18.10   Verification and Validation

Human factors engineering (HFE) V&V consists of techniques used to establish that the design of the HSI meets HFE design requirements and supports the performance of personnel tasks. V&V also establishes that the HSI design adheres to established human factors practices and meets all operational requirements.

HFE V&V consists of a variety of activities, many of which are not executed in a single step at the end of design activities, but are performed at various points throughout the design process. Some activities are performed iteratively as the level of detail of the design progresses.

18.10.1   Objectives

The first objective of HFE V&V is to establish that the design of the HSI meets design requirements. To verify the HSI design requirements, V&V demonstrates that:

- Required control capabilities and displayed quantities are provided.

- Each part of the HSI is configured as intended, as required by design-specific HFE guidance, and as described in the style guide (see Section 18.7.6.1) and industry standard practices.

- Conflicts between the various requirements and specifications have been addressed and resolved.

The second objective of HFE V&V is to establish that the HSI is effective in supporting the performance of personnel tasks. To validate that the HSI supports task performance, the entire system is tested to establish that the integrated functionality of individual requirements provides the functions and achieves the performance needed. HFE validation considers the HSI and the operators as a single system (i.e., a team type human-machine environment).

18.10.2   Scope

The HFE V&V process applies to HSIs (i.e., controls, displays, and alarms) in the MCR, the RSS, and appropriate local control stations (LCS). Functions considered critical to plant safety (i.e., risk-important HAs are specific targets to require sample V&V activities).

HFE V&V is also applied to the following features of the design or changes to the design:

- Procedures (hard copy and computer-based).

- Crew coordination and communication.

- Display navigation, information retrieval, and access to controls.

- Automation and the features of automation including monitoring and control.

- Layout, configuration, and anthropometrics of workplaces and workstations and the features and equipment required for those spaces (e.g., laydown areas, access and egress, radios, phones, and hard copies of procedures and drawings).

- Workplace environment (e.g., lighting, temperature, noise).

- Provisions for routine tests and maintenance.

The techniques for HFE V&V are described in Section 18.10.3. Application of the various techniques to different aspects of the HFE design is included in the description of the technique.

18.10.3   Methodology

The first step in verification is to identify the HSI components that are subject to verification. The HSI inventory and characterization activity describes the HSI displays, controls, and related equipment within the scope of the HSI design to be verified. HSI inventory and characterization is described in Section 18.10.3.1.

The second step in verification is the HSI task support verification (TSV) used to establish that the HSI provides the alarms, information, and control capabilities required as a result of the functional requirements analysis (FRA) and TA activities. TSV is also used to establish that the characteristics of those alarms, information, and controls conform to the requirements developed during the TA. HSI TSV is described in Section 18.10.3.2.

HFE design verification (DV) (see Section 18.10.3.3) verifies that the characteristics of the HSI and the environment in which it is used conform to the established design-specific HFE guidelines, as described in the style guide (see Section 18.7.6.1) and the industry standard practices in accordance with NUREG-0700 (Reference 1).

There are a large number of HSI components used in the U.S. EPR. Each HSI component represents at least one personnel task; therefore, a large number of events could be encountered during operation of the plant. It is neither practical nor appropriate to evaluate every scenario to confirm the adequacy and effectiveness of the HSI and establish that the performance requirements are met for each operating condition. Operational condition sampling (OCS) (see Section 18.10.3.4) is used to choose a representative set of scenarios for validation.

Performance-based tests are used to evaluate an integrated system design to determine if the HSI supports safe operations of the plant. This ISV evaluates those aspects of design that can not be assessed analytically. The goal is to test the integration of personnel and plant systems and to validate the integration of the design with personnel actions, plant response, HSIs, and procedures. ISV is performed using a high-fidelity simulator. Generally, ISV participants are operators with training and qualifications consistent with the description in Section 13.2. Multiple groups of operators are used for ISV scenarios so that results are not biased towards well-qualified crews. Details on ISV are provided in Section 18.10.3.5.

Human engineering discrepancy (HED) resolution is performed iteratively throughout the HSI design process so that issues are identified and corrected early. Some HEDs identified during verification are resolved prior to proceeding with validation of the HSI design. HEDs are not considered in isolation and, to the extent possible, their potential interactions are considered when developing and implementing solutions. More details on HED resolution are provided in Section 18.10.3.6.

