FINAL SAFETY ANALYSIS REPORT

CHAPTER 17

QUALITY ASSURANCE AND RELIABILITY ASSURANCE

17.0 QUALITY ASSURANCE AND RELIABILITY ASSURANCE

This chapter of the U.S. EPR Final Safety Analysis Report (FSAR) is incorporated by reference with supplements as identified in the following sections.

17.1 QUALITY ASSURANCE DURING DESIGN

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

17.2 QUALITY ASSURANCE DURING THE OPERATIONS PHASE

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 17.2:

> A COL applicant that references the U.S. EPR design certification will provide the Quality Assurance Programs associated with the construction and operations phase.

This COL Item is addressed as follows:

This information is provided in Section 17.5.

17.3 QUALITY ASSURANCE PROGRAM DESCRIPTION

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

17.4 RELIABILITY ASSURANCE PROGRAM

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

17.4.1 Reliability Assurance Program Scope, Stages, and Goals

No departures or supplements.

17.4.2 Reliability Assurance Program Implementation

The U.S. EPR FSAR includes the following COL Item in Section 17.4.2:

> A COL applicant that references the U.S. EPR design certification will identify the site-specific SSC within the scope of the RAP.

This COL Item is addressed as follows:

Based on a review of site-specific information, the design certification probabilistic risk assessment (PRA) is bounding and representative of the U.S. EPR plant proposed at the {CCNPP} site. It is concluded that the U.S. EPR design-specific PRA model can be used, without modification, as the plant-specific PRA. This is based on the plant-specific features being conservatively modeled in the design-specific U.S. EPR PRA. Site and plant parameters that could influence the PRA results are addressed in the evaluation and it is determined that the design-PRA: (1) bounds or sufficiently captures site and plant parameters; and (2) the site and plant parameters do not have a significant impact on the PRA results and insights. Therefore, no changes to the design-specific internal events PRA are necessary when considering specific site and plant parameters.

Based on the above evaluation, no additional components related to the site are identified by the PRA for the site-specific RAP scope. Accordingly, the SSC identified by the PRA for consideration to be within the RAP during the design certification process are the same SSC for consideration within the plant-specific RAP scope.

U.S. EPR FSAR Tier 2 Tables 17.4-1 and 17.4-2 specify the SSC identified by the PRA for consideration within the scope of RAP.

For systems and structures within the design certification scope, deterministic insights in the risk-significant SSC determination process are incorporated by using an expert panel. A list of systems and structures within the design certification scope and the bases to be included within the RAP is provided in U.S. EPR FSAR Tier 2 Table 17.4-3.

Site specific systems were qualitatively evaluated based on deterministic criteria including but not limited to:

- A contribution to the initiators
- An implicit contribution to the CDF
- An implicit contribution to the LRF
- A contribution to seismic margin analysis, performance history/operating experience of the component

- Technical Specifications considerations for the component
- Detection of component failures
- The effect of component failure on the other systems

As a result of this qualitative evaluation Table 17.4-1 provides a list of plant specific systems and structures to be included within the RAP.

17.4.3 Organization, Design Control, Procedures and Instructions, Corrective Actions, and Audit Plans

No departures or supplements.

17.4.4 Reliability Assurance Program Information Needed in a COL Application

The U.S. EPR FSAR includes the following COL Item in Section 17.4.4:

> A COL applicant that references the U.S. EPR design certification will provide the information requested in Regulatory Guide 1.206, Section C.I.17.4.4.

This COL Item is addressed as follows:

An introduction to the objectives of the Reliability Assurance Program including Design Reliability Assurance (D-RAP) is provided in the U.S. EPR FSAR Section 17.4. This section discusses post-certification D-RAP and the transition to reliability assurance activities during operations.

Reliability assurance activities are implemented in two stages. Stage 1 encompasses D-RAP conducted during certification of the U.S. EPR (described in the U.S. EPR FSAR Section 17.4) and the D-RAP for the site-specific design including procurement, construction, and fabrication and testing leading up to initial fuel load. D-RAP is largely accomplished for {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC} by the NSSS vendor and the Architect Engineer.

Stage 2 reliability assurance activities are conducted principally by {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC} and commence during the transition to fuel load and plant operation and are implemented concurrently with and as part of the Maintenance Rule (MR) program described in Section 17.7 and the other programs described below. The MR program is implemented prior to authorization to load fuel per 10 CFR 52.103(g).

Stage 2 reliability assurance activities continue for the life of the plant and with the MR program are implemented using traditional programs for surveillance testing, inservice inspection, inservice testing, the general preventive maintenance program and the Quality Assurance Program Description.

Sections 17.4.4.1 through 17.4.4.9 are added as a supplement to the U.S. EPR FSAR.

