraded, corrective actions are performed.

Risk-significant HAs are monitored more frequently so that degradation of safety-related performance is corrected before the safety of the plant is compromised.

18.12.2.23 Design Change Process

Before a design change that has a significant impact on a Human System Interface (HSI) ~~FRA, FA, TA, HSIs, procedures, or training~~ is implemented in the plant, the change is typically modeled on the simulator. Human performance is monitored using applicable scenarios developed during operational condition sampling and used during the integrated system validation (see Section 18.10). These scenarios are limited to only those that use tasks affected by the design change to allow analysis of performance efficiency, degradation, or improvement. During simulation, user actions are observed for their efficiency and ability to perform tasks with the new design. The results are verified against the existing trend of human performance to determine if the performance was degraded by the design change.

Any degradation in performance resulting from the design change is entered into the corrective action program to be analyzed for possible areas of improvement and used as input to human performance trending. Significant impacts to human performance require that the design change be modified. If no degradation in performance is observed, the design is implemented and results of the HPM are entered into the current trend.

Operational feedback is used to validate that the design is implemented and is operating as expected.

18.12.2.34 Performance Indicators

An operational focus index is used to trend performance of operator's day to day activities. Indicators are used to exhibit the level of performance and risk associated with different operational activities.

Adverse trends are entered into the corrective action program. Further analysis may be required to understand the adverse trend and identify effective corrective actions.

18.12.2.45 Probabilistic Risk Assessment

Probabilistic risk assessment (PRA) models are used when plant or personnel performance can not be simulated, monitored, or measured. Performance data

from modeled risk-significant HAs are used to evaluate the risk of the proposed design change on human performance during different operation modes. UniStar Nuclear Operating Services maintains the PRA model. After a design change, the PRA model is updated to reflect the new design.

18.12.2.56 Existing Plant Maintenance and Inspection Programs

No departures or supplements. Additional plant programs are used to support human performance. Barriers, including the inservice inspection and inservice testing program and the maintenance rule, are used to prevent a negative impact on human performance. To maintain acceptable human performance, structures, systems, and components (SSC) must be maintained in proper working order. Routine testing and inspection of SSC is performed so that deficiencies are corrected before the SSC become ineffective or inoperable.

Operators require proper notification when an SSC is out of commission for maintenance or repair in order to maintain sufficient human performance. Use of an inoperable SSC could potentially be tracked as an error in human performance and indicate a false trend.

18.12.3 Results Summary

HPM is continued throughout the life of the plant. Reports summarizing human performance-related issues, resolution of those issues, implementation status, and operating experience results are maintained for trending purposes. Operating conditions determine the necessary frequency of these summary reports.

UniStar Nuclear Operating Services shall maintain an HPM program which meets the intent given in this section. Documentation of HPM summarizes the following:

- ◆ Baseline human performance criteria established during V&V.
- ◆ HPM implementation strategy.
- ◆ Any trends in human performance.
- ◆ Operator focus index.
- ◆ Human performance-related issues, resolution, implementation status, and operating results.
- ◆ Specific human performance issues that can be applied to the standard U.S. EPR plant

18.12.4 References

NRC, 2004. NUREG-0711, "Human Factors Engineering Program Review Model," 2004.}

~~AREVA, 2007. Letter, Ronnie L. Gardner (AREVA NP Inc.) to Document Control Desk (NRC), Request for Review and Approval of ANP-10279, Revision 0, "U.S. EPR Human Factors Engineering Program," NRC:07:004, January 23, 2007.~~

~~UNE, 2007. "UniStar Nuclear, NRC Project No. 746, Submittal of the Published UniStar Topical Report No. UN-TR-06-001-A, 'Quality Assurance Program Description,' Revision 0", UniStar Nuclear, April 9, 2007.)~~

COLA Part 7, Departures and Exemption Requests, Section 1.1 will be revised as follows:

1.1 DEPARTURES

...

9. Generic Technical Specifications and Bases - Setpoint Control Program
- X. Human Performance Monitoring

A new COLA Part 7, Departures and Exemption Requests, Section 1.1.X will be added as follows:

1.1.X Human Performance Monitoring

Affected US EPR FSAR Sections: Tier 2 Section 18.12

Summary of Departure:

The U.S. EPR FSAR Section 18.12 provides an outline and criteria of the Human Performance Monitoring Program (HPM) performed throughout the life of the plant. The corresponding CCNPP Unit 3 FSAR Chapter 18.12 replaces the U.S. EPR FSAR program with the UniStar Nuclear Energy (UNE) Human Performance Monitoring Program.

