U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

APPENDIX 18-A CREDITING MANUAL OPERATOR ACTIONS IN DIVERSITY AND DEFENSE-IN-DEPTH ANALYSES

REVIEW RESPONSIBILITES

Primary - Organization responsible for the review of human performance

Secondary - Organization responsible for the review of instrumentation and controls

A. INTRODUCTION

This Appendix defines a methodology, applicable to both existing and new reactors, for evaluating manual operator action as a diverse means of coping with Anticipated Operational Occurrences and Postulated Accidents (AOO/PA) that are concurrent with a software Common Cause Failure (CCF) of the digital instrumentation and control (I&C) protection system. This Appendix supersedes, and incorporates with limited modifications, the guidance in Section 3 of Digital Instrumentation and Control (DI&C) Interim Staff Guidance (ISG), DI&C-ISG-05, Revision 1, "Highly Integrated Control Rooms—Human Factors Issues."

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B. BACKGROUND

Software CCFs of the digital I&C protection system are discussed in the Background of Branch Technical Position (BTP) 7-19, "Guidance for Evaluation of Diversity and Defense-in-Depth in Digital Computer-Based Instrumentation and Control Systems." To provide additional guidance for BTP 7-19, the U.S. Nuclear Regulatory Commission (NRC) staff issued DI&C ISG-02, "Diversity and Defense-in-Depth Issues," Revision 1 in September 2007. DI&C-ISG-02, Revision 1, specifically discussed adequate diversity and manual operator actions as follows:

> Manual operator actions may be credited for responding to events in which the protective action subject to a CCF is not required for at least the first 30 minutes and the plant response is bounded by BTP 7-19 recommended acceptance criteria.

DI&C-ISG-02, Revision 1, further stated the following:

> The licensee or applicant should demonstrate through a suitable human factors engineering (HFE) analysis that manual operator actions that can be performed inside the control room are acceptable in lieu of automated backup functions.

Subsequent to issuing DI&C-ISG-02, the NRC staff determined that further guidance was necessary for crediting manual operator action during an AOO/PA concurrent with a software CCF. As a result, on November 3, 2008, the NRC staff issued DI&C-ISG-05, Revision 1. The guidance, provided as Section 3 of DI&C-ISG-05, Revision 1, described a general methodology applicable to crediting operator action in lieu of automated back-up functions, regardless of whether the protective action was required in more or less than 30 minutes.

In April 2009, the Advisory Committee on Reactor Safeguards (ACRS) reviewed DI&C-ISG-05, Revision 1. The ACRS noted that Phase 1 of the guidance for crediting of operator actions included a list of methods acceptable to the NRC staff for deriving estimates of time required for task components and concluded that the time estimates using these methods can be biased and the associated uncertainties can be difficult to assess. Furthermore, as the difference between the time available and time required decreases, confidence in the analysis decreases. In an April 21, 2009, letter to then Chairman Dale E. Klein, the ACRS provided these observations with associated recommendations to revise the guidance in DI&C-ISG-05, Revision 1.

On June 5, 2009, the staff issued DI&C-ISG-02, Revision 2. Consistent with the ACRS observations and recommendations regarding DI&C-ISG-05, the NRC staff revised DI&C-ISG-02 to note that "for actions with limited margin, such as less than 30 minutes between time available and time required for operators to perform the protective actions, a more focused staff review will be performed. Similarly, the NRC staff reviewed the ACRS recommendations relative to the guidance in DI&C-ISG-05, Section 3. Accordingly, this Appendix incorporates, with limited modifications, the guidance contained in Section 3 of DI&C-ISG-05, Revision 1."

C. STAFF POSITION

A diversity and defense-in-depth analysis should include the justification of any operator actions that are credited for response to an AOO/PA concurrent with software CCF as described in BTP 7-19. Manual operator actions for these scenarios should be based upon, and ultimately included within, the Emergency Operating Procedures (EOPs) and executed from the main control room (MCR).