17.4.4.1 Identification of Site-Specific SSCs for D-RAP

Section 17.4.2 describes a methodology for ensuring site-specific SSCs are identified and included in the RAP.

The initial list of site-specific SSCs and their risk rankings are included in Section 17.4.2. The PRA model will continue to be refined over the life of the plant and this will require periodic adjustment to the risk rankings of SSCs in Section 17.4.2.

As D-RAP enters the detailed design, procurement, fabrication and construction phase, an expert panel with {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC} representation will be established and utilized to:

- Augment PRA techniques in the risk ranking of SSCs using deterministic techniques, operating experience and expert judgment.
- Identify risk significant SSCs not modeled in the PRA (if any).
- Act as the final approver of risk significant SSCs.
- Recommend design changes where appropriate to reduce risk.
- Revise/adjust recommend operations phase maintenance/testing activities for risk significant SSCs described in Section 17.4.2.
- Designate and chair NSSS and Architect Engineer working groups as necessary to assist in accomplishing the objectives of the expert panel.
- Review and approve the recommendations of the working groups.
- Assess the overall station risk impact due to SSC performance and all implemented risk-informed programs (including D-RAP) after each plant-specific data update of the PRA.

The expert panel is made up of members with diverse backgrounds in engineering, operations, maintenance, risk and reliability analysis, operating experience and work control. The expert panel will have a minimum complement of five persons. During the detailed design phase of D-RAP, each major engineering organization performing detailed design will be represented on the panel (or working groups) as deemed necessary. The composition of the panel will change during the period leading up to fuel load and operations. The panel will continue to function during operations for the life of the plant.

17.4.4.1.1 Organization

17.4.4.1.1.1 Program Formulation and Organizational Responsibilities

{Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC overall site organization is described in Section 13.1. The Senior Vice President, Procurement and Engineering is responsible for formulating the reliability assurance activities as described in this section.

D-RAP is fundamentally an engineering program. The Senior Vice President, Procurement and Engineering retains responsibility for reliability assurance activities during design and construction even though implementation will reside principally with AREVA and other contractors (such as Bechtel) responsible for completion of detailed design and the development of engineering and procurement specifications. UniStar Nuclear Operating Services, LLC has delineated D-RAP requirements expected of the Plant Designer (NSSS and Architect Engineer vendors) including participation on the expert panel. The organizational relationships of UniStar Nuclear Operating Services, LLC and its contractors are further described in the QAPD.

For Stage 2, the organizational emphasis will shift from engineering and construction to systems engineering and maintenance. Design engineering will continue to play a role in maintaining the Master Equipment Database (as discussed in Section 17.4.4.1.2.1), configuration control and application of the design change process, if necessary, to improve SSC reliability.

The Expert Panel is composed of a Chairman and additional senior level managers as designated by the Senior Vice President and Chief Nuclear Officer, UniStar Nuclear Operating Services, LLC. The Expert Panel membership may be augmented as determined by the Senior Vice President and Chief Nuclear Officer, UniStar Nuclear Operating Services, LLC. Any change to the Expert Panel membership requires approval of the Senior Vice President and Chief Nuclear Officer, UniStar Nuclear Operating Services, LLC.

The Probabilistic Risk Assessment organization maintains representation on the expert panel and has major input to determinations that SSCs are maintaining performance levels consistent with PRA model assumptions over the life of the plant. The PRA organization will report to the Senior Vice President, Procurement and Engineering.}

17.4.4.1.1.2 Reliability Assurance Interface Coordination

Reliability assurance activity interface issues are coordinated through the Expert Panel since the organizations involved have representation on the panel. Specific interface responsibilities of the panel members are detailed in a controlling procedure. These interface responsibilities include the following:

- The Plant Designer panel member maintains the design interface to ensure that any proposed design changes that involve risk significant SSCs modeled in the PRA are identified and periodically reviewed with the expert panel at a frequency determined by the panel.

- The Plant Designer panel member maintains the design interface to ensure that any proposed changes to the plant PRA model, as identified by the {UniStar Nuclear} PRA representative on the Expert Panel, are appropriately reviewed for design impact and the results of the review appropriately distributed throughout the Plant Designer's and subcontractor's organizations.

- The Plant Designer panel member coordinates with the design organizations and expert panel members to ensure that significant design assumptions related to equipment reliability are realistic and achievable.

- The {UniStar Nuclear} PRA panel member is responsible to inform the panel of changes to the PRA model and to advise other panel members on the potential impact of the change on SSC risk rankings, assumed reliability of SSCs for design activities and the need for adjustments to the MR program.

17.4.4.1.1.3 PRA Organization Input to the Design Process

The {UniStar Nuclear} PRA panel member is responsible to review and concur in design changes involving risk significant SSCs identified by the Plant Designer's expert panel member. During implementation of the MR program prior to fuel load, responsibility for design and configuration control will transition from the Plant Designer to {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC}. The procedure for Design Change Packages will ensure screening of proposed design changes and PRA review and approval when necessary.

