**NRC INSPECTION MANUAL** IQVB

INSPECTION PROCEDURE 37805

ENGINEERING DESIGN VERIFICATION INSPECTIONS

PROGRAM APPLICABILITY: IMC 2507

37805-01 INSPECTION OBJECTIVES

* 1. Verify that the design authority (e.g., the organizations contracted by an NRC applicant to provide engineering, procurement, and construction support) has developed processes that allow for the complete and accurate transfer of the high level design information and performance requirements specified in the Final Safety Analysis Report (FSAR) into detailed procedures, specifications, calculations, drawings, procurement, and/or construction documents, in a manner consistent with the requirements of Appendix B to 10 CFR Part 50.

01.02 Verify that the design authority has developed processes to ensure changes to the design are adequately controlled.

01.03 Verify, through a detailed technical review of selected systems, that the design authority’s implementation of its design and design control processes has produced detailed procedures, specifications, calculations, drawings, procurement, and/or construction documents that are consistent with NRC regulations, the FSAR, and the NRC’s Safety Evaluation Report (if issued).

37805-02 INSPECTION REQUIREMENTS

Through a detailed technical review of selected systems, this Engineering Design Verification (EDV) Inspection will provide the NRC an opportunity to assess the design authority’s implementation of its processes for completing and controlling the detailed design. The detailed technical review will provide reasonable assurance that the design authority’s processes are sufficient to result in the complete and accurate transfer of the high-level design information contained in the FSAR into detailed engineering, procurement, and /or construction documents consistent with NRC requirements and FSAR. The successful completion of this inspection will also provide confidence in the validity of the resulting detailed design information which may ultimately be utilized by Combined License holders to support the closure of Inspections, Tests, and Acceptance Criteria (ITAAC).

It is anticipated that one EDV (and related follow-up inspections) will be completed for each certified design.

02.01 Inspection Preparation.

* + 1. Pre-inspection Meeting with Design Authority. Prior to the beginning of the actual inspection, the team leader and selected members of the inspection team should visit the design authority’s offices to ensure sufficient progress has been made in completing the detailed design to allow for the successful completion of this inspection. To aid in this determination, the design authority should be asked for a list of all systems indicating the status of design completion for each system. These should be systems for which the design has been “frozen” from a licensing basis perspective.

The EDV inspection should be performed when the detailed design is complete for at least 70% of safety systems. Design complete in this context means that the initial detailed design is complete for the system. Additional activities to validate the detailed design to actual “as purchased” or “as installed” component level data may remain since these activities may be incomplete at the time of the inspection.

An additional limited scope EDV may be performed at a later date if detailed design work for a significant system was not complete at the time of the initial EDV (such as would be the case if the I&C system design was incomplete) or if significant design validation activities remain to be completed.

The team leader should acquire the following documents which will be provided to the team to aid in the system sample selection process:

 Latest revision of the FSAR

 NRC Safety Evaluation Report (drafts if not completed)

 Listing and description of scope of design work performed by each organization contributing to the development of the detailed design

 Engineering / design control procedures and quality assurance (QA) procedures related to design

 diagrams indicating the flow of design information

 design and engineering procedures specified for contractor and subcontractor use

 documents listing the scope and standards for engineering and design work expected to be done in the field

 documents indicating the scope of and procedure for the exchange of design information among the design organizations including procedures used to control design interfaces and procedures associated with the design change process

 procedures related to the software development and life-cycle control process supporting safety-related design activities.

 procedures describing the design authority’s involvement in the engineering process (e.g., oversight and audit of engineering activities)

 QA manuals for all organizations performing design work on the project

 Significant reports and other correspondence related to progress, status,

or control of the engineering and design process

* + 1. System Selection. Prior to selecting its inspection sample, the team should meet with NRR’s Division of Risk Assessment (DRA), Division of Engineering and External Hazards (DEX), Division of Reactor Oversight (DRO), and Division of New and Renewed Licenses (DNRL) to obtain information on the systems, design features, and components that are important based upon their relative risk significance. The NRR technical divisions should also be asked to provide insights on systems and design features that they believe would be good candidates for review during the inspection. Considering the insights obtained above, the information obtained during the team’s pre-inspection visit, and the following considerations, two systems should be selected for review:

 uniqueness and degree of industry experience with system design features

 margins to design requirements

 representative of safety-related features in other systems

 a design that involves internal interfaces between the various functional areas and external interfaces between the design authority and designated design, fabrication and construction organizations

In general, the systems selected for review should be mechanical systems. The Electrical and Instrumentation and Control (I&C) features of the design should be reviewed as supporting to the selected mechanical systems. Note: It is possible that at the time this inspection is performed the detailed design for the I&C system may be incomplete. In such cases, a separate inspection of the I&C system may be required. In addition, at least one civil structure associated with the selected mechanical systems should be reviewed.