To credit operator actions, an acceptable method would be to demonstrate that the manual actions in response to a BTP 7-19 software CCF are both feasible and reliable, given the time available, and that the ability of operators to perform credited actions reliably will be maintained for as long as the manual actions are necessary to satisfy the defense-in-depth analysis. The time available for manual actions should be based upon the methods and criteria prescribed in BTP 7-19. The time required for operator action should be estimated and validated using the guidance of this Appendix. To demonstrate that the manual actions are both feasible and reliable, and that the ability to perform the actions reliably within the time available is maintained, the vendor/ licensee/applicant should follow a process of analysis, validation, and long-term monitoring consistent with this Appendix.

Credited manual operator actions and their associated interfaces (controls, displays, and alarms) should be specifically addressed in the vendor/licensee/applicant's HFE Program. The vendor/licensee/applicant should commit, in the defense-in-depth submittal, to include the proposed defense-in-depth coping actions in a HFE Program consistent with that described in NUREG-0711, "Human Factors Engineering Program Review Model," and to provide the results of the HFE Program to the staff prior to implementation of the proposed action(s).

PHASE 1: ANALYSIS

This section describes the attributes of an acceptable method of analyzing the time available and time required for manual operator actions that are to be credited in a defense-in-depth analysis.

1.A. Method

The analysis must demonstrate that:

- the time available to perform the required manual actions is greater than the time required for the operator(s) to perform the actions.

- the operator(s) can perform the actions correctly and reliably in the time available.

The time available to perform the actions should be based on analysis of the plant response to the AOO/PA using realistic assumptions, and the acceptance criteria of BTP 7-19. The time required for operator action should be based on an HFE analysis of operator response time. The basis of the documented sequence of operator actions can be task analysis, vendor-provided generic technical guidelines for emergency operating procedure development, or plant-specific EOPs, depending on the maturity of the design. The documented sequence of operator

actions should be analyzed at a level of detail necessary to identify critical elements of the actions and performance shaping factors (e.g., workload, time pressure) that affect time required and likelihood of successful completion of the action sequence. The vendor/ licensee/applicant should establish time estimates for individual task components (e.g., acknowledging an alarm, selecting a procedure, verifying that a valve is open, starting a pump) and the basis for the estimates, through a method applicable to the human-system interface (HSI) characteristics of digital computer-based I&C.

Acceptable methods for deriving analysis time estimates for individual task components include, but are not limited to:

- Operator interviews and surveys
- Operating experience reviews
- Software models of human behavior, such as task network modeling
- Use of control/display mockups
- Expert panel elicitation[1]
- ANSI/ANS 58.8, "Time Response Design Criteria for Safety-Related Operator Actions"[2]

Methods that are dependent on expert judgment to derive time estimates for task components are potentially subject to bias. In addition, the uncertainties associated with estimates derived through these methods are difficult to quantify. Accordingly, these methods should be employed using structured approaches that minimize bias and help identify and assess uncertainties (see example: NUREG/CR-6372, "Recommendations for Probabilistic Seismic Hazard Analysis: Guidance on Uncertainty and Use of Experts," or "Eliciting and Analyzing Expert Judgment: A Practical Guide, Cambridge University Press," 1991).

Prior experience with tasks or subtasks similar to the actions proposed to be credited in the defense-in-depth analysis may provide valuable insights for the analysis/estimates of operator response times. Operating Experience Review (OER) data used to provide input to the analysis/estimates of operator response times should be supplemented with information about the similarities and differences between the credited actions and the actions identified in the OER.

A time margin should exist between the analyzed time(s) as the difference between time available and time required for operator action is a measure of the safety margin and as it decreases, uncertainty in the estimate of the difference between these times should be appropriately considered. This uncertainty could reduce the level of assurance and potentially invalidate a conclusion that operators can perform the action reliably within the time available. One acceptable method is for the time margin to equal the maximum recovery time for any single credible[3] operator error. The basis for the specific time margin used in the analysis

[1] For an example of an expert panel elicitation, see NUREG-1852, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire."

[2] ANSI/ANS 58.8, "Time Response Design Criteria for Safety-Related Operator Actions," provides an acceptable task decomposition methodology for this purpose. However, the time intervals described in ANSI/ANS 58.8 were validated using analog controls and; therefore, may not be accurate for this application.