17.4.4.1.1.4 PRA Organization Design Reviews

The PRA organization's participation in periodic design reviews is principally via the PRA configuration control program that incorporates a feedback process to update the PRA model. These updates fall into two categories:

- The plant operating update incorporates plant design changes and procedure changes that affect PRA modeled components, initiating event frequencies, and changes in SSC unavailability that affect the PRA model. These changes will be incorporated into the model on a period not to exceed 36 months.

- The comprehensive data update incorporates changes to plant-specific failure rate distributions and human reliability, and any other database distribution updates (examples would include equipment failure rates, recovery actions, and operator actions). This second category will be updated on a period not to exceed 48 months.

The PRA model may be updated on a more frequent basis.

17.4.4.1.2 Design Control

17.4.4.1.2.1 Configuration Control of SSCs

The initial focal point for configuration control as it relates to D-RAP is the list of SSCs and their risk rankings in Section 17.4.2. During detailed design, a process will be implemented for a Master Equipment Database (MED). During the detailed design phase, this database, for the risk significant SSCs identified in Section 17.4.2, will be populated from a review performed by the Expert Panel or associated working groups.

The MED will be developed and maintained as a source of approved risk information.

17.4.4.1.2.2 Design Change Feedback

The design control and change processes provide feedback to the PRA organization via identification of components on the MED that are affected by a proposed change. Those affected SSCs with risk significance are given additional review in accordance with approved criteria to ensure there is no potential impact to the risk ranking of the affected components. If potential impact is identified then the Risk and Analysis Organization must concur in the change.

17.4.4.1.2.3 Design Interface with PRA Organization

Assurance that SSC performance relates to reliability assumptions made in the PRA and deterministic methods for identifying risk significant SSCs is provided by monitoring the performance of SSCs during plant operation and the review and feedback of Operating Experience. This interface occurs through implementation of the MR and the functioning of the expert panel.

A wide range of traditional sources for relevant operating information is available. The industry and vendor equipment information that is applicable and available to the nuclear industry with the intent of minimizing adverse plant conditions or situations through shared experience. Sources include the NRC (Information Notices and Generic Letters), INPO (EPIX, NPRDS, Operating Events, and Significant Event Reports, etc.) and vendor documentation and NSSS supplier information.

17.4.4.1.2.4 Engineering Design Controls for SSC Identification

Engineering design controls applied for determining the SSCs within the scope of the RAP are generally those specified in 10 CFR 50, Criterion III, "Design Control." These include, for example, the use of procedures for establishing risk via deterministic methods, proceduralized criteria for PRA risk ranking and independent verification and peer checking of the inputs necessary for utilization (or when necessary modification) of the site-specific PRA model.

17.4.4.1.2.5 Alternative Design

The process for proposing changes to the design for risk significant SSCs is proceduralized via the Design Change Package process. This process includes the use of a detailed checklist to establish the impact of the change on the PRA or deterministic evaluations performed to establish risk for affected SSCs. Changes identified as having an impact on SSCs and their risk rankings require appropriate special or interdisciplinary reviews.

17.4.4.1.2.6 Identification of SCC Boundaries and Interfaces

Plant components have a unique tag number, indicating designators that group these components by function. The determination of these groupings and identifiers is accomplished through the application of engineering conventions to standardize the approach and to ensure that system interfaces are consistently and completely identified. As an example, heat exchangers are generally included as part of the higher pressure system.

Instrumentation sensors are included as part of the mechanical system they are part of (as opposed to being included in the I&C systems that the sensors are connected to). These groupings are referred to as systems. As such, each system has system boundaries that are defined as the point of demarcation at interface points where the physical transition is made from one system to another. A typical example of these system boundary points is the isolation valve between two mechanical systems.

In the U.S. EPR design, system boundaries are shown on piping and instrumentation diagrams (P&IDs) and can be clearly identified by making reference to the tag numbers for the components. These system boundaries and associated interfaces are described in detailed design documents.

17.4.4.1.3 Expert Panel

The Expert Panel and designated working groups consist of designated individuals having expertise in the areas of risk assessment, operations, maintenance, engineering, and licensing.

As a minimum, the combined expert panel and working groups include at least five individuals with a minimum of five years experience at similar nuclear plants, and at least one individual who has worked on the modeling and updating of the PRA for similar plants for a minimum of three years.

When utilized, expert panel representatives from contractor design organizations are required to have a minimum of three years experience establishing risk rankings for nuclear plant SSCs using PRA or deterministic techniques (which may include Failure Modes and Effects Analysis).