It is important to note that the EDV is an inspection activity that is meant to assess the adequacy of the design authority’s processes for developing and controlling the detailed design and is not meant to take the place of specific technical reviews performed as part of the licensing process or as part of ITAAC verification inspections. As such, the EDV may not be able to cover all the technical staff’s suggested systems and design features. In certain instances, and in order to meet the objectives of the inspection, some inspection may also be authorized by the team leader beyond the boundaries of the sample systems.

* + 1. Notification of Design Authority of Sample Selection. At least two weeks prior to the scheduled start of the onsite inspection, the team leader will notify the design authority of the results of the sample selection process. At this time, notification should also be made to any sub-vendors doing design work where it is anticipated the team will need to perform offsite inspection activities. The team leader should request the design authority collate the following documents relative to the selected systems and have copies of the documents ready for the team’s review onsite:

 principal design criteria

 system descriptions describing design bases, system functions and operation,

 component data

 data regarding associated I&C and electrical system interfaces

 engineering, design, and purchase specifications

 system flow diagrams showing flow paths, calculated flows, and temperatures and pressures for designed conditions of operation

 piping and instrumentation diagrams for the sample systems and interfacing systems, including the symbols and legend diagrams

 functional logic diagram

 independent validation and verification reports

* applicable calculations and analyses

 applicable electrical system calculations for onsite and offsite interfaces (e.g. load flow/voltage regulation studies, short circuit analyses, equipment sizing studies, equipment coordination and protection studies, insulation coordination, and grounding)

 component qualification test reports

 significant design reports, including audits and assessments

 design documents prepared by the design authority and designated design, fabrication, and construction organizations

 engineering contractor correspondence and documentation

* + 1. Development of Inspection Plans. Each team member should develop a customized inspection plan based upon the scope of work assigned to them by the team leader. Team members should utilize the guidance included in Appendix A as an aid in developing their individual inspection plans. As applicable, inspection procedures contained in IMC 2502 through 2508 may also be utilized to help in developing an inspection plan. The sample size for each document type to be reviewed should be established by each member of the inspection team and discussed with the team leader. Based on the in-progress inspection and results, the initial inspection plans may be revised as needed.

02.02 Inspection Implementation.

The following inspection requirements should be completed for work controlled by the design authority. Parallel inspection activities may be necessary for design work being completed by sub-vendors under control of the design authority.

* + 1. Design Program Review. Review the design authority’s processes that govern the transfer of the high-level design information and performance requirements into detailed procedures, specifications, calculations, drawings, procurement, and/or construction documents. Verify the design authority’s processes meet the requirements of Appendix B to 10 CFR Part 50 as well as the applicable requirements contained in the FSAR. This inspection requirement should be completed by a subset of the inspection team as directed by the inspection team leader. Ensure that sufficient processes are in place to validate the detailed design against “as procured” and “as installed” component level data.
		2. Design Document Review. For the selected sample, confirm that the design documents have been prepared in accordance with the applicable design procedures, specifications and instructions. Specific design control attributes to be checked include:

 control of design inputs and outputs

 design interface control (including control and integration of design work performed by sub-vendors)

 design verification

 design change control

 document control

* + 1. Design Technical Review. Utilizing the guidance contained in Appendix A for each design discipline, verify that the design authority’s implementation of its design and design control processes has produced detailed procedures (including maintenance, operating, and emergency operating procedures), specifications, calculations, drawings, procurement, and/or construction documents that are consistent with NRC regulations, the FSAR, and the NRC’s Safety Evaluation Report (if issued).

02.03 Problem Identification and Resolution.

Verify that the design authority has identified and entered design issues in the applicable corrective action programs. Verify the adequacy of a sample of corrective actions for the system(s) selected for review.

37805-03 INSPECTION GUIDANCE

Inspection Manual Chapter 2507 will be followed for additional guidance.