[3] As used here, credible operator errors are any errors of omission or commission that are plausible considering applicable operating experience and a human reliability analysis for the task.

should be justified and documented. Insights from the HFE program, especially the OER and Human Reliability Analysis, should be used. The identification of potential errors, error detection methods, and error recovery paths in event trees may be used to provide estimates of how much margin should be added to the operator response time estimates. For complex situations and for actions with limited margin, such as less than 30 minutes between time available and time required, a more focused staff review will be performed.

1.B. Review Criteria

The responsible reviewers evaluate vendor/licensee/applicant's submittals for compliance with the following criteria:

- The analysis establishes the time available using an analysis method and acceptance criteria consistent with the guidance of BTP 7-19. The basis for the time available is documented.

- The analysis of the time required is based on a documented sequence of operator actions. The basis of the documented sequence of operator actions can be task analysis, vendor-provided generic technical guidelines for emergency operating procedure development, or plant-specific EOPs, depending on the maturity of the design.

- Techniques to minimize bias are used when estimates of time required are derived using methods that are dependent on expert judgment. Uncertainties in the analysis of time required are identified and assessed.

- The sequence of actions uses only alarms, controls, and displays that would be available in the MCR (MCR equipment) and operable during the assumed CCF scenario(s). Here operable means the MCR equipment that would still be available based on the defense-in-depth analysis of the postulated CCF associated with each event that is evaluated in the accident analysis section of the Safety Analysis Report (SAR).

- The estimated time available for operators to complete the credited action is sufficient to allow successful execution of applicable steps in the symptom/function-based EOPs.[4]

- The initial MCR operating staff size and composition assumed for the analysis of time required is the same as the minimum MCR staff defined in the plant's Technical Specifications.

- If credited manual actions require additional operators beyond the Technical Specification minimum crew, the justification for timely availability of the additional

[4] The Phase 1 analysis may be conducted using a task sequence based on task analysis, vendor-provided generic technical guidelines for emergency operating procedure development, or plant-specific EOPs, depending on the maturity of the design. Accordingly, it is recognized that it will not be possible in all circumstances to directly assess time available relative to this criterion during the Phase 1 analysis.

staffing is provided and the estimate of time required includes any time needed for calling in additional personnel.

- The analysis of the action sequence is conducted at a level of detail sufficient to identify individual task components, including cognitive elements such as diagnosis and selection of appropriate response, and the associated performance shaping factors that affect time required and the potential for operator error.

- The analysis identifies a time margin between the time required and time available to perform the action and documents the basis for the adequacy of the margin, including consideration of the uncertainty in the estimation of the margin.

PHASE 2: PRELIMINARY VALIDATION

This section describes the attributes of an acceptable method for preliminarily validating the time required to take manual operator actions that are credited in a defense-in-depth analysis.

Note: Licensees upgrading existing operating plants may skip this phase and go directly to Phase 3, Integrated System Validation (ISV). A preliminary validation is only required for those vendors/applicants who are using the Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52 process and as a result, would not have achieved the level of design development necessary to validate the operator manual actions by conducting an ISV prior to the time the staff must issue a safety evaluation applicable to the defense-in-depth analysis.

2.A. Method

The preliminary validation should provide independent confirmation of the validity of the "time required" estimate derived in the Phase 1 Analysis through the use of methods such as the following:

- Tabletop analysis
- Walkthrough/talkthrough analysis
- Software models of human behavior, such as task network modeling
- Use of control/display mockups
- Man-in-the-loop prototype testing
- Pilot testing
- Real-time validation on a suitable[5] part-task simulator

Note: The preceding list is not all-inclusive – other validation methods may be used if sufficient technical justification is provided.