17.4.4.1.4 Methods of Analysis for Risk Significant SSC Identification

The process for maintaining, revising, and, when necessary, establishing new risk rankings for modified design are based on PRA and deterministic techniques. The process utilized in categorizing components consists of the following major tasks:

- Identification of functions performed by the subject plant system.
- Determination of the risk significance of each system function.
- Identification of the system functions supported by that component.
- Identification of a risk categorization of the component based on PRA insights (where the component is modeled).
- Development of a risk categorization of the component based on deterministic insights.
- Designation of the overall categorization of the component, based upon the higher of the PRA categorization and the deterministic categorization.
- Identification of critical attributes for components determined to be safety/risk significant.

The PRA and deterministic methods are described more fully below.

17.4.4.1.4.1 PRA Risk Ranking

A component's risk determination is based upon its impact on the results of the PRA. Both core damage frequency (CDF) and containment response to a core damaging event, including large release frequency (LRF) are calculated. The PRA models internal initiating events at full power and low power shutdown, and also accounts for the risk associated with external events. The PRA risk categorization of a component is based upon its Fussell-Vesely (FV) importance, which is the fraction of the CDF and LRF to which failure of the component contributes, its risk achievement worth (RAW), which is the factor by which the CDF and LRF would increase if it were assumed that the component is guaranteed to fail. Specifically, PRA risk categorization to identify SSC is based upon the following:

PRA Ranking	PRA Criteria
Greater than Low Significance	FV $\geq$ 0.005 or RAW $\geq$ 2.0 or CCF RAW $\geq$ 20
Low Significance	FV $<$ 0.005 and RAW $<$ 2.0 and CCF RAW $<$ 20

17.4.4.1.4.2 Deterministic Risk Ranking

Components are subject to a deterministic categorization process, regardless of whether they are also subject to the PRA risk categorization process.

A component's deterministic categorization is directly attributable to the importance of the system function supported by the component. In cases, where a component supports more than one system function, the component is initially classified based on the highest deterministic categorization of the function supported. In categorizing the functions of a system, five critical questions regarding the function are considered, each of which is given a different weight.

These questions and their weight are as follows:

Question	Weight
Is the function used to mitigate accidents or transients?	5
Is the function specifically called out in the Emergency Operating Procedures (EOPs)?	5
Does the loss of the function directly fail another risk-significant system?	4
Is the loss of the function safety significant for shutdown or mode changes?	3
Does the loss of the function, in and of itself, directly cause an initiating event?	3

Based on the impact on safety, if the function is unavailable and the frequency of loss of the function, each of the five questions is given a numerical answer ranging from 0 to 5. This grading scale is as follows:

″0″ — Negative response

″1″ — Positive response having an insignificant impact and/or occurring very rarely

″2″ — Positive response having a minor impact and/or occurring infrequently

″3″ — Positive response having a low impact and/or occurring occasionally

″4″ — Positive response having a medium impact and/or occurring regularly

″5″ — Positive response having a high impact and/or occurring frequently

The definitions for the terms used in this grading scale are as follows:

Frequency Definitions

- Occurring Frequently - continuously or always demanded
- Occurring Regularly - demanded > 5 times per year
- Occurring Occasionally - demanded 1-2 times per cycle
- Occurring Infrequently - demanded < once per cycle
- Occurring Very Rarely - demanded once per lifetime

Impact Definitions

- High Impact - a system function is lost which likely could result in core damage and/or may have a negative impact on the health and safety of the public

- Medium Impact - a system function is lost which may, but is not likely to, result in core damage and/or is unlikely to have a negative impact on the health and safety of the public

- Low Impact - a system function is significantly degraded, but no core damage and/or negative impact on the health and safety of the public is expected

- Minor Impact - a system function has been moderately degraded, but does not result in core damage or negative impact on the health and safety of the public

- Insignificant Impact - a system function has been challenged, but does not result in core damage or negative impact on the health and safety of the public

Although some of these definitions are quantitative, both of these sets of definitions are applied based on collective judgment and experience.

The numerical values, after weighting, are summed; the maximum possible value is 100. Based on the sum, functions are categorized as follows:

SCORE RANGE	CATEGORY
100-41	High Safety Significance (HSS)
40-0	Low Safety Significance (LSS)

A function with a LSS categorization due to a low sum can receive a higher deterministic categorization if any one of its five questions received a high numerical answer. Specifically, a weighted score of 15 or more on any one question results in an HSS categorization. This is done to ensure that a function with a significant risk in one area does not have that risk contribution masked because of its low risk in other areas.

In general, a component is given the same categorization as the highest categorized system function that the component supports. However, a component may be ranked lower than the associated system function based upon diverse and/or multiple independent means available to satisfy the system function.