Refer to the guidance in Appendix A for discipline-specific design review attributes. The information in Appendix A is intended to provide a focus for each inspection team member’s discipline-specific reviews. An inspection team member is not required to address all of the inspection elements in Appendix A or restrict the scope of the inspection to the inspection elements listed in the appendix.

Appendix B provides detailed administrative inspection guidance to the inspection team leader and the inspection team members.

37805-04 RESOURCE ESTIMATE

This inspection is estimated to require 1280 hours of preparation time, 1600 hours of direct inspection, and 800 hours of documentation (assuming a ten-person team). This does not include time for any follow-up inspection activities, the extent of which will vary based upon the results of the inspection. Appendix B provides additional discussion of the projected level of effort, program scope and timetable, and the team composition expected to be used in the conduct of an initial or follow-up EDV inspection.

37805-05 REFERENCES

10 CFR 52.47, “Contents of Applications; Technical Information”

Appendix B to 10 CFR 50, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants”

10 CFR Part 21, “Reporting of Defects and Noncompliance”

Manual Chapter 2507, “Vendor Inspections”

37805-06 COMPLETION STATUS

An EDV inspection is completed when the staff has performed an inspection that meets the inspection objectives and the staff’s follow-up inspections confirm that the design authority has adequately closed the inspection team’s initial findings.

END

Attachments: Appendix A, Functional Area Inspection Plan Guidelines Appendix B, Inspection Team Responsibilities and Authorities Attachment 1, Revision History Sheet

APPENDIX A

FUNCTIONAL AREA INSPECTION PLAN GUIDELINES

The information in this appendix is intended to provide a focus for each inspection team member’s discipline-specific reviews. An inspection team member is not required to address all of the inspection elements in this appendix or restrict the scope of the inspection to the inspection elements listed in the appendix. While this inspection is not meant to verify ITAAC, inspectors should be familiar with the ITAAC level design requirements that apply to the selected systems and consider such requirements when constructing their individual inspection plans. Applicable sections of the NRC’s Standard Review Plan and associated Regulatory Guides may be referred to for additional guidance.

Mechanical Systems Inspection Plan Guidelines

1. The overall design basis of the mechanical fluid system should be known by the inspection team. Particular attention should be given to the functional and performance requirements imposed on the system for the purpose of assuring reactor safety. To accomplish a review of the mechanical fluid system, the inspection team should review the design requirements in the FSAR as well as the system description for the selected fluid system.

If the selected fluid system is directly connected to or related in function and behavior to the reactor coolant system, it will be necessary to review the requirements imposed by the reactor coolant system. The associated parameters could include such items as temperature, pressure, flow rates, chemical characteristics as well as information related to redundancy, accident analyses, physical location and protection from or control of the surrounding environment. Review calculations to confirm that the design requirements in the FSAR will be met.

1. Identify a function which is related to the selected mechanical fluid system. Determine if the design ensures that this function will be met during all plant conditions. Various system parameters, such as temperature, pressure, flow rates, and action times, should be reviewed to verify proper design basis and to evaluate system interfaces. The system flow diagram and supporting calculations should be reviewed to evaluate whether the design ensures that system functions will be met under all anticipated conditions.
2. Review calculations that are important to the performance of the system to be inspected, e.g., net positive suction head calculations for fluid systems and flow calculations for systems where required flow rates are safety-related items.
3. Review the design methods and assumptions used in evaluating the effects of pipe rupture on surrounding structures, systems, and components. Interfaces are involved in reviewing the designs of protective structures, pipe whip restraints, break exclusion runs, environmental effects of pipe rupture on essential electrical equipment and instrumentation, sub-compartment pressurization, inservice inspection, and inservice testing of piping components within protective structures or guard pipes.
4. Verify that the portions of the system penetrating the containment barrier are designed with isolation features that are acceptable for maintaining containment integrity for all operating and accident conditions. Check interfaces with the instrumentation and control functional area relative to isolation valve actuation and control.
5. Evaluate the classification of the structures related to the selected fluid system for conformance to the requirements for safety-related systems. Evaluate the spectrum of conditions that have been considered in the design of the structures. Evaluate the loading conditions that arise from events such as pipe rupture, LOCA, earthquakes, operational transients, reactor trip, loss of component cooling, etc.
6. Verify the compatibility of the materials and components of the selected fluid system with the service conditions, including normal and accident conditions as well as the design life. Ensure that the fluid system's components have proper safety and code classifications.