As the difference between time available and time required for operator action decreases, the importance of reducing uncertainty and minimizing potential bias in the estimates increases. Accordingly, the vendor/applicant should use several diverse methods to estimate operator response times to maximize the cross-validation value of the methods (i.e., minimize the

[5]A suitable part-task simulator is one of demonstrated scope and fidelity sufficient for the conduct of the specific validation.

potential for bias and reduce sources of uncertainty in the estimates of operator response times). For example, when the design has advanced to the point where a part-task simulator is available, the vendor/applicant should use it to cross-validate previous time estimates derived from other activities, such as expert elicitation, tabletop analysis, or walkthrough/talkthrough. It is expected that the vendor/applicant will estimate operator response time using as realistic an environment as is available at the time of the preliminary validation.

The group of individuals who conduct the preliminary validation of the analysis should not include individuals who conducted the analysis. Independence between these groups will help to ensure that any undocumented assumptions and analytical methods used in the analysis are identified and documented during the analysis. However, it is recognized that communication between the groups will be necessary, especially after the preliminary validation is complete. The processes of validation and design are iterative and feedback from the preliminary validation should be used to refine the design, the procedures, and the training provided to the operators.

The preliminary validation should be rigorous and conducted by operators, system technical experts, and human factors experts. These personnel should verify that the analysis is logical for its purpose, contains a sufficient level of detail, and that the analyzed action sequence presents no physical or spatial difficulty for performance. The language and the level of information presented in the documented sequence of manual operator actions should be compatible with the minimum number, qualifications, training, and experience of the operating staff.

Operators and system technical experts should ensure that the documented sequence of manual operator actions, independent of the time required, is technically correct and will achieve the desired technical result(s). These personnel should verify the documented sequence of manual operator actions is supported by the existing or planned displays and controls to be used by the operator. Walkthrough/talkthrough of planned displays and controls for new plants should be conducted to the extent practical, according to the state of the design and supplemented as necessary by use of such aids as arrangement diagrams, vendor drawings, and panel fabrication drawings.

Results should be documented in the defense-in-depth analysis for NRC review. Preliminary validation results should be such that there is high confidence that the time required for manual operator actions will satisfy the success criteria for the integrated system validation described below. Unacceptable preliminary validation results should result in modification of the defense-in-depth coping strategy. Modification of the defense-in-depth coping strategy will require re-analysis, re-validation and re-submittal for NRC staff review. If a successful manual action strategy cannot be achieved, diverse automation is required.

When the vendor/applicant believes that the analysis provides high confidence that the time required for operator action will satisfy the success criteria for integrated systems validation, the complete defense-in-depth analysis, which provides time available and time required, and the supporting analyses, is submitted for NRC review. This defense-in-depth analysis will be submitted as part of the supporting justification for a design certification, design certification amendment, combined license application, or license amendment. When the NRC reviewers have high confidence that the manual operator actions will be accomplished correctly, reliably,

and within the time available, the NRC staff will make a safety determination as part of the Safety Evaluation Report (SER) on the associated licensing action. Acceptable implementation shall be verified through completion of specified Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) or License Conditions.

2.B. Review Criteria

The responsible reviewers evaluate vendor/applicant's submittals for compliance with the following criteria:

- The preliminary validation is conducted as an independent confirmation of the Phase 1 Analysis that compared time available and estimated time required.

- The preliminary validation is conducted by a multi-disciplinary team with the knowledge and skills necessary to verify the rigor and assumptions of the analysis and validate the analysis conclusions regarding the ability of operators to perform the actions reliably within the time available.

- The preliminary validation uses methods appropriate to assessing time required for the task. For complex situations and for actions with limited margin, such as less than 30 minutes between time available and time required, the preliminary validation uses two or more methods to validate the analysis.

- The preliminary validation results support the conclusion that the time required, including margin, to perform individual steps and the overall documented sequence of manual operator actions is reasonable, realistic, repeatable, and bounded by the Phase 1 Analysis documentation.[6]

Note: As the difference between time available and time required for operator action decreases, there is increasing potential that uncertainty in the estimate of difference between these times will invalidate a conclusion that operators can perform the actions reliably within the time available.

Preliminary validation results that are unacceptable to the NRC reviewer(s) should result in modification of the defense-in-depth coping strategy. Modification of the defense-in-depth coping strategy will require re-analysis, re-validation and re-submittal for NRC staff review.