17.4.4.2 Procurement, Fabrication, Construction, and Test Specifications

Procurement, fabrication, construction, and test specifications for safety-related and non-safety-related SSCs within the scope of RAP are prepared and implemented under the approved QAPD referenced in Section 17.5. The approved QAPD describes the planned and systematic actions necessary to provide adequate confidence that SSCs will perform satisfactorily in service. These actions are applied to procurement, fabrication, construction, and test specifications.

Procurement, fabrication, construction, and test specifications will incorporate the essential elements of D-RAP, including appropriate graded QA controls for the non-safety-related, within-scope SSCs, and completion of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for the D-RAP.

Procedures describing equipment selection require consideration of the manufacturer's recommended maintenance activities and the manufacturer's time estimates for accomplishing these activities such that the equipment selected is able to meet availability assumptions while in service, including conservative allowances for unplanned maintenance.

Test specifications will describe to the extent practical the actual conditions that will exist when SSCs are called upon to perform their risk significant functions and testing will document proper performance under the specified conditions when these conditions can be practically established in the field. When these conditions cannot be duplicated, acceptance will be established based on qualification testing performed by the equipment vendor under controlled conditions.

The approved QAPD applies 10 CFR 50 Appendix B (CFR, 2008a) requirements to safety-related SSCs. For non-safety-related SSCs within the scope of RAP, the QAPD describes the process for selectively applying program controls to those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The QAPD specifies the quality requirements required for non-safety-related SSCs credited in mitigating defined events such as Anticipated Transients Without Scram (ATWS) and Station Blackout (SBO). When SSCs are risk significant due to their role in mitigating these defined events then the specified quality requirements for these SSCs will be satisfied.

17.4.4.3 Quality Assurance Implementation

Implementation of the QAPD during procurement, fabrication, construction and preoperational testing of SSCs is accomplished in accordance with written instructions, procedures or drawings of a type appropriate to the circumstances, and where applicable, include quantitative or qualitative acceptance criteria. These procedures are {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC} implementing procedures or supplier implementing procedures governed by a supplier quality program approved by {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC.}

17.4.4.4 Maintenance Rule/Operational Programs

The {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC} MR program is described in Section 17.7. Risk significant SSCs identified by reliability assurance activities are included in the MR program as high safety significance (HSS) components (Section 17.7). The opportunity to judge SSC performance under the MR program is provided by the operational programs discussed in Section 17.7.

Many SSCs would meet the criteria to be in the MR program without considerations related to the RAP. In cases where the RAP identifies a risk significant SSC that would not otherwise have been in the MR program, the SSC is added. For those SSCs already in the Technical Specifications (TS), Inservice Inspection (ISI), or Inservice Testing (IST) programs, their performance under these programs is factored into the performance monitoring accomplished under the MR program.

In cases where a SSC requires periodic testing or inspection not already accommodated by an existing program, then special provisions will be made to accommodate the necessary testing or inspection, for example, in the Preventive Maintenance (PM) program.

17.4.4.4.1 Performance Goal

Reliability performance assumptions for SSCs are established under the MR at two levels of performance monitoring. The first level of performance monitoring (10 CFR 50.65(a)(2)) (CFR, 2008b) establishes conservative criteria used to judge that SSCs are meeting expected performance objectives. For SSCs that entered the RAP program through the expert panel and the PRA criteria discussed in Section 17.4.4.1.4.1, the performance monitoring criteria are established consistent with the reliability and availability assumptions used in the PRA. For SSCs that entered the RAP Program through the expert panel and criteria other than the PRA criteria specified in Section 17.4.4.1.4.1, performance criteria and goals are established per the Maintenance Rule program, which is described in Section 17.7. Those performance criteria (e.g. failure rate, unavailability, or condition-based) are chosen such that they are reasonable, measureable, and technically appropriate for the purpose of timely identification of degraded SSC performance or condition. Failure to meet these objectives would trigger performance monitoring at the second level (10 CFR 50.65(a)(1)) accompanied by the establishment of specific defined goals to return the component to expected performance levels (Section 17.7).

17.4.4.4.2 Feedback of Actual Equipment Performance and Operating Experience

The feedback mechanism for periodically evaluating reliability assumptions based on actual equipment, train or system performance is realized in the implementation of the MR program. Since the performance monitoring criteria established under the MR program are set consistent with the assumed reliability assumptions used in the PRA, the failure to meet these performance objectives (i.e., equipment, train or system placed in 10 CFR 50.65(a)(1) category) requires an assessment of the assumed reliability as described in Section17.4.4.4.1 above. This assessment requires that the assumed reliability be reviewed to ensure it is reflective of actual {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC} and industry performance. The process requires review by the PRA organization to concur that goals have been met before moving a component from a 10 CFR 50.65(a)(1) status back to a 10 CFR 50.65(a)(2) status.