Mechanical Components Inspection Plan Guidelines

1. Select a sample of calculations and qualification reports to be reviewed; the sample should include the following items:
	* piping analysis problems
	* major components attached to the piping problem such as a pump, heat exchanger or tank
	* valves in the pipe run
	* pipe supports: rigid, snubber, and spring
2. Review all input information used in the piping analysis. This will require coordination with other team members to determine that the correct design inputs are used. Verify that the piping analysis will be updated to incorporate as-built information, when that data becomes available.
3. Review the model used in the piping analysis. This includes review of the analyses performed (thermal, deadweight, seismic, etc.), review of the computer programs

and the analytical model for conformance with the design requirements of the FSAR and procedures. Particular attention should be given to the model used for seismic analysis for the appropriateness of the boundary conditions assumed at anchors and supports.

1. Review stress and support load summary sheets for correct load combinations as specified in the FSAR. Also verify that these documents have been transmitted to the appropriate group for support evaluations.
2. Review component design reports to verify that the basic premises are correct, and that data are in conformance with the design requirements of the FSAR. Review test qualification documents, if applicable, including correctness of the test parameters for conformance with the design requirements of the FSAR. This review should verify that the loads from the piping analysis are included in the component evaluation.
3. Review valve design reports for conformance with the design requirements of the FSAR. Particular attention should be given to the operability evaluation for seismic events. Also, valve actuator qualification documentation should be reviewed for conformance with licensee commitments the design requirements of the FSAR.
4. Review the loads used in the evaluation of pipe supports and verify that these are the correct loads from the piping analysis. Review the support analysis for conformance with the design requirements in the FSAR and procedures. The load combinations should be checked for the correct specification of primary and secondary loadings. Verify that integral attachments have been evaluated for their effects on the piping and that buckling of compression members has been considered. For spring hangers and snubbers, verify that thermal movements were considered. Review the attachments to the structure and verify that the loads have been considered by the structural group.
5. Verify appropriate standards were applied on drawings to specify correct weld sizes, fastener sizes (bolts) and torque requirements.

Civil-Structural Inspection Plan Guidelines

1. Identify the location of the fluids system selected. Include associated equipment, such as:
	* pumps, heat exchangers, tanks
	* power supplies
	* control systems
	* piping supports

The load path of the structure or structural elements should be reviewed to ensure that the applied loads are properly carried through the structure or structural elements to the supporting points.

1. Verify that structural safety categories are consistent and correct. Consider the location and possible effect of non-safety-related items on the fluids system.

Review the safety categories defined in FSAR Section 3 and the classification of structures. Compare the safety categories of the mechanical fluid system selected against these criteria for compatibility.

1. Review the model and boundary conditions used in the structural analysis of the design configuration utilizing the output and information from other functional areas such as mechanical, electrical power, instrumentation and control, and systems design to verify the correctness. Also review the output provided from the civil- structural area to the other disciplines. Assess the safety impact of these reviews.
2. Verify that all pertinent loads and load combinations are considered in the analysis of structural elements, in addition to the piping system. Ensure that appropriate codes and standards are used in the design of structures. Examine the sensitivity of the structural analysis and design to changes in piping system loads, supports, and configurations as well as the influence on resulting structural deformations. Emphasis should be placed on the identification of the discipline boundaries and necessary interfaces in the design process. Determine that the correct loads and load combinations have been used and that methods for combining loads or load elements are correct.
3. Review samples of the design calculations based on the internal forces resulting from the analyses. Determine that the design techniques committed to in the FSAR have been or are being met. Also review specific areas of the design calculations.
4. Review examples of the design documents produced as a result of the design calculations, such as detailed specifications, drawings, and procedures to verify that analysis results have been correctly translated into structure and member sizes, reinforcement requirements, concrete requirements, fastener sizes, bolting requirements, etc..
5. Review examples where the basic design documents are used to produce product, components, or elements that will be integrated into the final structure. This review would include such items as fabrication and shop drawings, produced by a subcontractor, or installation procedures, defined by a supplier.
6. Review and evaluate the process by which design documents are checked and verified and the process by which the final documents are issued for use and construction.
7. Review and evaluate several types of design changes, such as those initiated by:

 design authority

 designated design office(s) field engineering

j. Review and evaluate the acceptance process used in the civil-structural area for final acceptance of the structures or elements thereof, including the incorporation of as-built information, when that information becomes available.