The UniStar Nuclear Energy Human Performance Monitoring Program contains recent operating experience, which further refines requirements and interfaces for continuous improvement of human performance. The key elements of the program are:

- Scoping of the performance monitoring strategy.
- Development and documentation of the human performance monitoring strategy for implementation and continuous improvement across organizations.
- Structuring the program such that,
 - Human actions are monitored commensurate with their safety importance
 - Feedback of information and corrective actions are accomplished in a timely manner

- Degradation in performance can be detected and corrected before plant safety is compromised
- Close approximation of performance data, in actual conditions, when measurable human performance information is not available,
- Ensuring the Corrective Action Program (CAP) is effectively incorporating identification, resolution and trending of human performance issues, in support of other programs such as self-assessments and peer reviews.

The Corrective Action Program is in accordance with the UniStar Nuclear Quality Assurance Program, which provides UniStar requirements for the documentation, review, resolution and tracking and trending of Human Performance issues throughout the life of the plant. The use of an operational focus index provides a rigorous approach to trend operator's day to day activities. The operation focus index leaves the flexibility, to include additional data sets in addition to industrial norms to ensure the rigor of issue analysis.

Scope/Extent of Departure:

This Departure is identified in CCNPP Unit 3 PART 2 FSAR, Section 18.12.

Departure Justification:

The US EPR FSAR Section 18.12 is replaced with UniStar Nuclear Energy's Human Performance Monitoring Program. This aligns with UNE's corporate strategy for HPM requirements and Corrective Action Program. The underlining objective of the UNE HPM strategy is to ensure no significant safety degradation occurs because of any changes that are made in the plant and to verify that the conclusions that have been drawn from the human performance evaluation remain valid over the life of the plant. UniStar Nuclear Energy's HPM Program meets the requirements of NUREG-0711, therefore, it is an acceptable replacement for the U.S. EPR HPM Program.

Departure Evaluation:

This Departure is associated with the details of implementing the Human Performance Monitoring Program. The additions, deletions, and changes to the US EPR FSAR Section 18.12 have been evaluated and determined to not adversely affect the safety function of any SSC, procedures or analysis of the plant. Accordingly, this departure does not:

1. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant specific FSAR;
2. Result in more than a minimal increase in the likelihood of occurrence of malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant specific FSAR;

3. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant specific FSAR;
4. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant specific FSAR;
5. Create a possibility for an accident of a different type than any evaluated previously in the plant specific FSAR;
6. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant specific FSAR;
7. Result in a design basis limit for a fission product barrier as described in the plant specific FSAR being exceeded or altered; or Result in a departure from a method of evaluation described in the plant specific FSAR used in establishing the design bases or in the safety analyses;
8. This Departure does not affect resolution of a severe accident issue identified in the plant specific FSAR.

Therefore, this Departure has no safety significance.

COLA Part 10 ITAAC will be revised as follows (only the impacted portions are shown):

...

COL Item 18.1-1 in Section 18.1

{Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC} shall execute the NRC approved Human Factors Engineering program as described in U.S. EPR FSAR Section 18.1.

COL Item 18.12-1 in Section 18.12

~~Prior to initial fuel load, {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC} shall implement a Human Performance Monitoring Program consistent to the one described in FSAR Section 18.12.~~

COL Item 19.1-9 in Section 19.1.2.2

As-designed and as-built information shall be reviewed, and walk-downs shall be performed, as necessary, to confirm that the assumptions used in the Probabilistic Risk Assessment (PRA), including design certification related PRA assumptions found in U.S. EPR FSAR Table 19.1-109 and PRA inputs to the Reliability Assurance Program and Severe Accident Mitigation Design Alternatives, remain valid with respect to internal events, internal flooding and fire events (routings and locations of pipe, cable and conduit), and Human Reliability Assurance (i.e., development of operating procedures, emergency operating procedures and severe accident management guidelines and training), external events including PRA-based seismic margins, high confidence, low probability of failure fragilities, and low power shutdown procedures. These activities shall be performed prior to initial fuel load.

...