The final step in verification is the design implementation activity, which confirms that the design description and documentation match the installed configuration and completes any V&V activities that could not be performed prior to installation. Any discrepancies identified at this stage are resolved by updating the appropriate documentation before the design is ready for operation. Design implementation is described in Section 18.11.

18.10.3.1   HSI Inventory and Characterization

The HSI inventory and characterization activity describes HSI components and related equipment associated with personnel tasks that are within the scope of the HSI design to be verified. The complete inventory is created by filtering certain portions of the instrumentation and controls (I&C) input/output (I/O) database which receives information from sources such as system description documents, design specifications, equipments lists, and process and instrumentation drawings. The accuracy of the inventory is confirmed by comparing it with the HSI elements described in the design specifications for the HSIs. The inventory includes aspects of the HSI that are used for interface management such as navigation and display retrieval in addition to those that control the plant.

The inventory provides an accurate and complete description of the HSI components and includes the following information:

- A unique component identification code, which includes the associated plant system and subsystem.

- The type of component.

- Component characteristics such as:

    – Display functionality.

    – Control functionality.

    – User-system interactions and dialog types.

    – Location within the display screen hierarchy.

    – Physical location.

    – Associated operator response time for critical human tasks.

The HSI inventory identifies aspects needed to verify that the interface meets its requirements. The focus is on characterizing the HSI and not the technical features of

the devices that comprise the HSI. Photographs or copies of process information and control system (PICS) and safety information and control system (SICS) screens and samples of SICS hardwired components are included in the inventory.

When the HSI inventory is fully defined, HFE DV is used to confirm that each individual component conforms to established HFE guidelines.

18.10.3.2   HSI Task Support Verification

The HSI TSV shows that the HSI provides alarms, information, and control capabilities required for identified tasks that are performed by personnel and that the characteristics of the alarms, information, and controls conform to the requirements developed during the TA. TSV does not identify HSI elements not needed to support personnel tasks unless additional activities are performed, such as annotating panel or screen display drawings. For the U.S. EPR, HSI elements that do not support personnel tasks are identified during the HSI design. The number of HSI elements or screens is reduced if the HFE and Control Room Design Team determines that an excessive number of display elements or screens interfere with operator awareness or leads to information overload issues. Individual HSI elements are arranged on screens according to criteria established in the style guide (see Section 18.7.6.1) while screens are arranged in layers of a hierarchy (see Section 18.7.6.1.2). HSI elements that are not needed to support personnel tasks are minimized on control screens that are most often used, and are shown in detail on control screens in lower levels of the hierarchy.

Initial TSV is performed early in the HSI design process to provide information for HSI screen layout. Initial TSV uses the results of the HSI inventory and characterization, the operating procedures, the TAs performed for those operating procedures, and the HRA results. Preliminary versions of system description documents, process and instrumentation drawings, logic diagrams, and hardware and software specifications also provide input. The initial TSV confirms that the inventory of HSI elements support personnel tasks as defined by the procedures, design goals, and analysis. The initial TSV verifies completeness of the HSI inventory; therefore, no performance measures are developed for this activity.

A dynamic TSV is performed when the HSI and simulator designs have evolved to the point that the simulator represents the complete HSI inventory. The dynamic TSV confirms that HSI components meet the specified operability requirements (e.g., response time, accuracy, precision) for selected tasks. A set of performance measures derived from performance requirements contained in the applicable hardware and software design specifications, and from the style guide (see Section 18.7.6.1) is defined prior to starting the dynamic TSV. These performance measures cover quantitative parameters, limits, and tolerances concerning performance such as completion time, range, accuracy, precision, frequency, and percent completion. To perform the dynamic TSV, test personnel are placed in-the-loop on the simulator. Task requirements not met by the inventory are identified with an HED and tracked until they are resolved or justification for no resolution is complete.

18.10.3.3   Design Verification

The HFE DV evaluates the final design against the design requirements and the design specifications. Design requirements are derived from the style guide (see Section 18.7.6.1) and NUREG-6393 (Reference 2). HFE guidelines in the style guide cover the following aspects of HSI design:

- Global features – room layout panel configuration (e.g., anthropometrics, and ergonomics), work environment (e.g., lighting, space, air conditions, and sound levels) and inter-personnel communication that support users of HSI (e.g., equipment functionality, and ease of use).