1. Review the seismic analysis of one seismic Category I structure that is associated with the sample system being inspected.

 Review seismic inputs, such as the developing of ground response spectra, artificial time-history generation.

 Review procedure of seismic modeling, including stiffness, masses, damping values. Verify that the seismic model is representative of and consistent with the actual structural configuration.

 Review the techniques dealing with modal combinations, peak broadening, closely spaced modes, etc.

 Review the adequacy of computer programs used for seismic analysis.

 Review the procedure for soil-structure interaction (SSI), if applicable, to ensure that the adequacy of the procedure and the methodology prescribed is consistent with FSAR commitments.

Electric Power Inspection Plan Guidelines

Note: for passive plants the electrical review should focus on the Class 1E safety related portions of the system (generally batteries and 120 VAC). Other non-safety portions of the electrical system may be reviewed based upon their relative risk significance.

1. Identify all components of the mechanical fluid system selected that require electric power to perform their safety function(s). Determine if the electric power system supplying power to each of these components will be capable of providing the required electric energy as needed by each component. Examine required voltage, current, and frequency (maximums, minimums, and nominal including transient values) and compare with power source voltage, current and frequency for several sample sets of conditions representative of maximum and minimum loads and expected perturbations on the power source. Determine if required power quality can be provided for the needed time of interest. A review of diesel generator (or other stand-by power source such as a gas turbine generator) load sequencing of the selected mechanical fluid system components (requiring power to perform their safety function) should be performed.

1. Identify all components of the mechanical fluid system that require disconnection from their electric power source in order to perform their safety function. Review the control circuit for at least two such components to determine if it meets its design requirements. Focus on time allowed for disconnection from power source in the electric power system design and the corresponding time assumed in safety analysis.
2. Examine the control relaying for at least two components of the mechanical fluid system that require power to perform their safety function and two components that require power disconnection to perform their safety function. Evaluate the documentation and actual installation of these circuits and assess the ability of the circuits to perform as required.
3. For several samples of each kind of electric component (i.e., motors, valve operators, relays, connections, cables), determine if the design meets acceptance criteria for performing the required safety function in the presence of the most severe environment specified in the component's design bases. Verify that acceptance criteria are consistent with licensee commitments the design requirements in the FSAR.
4. Examine the physical arrangement of redundant electric power source components, including separation, barriers, and environmental controls, to ensure that single failures affecting such components will not cause the mechanical fluid system to fail and be unable to perform its safety function(s).
5. Examine the qualification documentation of at least two motors, valve operators, relays, connections/connectors, and cables to determine if:

 the test conditions specified were consistent with predicted accident conditions at the equipment location

 required equipment performance was properly specified for the worst accident for which the equipment was required to operate

 test results showed the equipment able to meet specified performance under the design-basis conditions specified

1. Compare procurement specifications for the sample of equipment examined in item (f) above to determine if they are consistent with qualification specification for performance and environment.
2. Examine methods and procedures for providing electric power to operable electric equipment when the normal offsite source and the normal onsite emergency source are unavailable. Determine if these methods or procedures could compromise redundant power source independence or prevent supply of electric power to one or more redundant loads.
3. Confirm the power distribution system to safety-related electric loads has been adequately designed with regard to breaker, motor starter, and cable sizing, as well as breaker coordination. Review several sample calculations in this area.
4. For at least 2 electric loads, determine the basis for interruption of electric power in the case of an electric power demand in excess of the normal rating for the loads. Determine what basis was used to decide if the system was designed to ensure the performance of the safety function or to protect the equipment in cases of overloads. Review design of electric motor-operated valves provided with torque switches used to cause motor shutdown when excess torque is detected. Determine the validity of basis for torque switch settings. Review procedures for testing such switches.
5. Examine specifications for several items of electric equipment and compare to the expected environment in their designated location to determine if special environmental controls should have been provided or if a different location should have been selected.
6. Determine how the need for special environmental controls (e.g., battery room ventilation) on electric equipment was determined. Review design documentation (descriptions, drawings, etc.) to determine how the environment is to be maintained and how operating personnel are made aware of the needs for these special environmental controls.

Instrumentation and Control Inspection Plan Guidelines.

Note: Depending on the timing of this inspection, significant portions of the Instrumentation and Control System may be incomplete. In such cases, the team’s review should consist of verifying the details of the design to the maximum extent practicable. As an option, an additional limited scope inspection of the I&C system may be performed at a later date.