17.4.4.5 Non-Safety SSC Design/Operational Errors

The process for providing corrective actions for design and operational errors that degrade non-safety-related SSCs within the scope of RAP is procedurally defined. All SSCs (safety-related or non-safety-related) with risk significance greater than "low" are entered into the MR program as HSS. The {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC} MR program does not distinguish between a Maintenance Rule Functional Failure (MRFF) and a Maintenance Preventable Functional Failure (MPFF). Therefore, non-safety-related SSCs that have experienced a MRFF attributable to a design or operating error (i.e., could not have been prevented by maintenance) are corrected using the corrective action process described in the QAPD. Under the MR program, MRFFs require cause determination (may be an apparent cause determination) and corrective action is implemented to prevent recurrence.

17.4.4.6 Procedural Control

Implementation of the reliability assurance activities is considered an activity affecting quality and the controls for procedures and instructions used to implement reliability assurance activities are specified in the QAPD. In most cases where a single procedure describes the process for an activity that applies to both safety-related and non-safety-related components (for example, establishing the performance monitoring criteria for the MR or establishing risk significance for SSCs in RAP), a single procedure or procedures that meet the full quality program requirements of QAPD will be utilized. For activities such as procurement, non-safety-related SSCs in the RAP will be governed by Procedure Controls meeting the requirements of the QAPD.

The QAPD specifies the quality requirements required for non-safety-related SSCs credited in mitigating defined events such as ATWS and SBO. When SSCs are risk significant due to their role in mitigating these defined events then the specified quality requirements for these SSCs will be satisfied.

17.4.4.7 Records

Implementation of the reliability assurance activities is considered an activity affecting quality and the generation of records associated with this activity will meet the requirements of the QAPD.

Records of Expert Panel decisions and supporting documents are retained as QA records in the Records Management System (RMS) and consist of:

- Expert Panel decisions and meeting minutes including dissenting opinions and resolutions.
- Recommendations of the working groups.

The PRA includes models for power operation and for low-power and shutdown operation. For each model, documentation is maintained that includes sources of input data, modeling techniques, and assumptions used in the analysis. These documents are maintained in RMS for the life of the plant.

The QAPD specifies the quality requirements required for non-safety-related SSCs credited in mitigating defined events such as ATWS and SBO. When SSCs are risk significant due to their role in mitigating these defined events, the specified quality requirements for these SSCs will be satisfied.

17.4.4.8 Corrective Action Process

Under the {Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC} process for MR implementation, any SSC experiencing a MRFF requires use of the Corrective Action process to document the failure, its cause determination and actions to preclude recurrence. As previously discussed in Section 17.4.4.5, this also includes non-safety-related SSCs.

Other failures of SSCs that are not MRFFs will be documented and corrected as described by the QAPD.

The QAPD specifies the quality requirements required for non-safety-related SSCs credited in mitigating defined events such as ATWS and SBO. When SSCs are risk significant due to their role in mitigating these defined events, the specified quality requirements for these SSCs will be satisfied.

17.4.4.9 Audit Plans

The reliability assurance activities are collectively accomplished by programs related to design, procurement, fabrication, construction, preoperational testing, PRA modeling and PRA risk assessment, deterministic evaluations from the expert panel, maintenance rule, Technical Specifications and other operational programs and the corrective action program. These programs are subject to audit as described in the QAPD.

The QAPD specifies the quality requirements required for non-safety-related SSCs credited in mitigating defined events such as ATWS and SBO. When SSCs are risk significant due to their role in mitigating these defined events, the specified quality requirements for these SSCs will be satisfied.

17.4.5 References

{**CFR, 2008a.** Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, Title 10, Code of Federal Regulations, Part 50, Appendix B, U.S. Nuclear Regulatory Commission, 2008.

CFR, 2008b. Requirements for monitoring the Effectiveness of Maintenance at Nuclear Power Plants, Title 10, Code of Federal Regulations, Part 50.65, U.S. Nuclear Regulatory Commission, 2008.}

Table 17.4-1 — {Site Specific Systems and Structures Included Within RAP}

SSC Names	Qualitative Determination for Inclusion Within RAP
DISTRIBUTED UTILITIES	
UHS Makeup Water System	Considered in design basis analysis; The system function is considered important in the Safety Analysis Report; A contribution to initiators; Technical Specification considerations
ELECTRICAL SYSTEMS	
Offsite Power System-partial (plant specific scope)	Contains components important to maintaining system reliability; System failure modes may affect multiple trains/systems; Technical Specification considerations
Switchyard	Contains components important to maintaining system reliability; System failure modes may affect multiple trains/systems; Technical Specification considerations
STRUCTURES	
UHS Makeup Water Intake Structure	System failure modes may affect multiple trains/systems.
Switchgear Building	System failure modes may affect multiple trains/systems. (Station Blackout)
Circulating Water Makeup Intake Structure	SSC failure modes may affect multiple trains/systems.