- Standardization features – HSI characteristics and conventions (e.g., coding conventions, display formatting, navigation, and alarm hierarchy) are those features that are designed using HFE guidelines applied across individual control and display elements. For example, the display labeling is standardized based on the style guide.

- Detailed features – HSI features not addressed by general HFE guidelines.

The design verifiers define the criteria for the verification and capture them in a checklist of the relevant style guide requirements. Final design documentation such as panel drawings or mockups and screen shots are also used. The designers justify and document instances where the design deviates from the specifications or established practices. HSI design specifications capture performance requirements, and those requirements define the performance measures for the DV.

The DV consists of comparing the characteristics of the HSI components with the design requirements. An HED is generated when an HSI component does not conform to the operational requirements as defined in the validated procedure guidelines (i.e., derived in TA), HFE design specifications, or the style guide.

HEDs are also identified for:

- Failure to meet crew-identified functionality in addition to that specified by system designers.

- Poor integration with the rest of the HSI.

- Poor integration with procedures and training.

HEDs are documented and evaluated to determine the extent of the condition. For example, if the elements of a particular display screen are not in compliance with the required color coding scheme, other similar display screens are evaluated to establish that there are no generic implications. HEDs identified during DV do not always warrant a design change; if, for example, an HSI layout is not consistent with the style guide but is consistent with the physical plant, changing the HSI layout to meet the style guide requirement could adversely effect operator acceptance of that HSI layout and lead to errors in usage. It is also possible for HFE DV to uncover limitations in the style guide requirements if the DV is well documented and reasonable designer

decisions conflict with the guidance. HED resolution in this case could involve a revision to the style guide. For an explanation of the HED resolution process, see Section 18.10.3.6.

HFE DV is performed throughout the design process as soon as design elements such as individual screen layouts are complete. HFE DV is performed on each HSI element prior to the initial ISV.

18.10.3.4   Operational Conditions Sampling

The U.S. EPR has a large number of HSI components. Hundreds of personnel tasks will be encountered during operation of the plant. Sampling of the operational conditions is used to choose a representative set of scenarios for validation. There are three sampling dimensions addressed in the identification of scenarios for the ISV:

- Personnel tasks.

- Plant conditions.

- Situational factors known to challenge personnel performance.

18.10.3.4.1   Personnel Tasks

The HFE and Control Room Design Team addresses those personnel tasks that are related to the use of the HSI. As a minimum, the tasks identified in analysis activities associated with EOP development (see Section 18.8) and risk-significant HAs (see Section 18.6) are included in the sample. The sample set of tasks is augmented to include tasks that:

- Are found to be particularly difficult to design into the HSI.

- Require significant compromise during the HSI design.

- Have the potential to cause user errors because of its complexity.

Tasks that use design features retained or modified during the design process, because of the OER analysis, are included in the sample set to confirm the adequacy of the design to resolve the issue or the need for further consideration or tracking.

The other personnel tasks considered for inclusion in the sample are as follows:

- Range of knowledge-based tasks that are not well defined by detailed procedures. Knowledge-based decision-making involves greater reasoning concerning safety and operating goals and the various means of achieving them. A situation may require knowledge-based decision-making if the rules do not fully address the problem, or the selection of the appropriate rule is not clear.

- Human cognitive activities:

  - Detection and monitoring.

- – Situation assessment.

- – Response planning.

- – Response implementation.

- – Obtaining feedback.

- Range of human interactions – interactions among plant personnel, including tasks that are performed independently by individual crew members and tasks that are performed by crew members acting as a team.

- Tasks that are performed with high frequency.

18.10.3.4.2 Plant Conditions

The sample set includes representative plant conditions as appropriate for the HSI to be validated. These include normal operating events such as:

- Plant startup.

- Plant shutdown or refueling.

- Significant changes in operating power.

- Failure events (i.e., instrument failures, HSI failures, and other system component failures).

- Transients and accidents:

  - – Transients (e.g., turbine trip, loss of off-site power, station blackout, loss of all feedwater, loss of service water, loss of power to selected buses or MCR power supplies, and safety and relief valve transients).

  - – Accidents (e.g., main steam line break, positive reactivity addition, control rod insertion at power, anticipated transient without scram (ATWS), and various-sized loss-of-coolant accidents).

  - – Reactor shutdown and cooldown using the RSS.