1. Select two different process measurements, such as flow, level, pressure, temperature, etc., associated with the mechanical fluid system selected and select two associated control (or non-safety measurement) systems. The selected measurements (at least one) should be selected from those that perform a safety function, such as reactor trip or actuation of one or more engineered safety features.
2. Review all input information used for the design. It will be necessary to Interface with the electrical power system design and the mechanical system design. Verify that the design input parameters meet the design requirements for the fluid system design. This should include the ranges of system process parameters required for normal and accident conditions.
3. Review the appropriate functional, wiring, and installation drawings to assure conformance to licensee commitments.
4. Select several field design change requests and verify that the vendor's design verification program is being effectively and accurately implemented. The inspector should review: the verification method; the procedure for implementation; the authority for the design change; the associated equipment documentation, such as equipment specification purchase orders, IEEE Standards, Regulatory Guides, "Approved for Construction" drawings, and the as-built installation drawings, if available, that complete the design change cycle; the results of the functional tests after the components/systems have been installed; the documentation to assure that the field change had been evaluated for general implications.
5. Review qualification documentation associated with safety-related instruments to determine compliance with regulations, regulatory guides and national standards applicable to qualification. Included should be a review of software development controls for digital I&C components. Review installation drawings and instructions to determine their adequacy to maintain qualification
6. Identify alarms or annunciators provided from the instrumentation for the mechanical fluid system and review the basis for providing these alarms or annunciators, their set-points, and their locations.
7. Review the system description for any unusual operating requirements. Examples of these requirements could be: special operation required of the systems during and after an accident, capability of the systems to shut down the reactor from a remote location, or any special automatic/manual control features.
8. Verify that the instrumentation and control system detects and maintains essential parameters during all anticipated plant conditions. Check if the capability to provide the required detection and control during loss of offsite power, or other anticipated operational occurrences and accident conditions meets design requirements.
9. Review a sample of logic functions, i.e., interlocks, automatic actuation and permissives, to assure they have been properly implemented.
10. Assure that bypassed and inoperable status is indicated as necessary.
11. Review procedures and basis for developing set points. Verify setpoints for a sample of instruments were properly established, including consideration of any relevant as-built deviations from the original design.
12. Review sample I&C valve data sheets to make sure that appropriate process data, setpoints, accuracy specifications, and other features have been correctly considered.
13. Verify that all attributes of control system input and output points have been appropriately implemented.
14. Review the detailed I&C architecture diagrams to assure that all applicable requirements have been incorporated.
15. Ensure that the control room design is consistent with the detailed I&C architecture diagrams.
16. Review sample control room screen graphics to ensure that the control system input and output points and their functions have been correctly specified.
17. Check the traceability for the implementation of sample I&C functions and requirements.
18. Review the software lifecycle development documents related to the selected instrumentation, including software development and configuration management, software procurement and supporting services, and version control.
19. Review data communication interfaces.
20. Review implementation of I&C response timing.

END

APPENDIX B

INSPECTION TEAM RESPONSIBILITIES AND AUTHORITIES

RESPONSIBILITIES AND AUTHORITIES

* 1. Implementation. The Office of Nuclear Reactor Regulation, Division of Reactor Oversight, Quality Assurance and Vendor Inspection Branch is responsible for implementing initial EDV inspections.
	2. Level of Effort. The NRC staff should perform the EDV inspection when the detailed design is complete for at least 70% of the safety systems. Design complete in this context means that the initial detailed design is complete for the system. Additional activities to validate the detailed design to actual component level data may remain, since final procurement activities may have yet to be completed. An additional limited scope EDV may be performed if detailed design work for a significant system was not complete at the time of the initial EDV (such as would be the case if the I&C system design was incomplete). The NRC staff will perform additional inspections to follow up on identified problems and to verify corrective actions. The NRC staff will perform a sufficient number of follow-up inspections after the initial EDV inspection has been performed for the defined scope of review to confirm that the design authority has adequately closed any inspection team’s initial findings.

The typical EDV inspection is expected to involve eight to ten inspectors. At a minimum, each inspector will be assigned to the team for two weeks of preparation, three weeks of onsite inspection, one week of in-office inspection, and one week of in-office documentation, for a total of seven weeks (see below timeline). Follow-up inspections may also be required to closeout issues identified during the EDV.