17.5 QUALITY ASSURANCE PROGRAM DESCRIPTION

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

17.5.1 QA Program Responsibilities

{The QA Program is established in UniStar Nuclear Energy "Quality Assurance Program Description." The latest revision of this topical report is incorporated by reference. The QAPD is applicable to the siting, design, fabrication, construction (including pre-operational testing), operation (including testing), maintenance and modification of the facility. The QAPD conforms to the criteria established in 10 CFR 50, Appendix B, (CFR, 2008a). Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC commits to implement the:

- Basic Requirements and Supplements of ANSI/NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," (ANSI, 1994) as described in the QAPD.
- Specific subparts of NQA-1-1994, as described in the QAPD.

Calvert Cliffs 3 Nuclear Project, LLC and UniStar Nuclear Operating Services, LLC do not delegate any of the activities associated with planning, establishing, or implementing the overall QA program to others, and retain the responsibility for the program. Site characterization activities initiated prior to the approval of the UniStar Nuclear Energy QAPD were done under the Bechtel QA program which has been audited to confirm it satisfies the UniStar Nuclear Energy QAPD.}

17.5.2 SRP Section 17.5 and the QA Program Description

{The QAPD is established in the latest approved revision.}

17.5.3 Evaluation of the QAPD Against the SRP and QAPD Submittal Guidance

{Revision 0 of the QAPD, as established in Revision 0 of UN-TR-06-001-A (UniStar, 2007), was approved by the NRC (NRC, 2007a)(NRC, 2007b) and was determined to conform to the guidance provided in NUREG-0800 (NRC, 2007c). The most recent revision of the QAPD retains the essential elements of the NRC approved topical report and has been submitted to the NRC for their review and approval (UniStar, 2014).}

17.5.4 References

{**ANSI, 1994.** Quality Assurance Requirements for Nuclear Facility Applications, ANSI/ NQA-1-1994, American National Standards Institute, 1994.

CFR, 2008a. Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, Title 10, Code of Federal Regulations, Part 50, Appendix B, U.S. Nuclear Regulatory Commission, 2008.

NRC, 2007a. Letter from L. J. Burkhart (NRC) to R. M. Krich (UniStar Nuclear), "Final Safety Evaluation for Topical Report (TR) UN-TR-06-0001, 'Quality Assurance Program Description' (Project No. 746)," dated March 14, 2007.

NRC 2007b. Letter from L. J. Burkhart (NRC) to R. M. Krich (UniStar Nuclear), "Replacement Pages for the Final Safety Evaluation for Topical Report (TR) UN-TR-06-0001, 'Quality Assurance Program Description' (Project No. 746)," dated March 16, 2007.

NRC, 2007c. Standard Review Plan 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," NUREG-0800, Revision 0, U.S. Nuclear Regulatory Commission, March 2007.

UniStar, 2007. Letter from R. M. Krich (UniStar Nuclear) to the U.S. Nuclear Regulatory Commission, "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," dated April 9, 2007.

UniStar, 2014. Letter from Paul Infanger (UniStar Nuclear Energy) to the U.S. Nuclear Regulatory Commission, UN#14-055, "Submittal of the UniStar Quality Assurance Program Description, Revision 4," dated June 30, 2014.}

17.6 DESCRIPTION OF APPLICANT'S PROGRAM FOR IMPLEMENTATION OF 10 CFR 50.65, THE MAINTENANCE RULE

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 17.6:

> A COL applicant that references the U.S. EPR design certification will describe the program for Maintenance Rule implementation.

This COL Item is addressed as follows:

The Maintenance Rule Program description included in NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," Revision 0, dated March 2008, (NEI, 2008) is incorporated by reference with supplements in Section 17.7.

17.6.1 Scoping Per 10 CFR 50.65(b)

The U.S. EPR FSAR includes the following COL Item in Section 17.6.1:

> A COL applicant that references the U.S. EPR design certification will describe the process for determining which plant structures, systems, and components (SSCs) will be included in the scope of the Maintenance Rule Program in accordance with 10 CFR 50.65(b). The program description will identify that additional SSCs functions may be added to or subtracted from the Maintenance Rule scope prior to fuel load, when additional information is developed (e.g., emergency operating procedures, or EOP), and after the license is issued.

This COL Item is addressed as follows:

Maintenance rule scoping per 10 CFR 50.65(b) is described in Section 17.7.1.1.

17.6.2 Monitoring Per 10 CFR 50.65(a)

The U.S. EPR FSAR includes the following COL Item in Section 17.6.2:

> A COL applicant referencing the U.S. EPR design certification will provide a program description for monitoring SSCs in accordance with 10 CFR 50.65(a)(1).

This COL Item is addressed as follows:

Monitoring and corrective action per 10 CFR 50.65(a)(1) is described in Section 17.7.1.2.