- Reasonable, risk-significant, and beyond-design-basis events determined from the PRA.

- Consideration of the role of the equipment in achieving plant safety functions and the degree of interconnection with other plant systems.

18.10.3.4.3 Situational Related Performance Shaping Factors

Situational related performance shaping factors can negatively impact operator performance. Situational factors known to challenge human performance are included in the sample as follows:

- Operationally difficult tasks - tasks that have been found as problematic in the operation of complex HSIs (e.g., use of a procedure versus assessment of a situation based on operator knowledge and awareness).

- High workload conditions - situations where human performance can vary because of high workload and multitasking situations.

- Varying workload situations - where human performance can vary because of workload transitions.

- Fatigue - situations where human performance can vary because of personnel fatigue.

- Environmental factors - situations where human performance can vary because of environmental conditions such as poor lighting, extreme temperatures, high noise, and simulated radiological contamination.

The sample also includes error-forcing context situations specifically designed to create human errors in order to assess the error tolerance of the system and the capability of operators to recover from random errors.

18.10.3.4.4   Identification of Scenarios

When the complete set of operational condition samples is developed, the results are combined to identify a set of scenarios for ISV. The following criteria are used to fully define the scenarios to be validated.

- A given scenario identified for ISV that combines multiple characteristics of each dimension.

- A scenario defined to allow, where practicable, repetition with multiple ISV participants to establish consistency of results. The scenario definition includes, as a minimum:

  – A description of the scenario mission and any pertinent situational history necessary for operators to understand the state of the plant upon scenario startup.

  – Specific start conditions.

  – Events (e.g., failures) that will occur and their initiating condition(s).

  – Precise definition of workspace factors such as environmental conditions.

  – Communication requirements with remote personnel.

  – Crew behavior requirements.

  – Data to be collected by the operators including how they were collected and where they were captured and stored.

– Criteria required for terminating the scenario.

- The scenarios selected are not biased towards:

  – Positive outcomes.

  – ISV that is administratively easy to conduct scenarios.

  – ISV that is familiar and well-structured scenarios (i.e., textbook design basis accidents).

- Random scenario selection and sequencing is used to keep the testing unbiased. The easy scenarios are not always conducted first and testing participants get random assignments.

18.10.3.5 Integrated System Validation

ISV is a performance-based evaluation of integrated system design and human task performance to establish that the HSI is operable within performance requirements and supports safe operation of the plant. The ISV addresses the following:

- Adequacy of the entire HSI configuration for achievement of the HFE program goals.

- Confirmation of allocation of functions and the structure of tasks assigned to personnel and machine.

- Adequacy of staffing and HSI that support tasks.

- Adequacy of procedures and operating instructions.

- Validation of the dynamic aspect of HSI for task accomplishment.

The goals of ISV are to:

- Test the integration of personnel and plant systems.

- Validate the integration of the design with:

  – Personnel actions.

  – Plant response.

  – HSIs.

  – Procedures.

ISV is performed using a high-fidelity simulator. ISV seeks to confirm the adequacy of the HSI and the human performance assumptions, so appropriate performance measures are selected to include both HSI and human performance issues. ISV performance measurement is complex and addresses the following areas:

- Operational safety and task performance (e.g., avoidance of errors, alarm conditions, technical specification violations, response time, task completion time, and procedure compliance).

- Human error.

- Situational awareness.

- Operator workload.

- Crew communications and coordination.

- Anthropometrics (i.e., accessibility and operability of controls and visibility and readability of indicators).

- Display validation (i.e., behavior of the graphics, which is part of the overall HSI performance).

Tools and methods used to validate the conceptual design (i.e., ISV type activities performed prior to the final design) include interviews, questionnaires, checklists, walk-throughs, talk-throughs, static mockups, part-task simulators, and the full-scope simulator.

The scope of the ISV includes the MCR, the RSS, and appropriate LCS.

The simulator testing environment can not fully replicate the actual MCR environment considering that factors such as noise, lighting, temperature, and stress have an affect on operator performance in real situations. Simulator testing environments can also bias operator behavior because during a simulator test scenario, the operator is likely to anticipate the occurrence of an abnormal condition and be more attentive. This potential for bias is considered when evaluating test results. The guidance from NUREG-6393 (Reference 2) is used to avoid selecting scenarios which introduce bias.