* 1. Inspection Timeline. A typical schedule to complete an initial EDV inspection is outlined below:

|  |  |
| --- | --- |
| EDV Inspection Activity | Time Allocation (Weeks) |
| Team Leader Planning* Initial visit to design authority to determine readiness for inspection (including determination of design completion by system)
* Schedule Preparation
* Inspection Team Selection
* Acquisition of key program documents from design authority
 | 4 |

|  |  |
| --- | --- |
| EDV Inspection Activity | Time Allocation (Weeks) |
| Team Preparation* Team Indoctrination Meeting
* Review of Information Obtained from Pre-inspection visit
* Meetings with NRR technical divisions
* System Selection
* Preparation of Draft Inspection Plans

Notification to Design Authority of System Selection* Design Authority prepares document packages based upon sample selection
 | 22 |
| Commencement of Initial Inspection Activities- Inspection of Design Authority and Select Subvendor (opt.) | 2 |
| Inspection Plan Refinements and Additional Review in Office | 1 |
| Completion of EDV Inspection* Continued Inspection of Design Authority and Subvendors
* Exit Meeting
 | 1-2 |
| Team Members Complete Documentation of Inspection Results and Submit to Team Leader | 1 |
| Team Leader Integrates Inputs and Issues Draft Report Team Member Review of Draft ReportManagement Review and Issuance of Final Report | 212 |
| Identification of all Design Deficiencies and Potential Enforcement Findings | 1 |

d. Inspection Team Composition. Inspectors assigned to initial and follow-up EDV inspections should have the appropriate training and experience. Assigned team members should remain with the team for the duration of each inspection, with no other duties. Consideration should be given to participation in the initial EDV inspections by NRR technical staff, staff from Region II, and/or the host region.

Specific inspection and experience need for a particular team will depend on the certified design, the system or systems selected in the sample, and the safety and risk significance of specific disciplines such as digital instrumentation and controls (I&C). Some inspections may require the use of contractor support to augment available NRR and Regional staff.

At least 2 inspectors with a QA background should participate on an inspection team, particularly for an initial EDV inspection where the design authority is finalizing the design for its first plant in accordance with 10 CFR Part 52.

* 1. Additional Guidance. The guidance documented in IMC-2507, and the QA inspection procedures referenced in Attachment 1 of IMC-2507, provide additional guidance for the conduct of EDV inspections. See also the inspection procedures referenced in IMC-2515.
	2. Management Entrance and Exit Meetings. An entrance interview between the design authority’s management and the EDV inspection team members should be held on the first day of the onsite inspection.

At the conclusion the inspection, the inspection team should discuss their preliminary findings with the design authority’s management at a scheduled exit meeting. These exit meetings may be scheduled on the last day of planned inspection activities or deferred until some later date after a team meeting / briefing of NRC management personnel. The design authority should be briefed on ongoing inspection results daily over the course of the inspection.

* 1. Inspection Documentation. The team will prepare an inspection report that documents the results of the initial or follow-up inspection(s). The format of the inspection report will conform to the requirements of IMC-0617. Additional requirements concerning the inspection report documentation will be given by the team leader.
	2. Follow-up and Enforcement. Section 08 of IMC-2507 discusses enforcement actions associated with the inspection process. IMC-2507 also contains guidance for documenting violations and non-conformances.

During an inspection, a significant concern may be identified that warrants consideration of prompt action (e.g., NRC order, investigation of wrongdoing, or stop-work consideration). If the inspection team identifies a significant concern, the team will promptly inform NRR management. The inspection team=s priority will then become the continued assessment of the concern until the concern has been resolved.

END

Attachment 1 - Revision History Sheet for IP 37805

ENGINEERING DESIGN VERIFICATION INSPECTIONS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Commitment Tracking Number | Accession Number Issue Date Change Notice | Description of Change | Description of Training Required and Completion Date | Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information) |
| N/A | ML09351098404/01/10CN 10-010 | Conducted a 4-year search for commitments and found none. | No | ML100140219 |
| N/A | ML11087185804/25/11CN 11-007 | Revised Inspection Procedure to refer to Manual Chapter 2507. Added Manual Chapter 2507 to the references. This revision is in response to OIG audit (OIG-10-A-02 (ML103020267)). | None | N/A |
| N/A | ML20076G26204/08/20CN 20-020 | Revised Inspection Procedure due to merger between NRO and NRR offices. | None | N/A |