The U.S. EPR FSAR includes the following COL Item in Section 17.6.2:

> A COL applicant that references the U.S. EPR design certification will provide the process for determining which SSCs within the scope of the Maintenance Rule Program will be tracked to demonstrate effective control of their performance or condition in accordance with paragraph 50.65(a)(2).

This COL Item is addressed as follows:

Preventative maintenance per 10 CFR 50.65(a)(2) is described in Section 17.7.1.3.

17.6.3 Periodic Evaluation Per 10 CFR 50.65(a)(3)

The U.S. EPR FSAR includes the following COL Item in Section 17.6.3:

> A COL applicant that references the U.S. EPR design certification will identify and describe the program for periodic evaluation of the Maintenance Rule Program in accordance with 10 CFR 50.65(a)(3).

This COL Item is addressed as follows:

Periodic evaluation of monitoring and preventative maintenance per 10 CFR 50.65(a)(3) is described in Section 17.7.1.4.

17.6.4 Risk Assessment and Management Per 10 CFR 50.65(a)(4)

The U.S. EPR FSAR includes the following COL Item in Section 17.6.4:

> A COL applicant that references the U.S. EPR design certification will describe the program for maintenance risk assessment and management in accordance with 10 CFR 50.65(a)(4). Since the removal of multiple SSCs from service can lead to a loss of Maintenance Rule functions, the program description will address how removing SSCs from service will be evaluated. For qualitative risk assessments, the program description will explain how the risk assessment and management program will preserve plant-specific key safety functions.

This COL Item is addressed as follows:

Risk assessment and risk management per 10 CFR 50.65(a)(4) is described in Sections 17.7.1.5 and 19.1.1.4.

17.6.5 Maintenance Rule Training and Qualification

The U.S. EPR FSAR includes the following COL Item in Section 17.6.5:

> A COL applicant that references the U.S. EPR design certification will describe the program for selection, training, and qualification of personnel with Maintenance-Rule-related responsibilities consistent with the provisions of Section 13.2 as applicable. Training will be commensurate with maintenance rule responsibilities, including Maintenance Rule Program administration, the expert panel process, operations, engineering, maintenance, licensing, and plant management.

This COL Item is addressed as follows:

Maintenance rule training and qualification is described in Section 17.7.2.

17.6.6 Maintenance Rule Program Role in Implementation of Reliability Assurance Program (RAP) in the Operations Phase

The U.S. EPR FSAR includes the following COL Item in Section 17.6.6:

> A COL applicant referencing the U.S. EPR design certification will describe the relationship and interface between the Maintenance Rule Program and the Reliability Assurance Program (refer to Section 17.4).

This COL Item is addressed as follows:

Maintenance rule program relationship with reliability assurance activities is described in Section 17.7.3.

17.6.7 Maintenance Rule Program Relationship with Industry Operating Experience Activities

Maintenance rule program relationship with industry operating experience (IOE) activities is described in Section 17.7.4.

17.6.8 Maintenance Rule Program Implementation

The U.S. EPR FSAR includes the following COL Item in Section 17.6.8:

> A COL applicant referencing the U.S. EPR design certification will describe the plan or process for implementing the Maintenance Rule Program in the COL application, which includes establishing program elements through sequence and milestones and monitoring or tracking the performance and/or condition of SSCs as they become operational.

This COL Item is addressed as follows:

Maintenance rule program implementation is described in Section 17.7.5.

17.6.9 References

{This section is added as a supplement to the U.S. EPR FSAR.

NEI, 2008. Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52, NEI 07-02A, Revision 0, Nuclear Energy Institute, March 2008.}

17.7 MAINTENANCE RULE PROGRAM

This section is added as a supplement to the U.S. EPR FSAR.

The Maintenance Rule Program description included in NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," Revision 0, dated March 2008 is incorporated by reference. The text of the template provided in NEI 07-02A is generically numbered as "17.X." The template is incorporated by reference into this FSAR Section by changing the numbering from "17.X" to "17.7."

In Section 17.X.1.1.b of NEI 07-02A the "DRAP" (Reliability Assurance Program for the Design Phase) is defined to be located in FSAR "17.Y." The DRAP is included in Section 17.4. The template is incorporated by reference into this FSAR section by changing the numbering from "17.Y" to "17.4."

Descriptions of the programs listed in Subsection 17.X.3 of NEI 07-02A are provided in the following FSAR Chapters/Sections or Part 4:

- Maintenance rule program (Section 17.7).
- Quality assurance program (Section 17.5).
- Inservice inspection program (Sections 5.2 and 6.6).
- Inservice testing program (Section 3.9).
- Technical specifications surveillance test program (Part 4).
- Maintenance Programs (Section 13.5.2.2.6).