Formal ISV tests are performed using the plant simulator with a representative set of realistic scenarios selected from OCS input to confirm that the HSIs, the procedures, the function allocation, and the task design also supports the operator during task performance.

Since it is the purpose of the ISV to demonstrate that the design is an effective interface, it is important to establish that problems such as inadequate training or incomplete, unproven procedures are not encountered during the tests because correct interpretation of the results of the validation becomes more difficult. Another goal of ISV is to validate the effectiveness of procedures and operator training.

Initial design ISV activities such as evaluation of display navigation are conducted throughout the design phases without operating procedures via techniques such as interviews, walk-throughs, and laboratory simulators.

Some problems are revealed during training. If, for example, it is discovered that operators have difficulty learning how to use certain features of the HSI or experience

other challenges, HEDs are written to document the HSI problems. As described in Section 18.9, the HFE and Control Room Design Team provides input to the training program to identify useful areas of focus for HFE V&V activities. As issues develop they are evaluated so that decisions can be made to proceed with ISV or consider design changes based on preliminary results.

The full-scope simulator cannot evaluate every performance shaping factor such as ambient temperature and noise. See Section 18.11 for a description of how some of the aspects of the ISV that can not be performed by simulator are validated.

18.10.3.5.1 Validation Team

The Validation Team for ISV is an independent, multi-discipline team which includes significant involvement of the HFE and Control Room Design Team. To minimize the potential for bias, evaluations are performed independently. The Validation Team includes personnel with expertise in test and evaluation, test design, test procedure development, performance measures, and data analysis.

18.10.3.5.2 Scope

ISV considers actions required to be performed by operators to safely operate the plant during each plant operation mode and actions required to respond to a design basis event or an ATWS condition. Before performing any evaluations, HEDs identified during previous V&V efforts are resolved or retained for consideration after the ISV operational assessment.

18.10.3.5.3 Pilot Study

A pilot study is conducted prior to validation testing. The pilot study provides an opportunity to assess the adequacy of the test design, performance measures, and data collection method. The participants who will operator the integrated system in the validation test will not be used in the pilot study.

18.10.3.5.4 ISV Test Objectives

Detailed test objectives are developed prior to validation testing and define a systematic approach that relates scenario characteristics and performance measurement criteria. The objectives are developed to provide evidence that the integrated system adequately supports plant personnel in the safe operation of the plant. The objectives include the following:

- Validate the role of plant personnel.

- Validate that the shift staffing, assignment of tasks to crew members, and crew coordination is acceptable. This includes validation of nominal and minimal shift levels.

- Validate that for each human function, the design provides adequate alerting, information, control, and feedback capabilities during normal plant evolutions,

transients, design basis accidents (DBA), and select risk-significant events that are beyond design basis.

- Validate that the functional requirements are met for the major HSI features such as group-view displays, alarm systems, safety parameter display system functions, general display systems, procedures, controls, communication system, and EOP-related LCSs.

- Validate that the control room operators can make effective transitions between the HSI features (e.g., group-view display, alarm systems, SICS, PICS, procedures, controls, communication systems) in the accomplishment of their task and that interface management tasks such as display configuration and navigation are not a distraction or cause undue burden.

- Validate that the integrated system performance is tolerant of failures of individual HSI features.

- Identify aspects of the integrated system (e.g., staffing, communication, and training) that may negatively impact integrated system performance.

18.10.3.5.5   Strategy

ISV is performed on a high-fidelity simulator and includes the following steps:

- Develop detailed test objectives.

- Verify that the test bed meets the requirements in 10 CFR 50.34(f)(2)(xii)(C)(2) (i).

- Verify that previously generated HEDs have been addressed or are tracked for further consideration.

- Select participants:

    - Test participants are qualified operators that represent plant personnel who will interact with the HSI (e.g., operators currently licensed on similar plant designs rather than training or engineering personnel).

    - Test conductors are trained and qualified in the usage of test procedures, error introduction by inaccurate testing procedures, and importance of testing documentation.

    - Normal crew configuration is present for the test (see Section 18.7.2).

    - Sample participants for the validation test are randomly chosen to avoid significant overlap with regard to:

        · Operator license and qualification.

        · Age.

        · Skill and experience.

- General demographics.

- Test participants:

    - Are not a part of the design organization.