PHASE 3: INTEGRATED SYSTEM VALIDATION

This section describes the attributes of an acceptable method for conducting an ISV of manual operator actions that are to be credited in a defense-in-depth analysis.

[6] The preliminary validation results should provide high confidence that the performance time criteria will be met in the Phase 3, ISV. Unacceptable ISV results will require modification of the defense-in-depth coping strategy late in the design and licensing process.

3.A. Method

ISV is an evaluation using performance-based tests to determine whether an integrated system design (i.e., hardware, software, procedures, training, staffing and qualification, and physical environment) meets performance requirements and acceptably supports safe operation of the plant. The vendor/licensee/applicant should conduct an ISV of manual actions credited in the defense-in-depth analysis using a plant-referenced simulator in real time. Using the validation guidance in NUREG-0711, the vendor/licensee/applicant should measure operator response times (performance times) of all operating crews in representative event simulations, i.e., AOO/PAs with concurrent software CCF. Performance times should be compared to the time available (per defense-in-depth analysis results) and previous estimates of time required. The digital I&C system timing analysis results in support of determining the time available should be validated as necessary by testing on integrated digital I&C systems and components.

In selecting personnel for event simulations, consideration should be given to the assembly of both nominal and minimum crew configurations, including shift supervisors, reactor operators, shift technical advisors, etc., that will participate in the validation tests. The composition of operations personnel need only include personnel who are relevant to the credited actions.

Acceptable validation results will provide the basis for meeting the NRC's design certification, license application or amendment request approval requirements. Unacceptable validation results will require modification of the defense-in-depth coping strategy.

Modification of the defense-in-depth coping strategy would require reanalysis, re-validation and re-submittal for NRC staff review. If a successful manual action strategy cannot be achieved, diverse automation is required.

The ISV shall be implemented and documented as an ITAAC item or License Condition for plants licensed under 10 CFR Part 52 or as a License Condition for operating plants that have not upgraded the plant-referenced simulator in advance of the control room modifications. The complete defense-in-depth analysis, which provides time available and time required, the supporting analyses, which provides time available and time required, and validation results shall be submitted to the NRC for verification of ITAAC closure or completion of the License Condition.

3.B. Review Criteria

The responsible reviewers evaluate vendor/licensee/applicant's submittals for compliance with the following criteria:

General

- The ISV is completed as part of the HFE program that is implemented in accordance with NUREG-0711.

Simulator

- The ISV is conducted using a plant-referenced simulator that meets the functional and fidelity requirements of the adopted ANSI/ANS 3.5, "Nuclear Power Plant Simulators for Use in Operator Training and Examination," and is capable of real time, high fidelity plant simulation of the BTP 7-19 software CCF concurrent with an AOO/PA.

    - The simulator accurately represents digital I&C CCFs and digital failure modes.

    - The plant-referenced simulator used for the validation of manual operator actions demonstrates expected plant response to operator input and to normal, transient, and accident conditions to which the simulator has been designed to respond.

    - The plant-referenced simulator is designed and implemented so that it is sufficient in scope and fidelity to allow conduct of the evolutions associated with AOO/PA, including manual operator actions, as applicable to the design of the reference plant.

- The simulator accurately represents the HSI available and the postulated HSI failure(s) for the software CCF condition.

Personnel

- Participants in the validation are the plant personnel who would normally perform the actions.

- With the following exception, actions to be performed by licensed operators are validated using individuals holding a current operating license for the unit on which the actions are to be credited. For vendor/applicants using the 10 CFR Part 52 process for a design for which there are currently no licensed operators, the crews may be composed of individuals who hold or have held an NRC-issued license to operate a commercial nuclear reactor of the same type (i.e., pressurized water reactor or boiling water reactor) for which the design is being validated.

- Actions allocated to non-licensed operators are validated using non-licensed personnel trained in accordance with a program that meets the requirements of 10 CFR 50.120.

- The MCR operating staff size and composition used in the event simulations are the same as was used for the analysis and preliminary validation.

- All crews are included as part of the ISV. For vendor/applicants using the 10 CFR Part 52 process the minimum number of crews should be established in accordance with the guidance of NUREG-0711 (e.g., as specified in the vendor's/applicant's NRC-approved integrated system validation implementation plan).