    - Have not been involved in prior evaluations.

    - Were not selected based on a specific characteristic.

- Select and define scenarios from OCS.

- Develop test procedures.

- Develop human performance measures.

- Establish that test personnel and test participants have been properly trained.

- Conduct a pilot study to assess test design, performance measures, and data collection methods.

- Initiate simulation and conduct study.

- Analyze data, validate HRA assumptions, make appropriate design changes, as required.

- Create validation output reports.

18.10.3.6   Human Engineering Discrepancy Resolution

HEDs refer to deficiencies in the HSI design with respect to HFE issues. During the design phases, HEDs are captured in the HFE Issues Tracking Database (see Section 18.1.4). When the U.S. EPR operator has assumed responsibility for maintaining design documentation, HEDs are tracked via the site-specific corrective actions program (see Section 18.12.3).

HEDs are documented throughout the HFE design process, including the HFE analyses, informal design reviews and iterations, and in each of the V&V steps. To identify an HED, designers document the relevant HSI, task criterion, an explanation of the basis for the deficiency, and a recommendation for correcting the problem, if applicable. The documentation completely describes the HED including, as a minimum:

- Priority categorization.

- Associated plant system.

- Associated personnel function.

- Associated HSI or procedure.

- Whether the HED was corrected or justified as needing no correction and the bases for this determination in terms of consequences to plant safety or operations.

- Possible impact of similar areas of design.

- Impact on plant design.

- Impact on schedule.

Some HEDs are evaluated as acceptable; a justification of acceptability allows the HED to be closed with concurrence of the HFE verifiers. After resolution for the discrepancy has been established, the task or HSI component is re-evaluated to establish that it was adequately resolved and the HED records are updated to show the changes. HEDs also track HFE issues. Where possible, these issues are satisfactorily resolved by the completion of the final design (see Section 18.11). Some HEDs are not resolved due to design constraints on HSI equipment or other factors.

HEDs created during the V&V process are resolved iteratively with V&V. Where feasible, discrepancies are addressed and resolved prior to conducting other V&V activities.

An HED may indicate a similar problem in another area of the design. For example, a problem with the display format on one screen may indicate a similar problem on another screen. HED analysis includes impacts in similar areas of the design.

18.10.3.6.1   HED Prioritization

HEDs identified for correction are prioritized and entered into the applicable corrective action tracking database. The categories for prioritization are as follows:

- Priority 1 – HEDs with direct, indirect, or potential safety consequences such as an effect on personnel performance where that consequence could reduce the margin of plant safety below an acceptable level (e.g., violations of Technical Specification safety limits, operating limits, or limiting conditions for operations). Priority 1 HEDs are corrected immediately.

- Priority 2 – HEDs with potential consequences to plant performance or operability, non-safety-related personnel performance or efficiency, or other factors affecting overall plant operability. Priority 2 HEDs are corrected before plant startup.

- Other – HEDs that do not fit Priority 1 or Priority 2. These HEDs may not require correction.

18.10.3.6.2   HED Design Solution Development

For each HED that requires correction, a design solution is developed. The design solution follows the design process steps (i.e., OER, FRA, TA, and HSI design) from the original design. Changes to the original design may not cause deviations from design requirements.

18.10.3.6.3 HED Design Solution Evaluation

The proposed design solution is evaluated to establish that it:

- Adequately corrects the HED.

- Does not adversely impact other aspects of the design.

- Is consistent with HFE guidelines and that ISV can be conducted to evaluate its usability.

18.10.3.7 Results

Procedures and expected documentation requirements for various V&V activities are summarized in the preceding sections. A results summary addresses the following:

- Scope and objectives.

- Identification of participants, including their qualifications.

- Descriptions of HSIs involved.

- Methods and procedures used.

- Test conditions.

- Personnel performance issues (e.g., level of training of participants).

- Deviations from test methods, procedures, and acceptance criteria, if any.

- Identification of HEDs.

- Records of resolution or justification of deviations.

- Evaluation of test results and findings including any changes made to input assumptions or as a result of further analyses (i.e., FRA, FA, TA, Staffing, HSI design).

- Conclusions.

18.10.4 References

3. NUREG-0700, "Human-System Interface Design Review Guidelines," Revision 2, May 2002.

4. NUREG-6393, "Integrated System Validation: Methodology and Review Criteria," September 1995.