Procedures

- The manual operator actions to be credited in the defense-in-depth analysis are directed by procedure steps included within the EOPs and executed from the MCR.

Operational Conditions

- Event simulations for the ISV include a range of representative CCF and digital failure modes, postulated HSI failures, and operational conditions in which credited actions may be required.

Performance Times

- For each AOO/PA, the mean performance time of the crews is less than or equal to the estimated time required derived from the analysis phase.

- For each AOO/PA, the performance time for each crew, including margin determined in the time required analysis, is less than the analyzed time available.

PHASE 4: MAINTAINING LONG-TERM INTEGRITY OF CREDITED MANUAL ACTIONS IN THE DEFENSE-IN-DEPTH ANALYSIS

4.A. Method

Among other factors, changes in plant design, EOPs, and operator training can affect the ability of operators to correctly and reliably perform manual actions. Accordingly, the vendor/ licensee/applicant should establish a strategy for long-term monitoring of operator ability to reliably perform the manual operator actions credited in a defense-in-depth analysis. The scope of the performance monitoring strategy should provide adequate assurance that integrated system performance will be maintained within the bounds established by the ISV and continue to support the associated defense-in-depth analysis.

There is no expectation for the vendor/licensee/applicant to periodically repeat the full ISV; however, there should be sufficient controls to provide reasonable confidence that operators will maintain the skills necessary to accomplish the credited actions. The results of the monitoring need not be reported to the NRC, but should be retained onsite for inspection.

Consistent with 10 CFR Part 50, Appendix B, Criterion III, “Design Control,” Criterion V, “Instructions, Procedures and Drawings,” and Criterion VI, “Document Control,” the vendor/licensee/applicant should have in place sufficient configuration and design controls to assure that procedure steps that direct the credited action are administratively protected from inadvertent change, and that the design program has sufficient controls to assure that the design will continue to support the defense-in-depth analysis when the plant or MCR is modified.

Consistent with 10 CFR Part 50, Appendix B, Criterion II, “Quality Assurance Program,” in addition to the operations organization, training also should be provided to design personnel for the purpose of understanding the critical link between manual operator actions performed in response to a BTP 7-19 software CCF and the plant equipment used to implement these

actions. Instructors should ensure that trainees understand the philosophy behind the approach of the EOPs.

Consistent with 10 CFR Part 50, Appendix B, Criterion III, “Design Control,” and Criterion XVI, “Corrective Action,” long-term monitoring should have a formal mechanism for feedback such that results, including problems identified by the operating staff during operations or training, are brought to the attention of the reference plant operations department management and the design organization. The vendor/licensee/applicant may integrate, or coordinate, their long-term monitoring with existing programs for monitoring operator performance, such as periodic operator surveys or the licensed operator training program.

4.B. Review Criteria

The responsible reviewers evaluate vendor/licensee/applicant’s submittals for compliance with the following criteria:

- A long-term monitoring strategy is developed and documented by the vendor/licensee/applicant that is capable of tracking performance of the manual operator actions to demonstrate that performance continues to support the associated defense-in-depth analysis.

- The program is structured such that corrective actions are formal, effective, and timely.

Rationale

Guidance for HFE analyses that would be suitable to support defense-in-depth analyses is described in NUREG-0711. The NRC staff has a high degree of confidence that a vendor/licensee/applicant using the NUREG-0711 model will provide adequate HSI design to allow operators to accomplish the manual actions required by their designs. However, the typical HFE Program per NUREG-0711 does not conclude until just before fuel load or startup. This Appendix provides guidance for a methodology that provides early feedback in the design and regulatory review process and allows the vendor/licensee/applicant to move forward with relative confidence that credited manual operator actions will be demonstrated as both feasible and reliable in the ISV. Ultimately, the ability to reliably perform credited manual operator actions will be verified through completion of ITAAC or License Conditions related to the actions credited in the defense-in-depth analyses. Furthermore, the ability to reliably perform the credited manual actions within the time available shall be maintained through a long-term monitoring strategy.

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