

NRC INSPECTION MANUAL

MANUAL CHAPTER 2502

CONSTRUCTION INSPECTION PROGRAM: PRE-COMBINED LICENSE (PRE-COL) PHASE

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CONSTRUCTION INSPECTION PROGRAM: PRE-COMBINED LICENSE (PRE-COL) PHASE

2502-01 PURPOSE

To provide inspection policy and guidance for the implementation of the inspection program during licensee preparation and NRC review of Combined License (COL) applications submitted under 10 CFR Part 52.

2502-02 OBJECTIVES

02.01 To assure that the information in the COL application is accurate and that technical, quality, and administrative requirements important to public health and safety are effectively implemented during the design and procurement of a nuclear power plant.

02.02 To verify effective implementation of the quality assurance program, as described in the application for a combined license, as a means of assuring the quality of information submitted as part of the COL application.

02.03 To provide guidance for the early inspection and review of licensee design engineering that was not covered as part of the design certification process. Included in this is the assessment of First-of-a-Kind (FOAK) Engineering.

02.04 To verify that the applicant has implemented environmental programs commensurate with site preparation and construction work in progress, and is complying with the environmental requirements in any Early Site Permit, as discussed in the final NRC Environmental Impact Statement (EIS).

02.05 To ensure that members of the public are aware of the inspections that will be conducted to support the license review.

02.06 To provide guidance for the early review of operational programs described in the COL application.

2502-03 DEFINITIONS

Definitions of terms used in this inspection program are as follows:

03.01 Audit. An applicant/contractor activity to determine through review or observation the adequacy of, and adherence to, established procedures, instructions, specifications, codes, and applicable contractual and licensing requirements, and the effectiveness of implementation.

03.02 Combined License (COL). A combined construction permit and operating license with conditions for a nuclear power facility, issued pursuant to 10 CFR Part 52, subpart C.

03.03 Contractor. Any person or entity under contract to furnish items or services to a person or entity subject to the requirements of Appendix B of 10 CFR Part 50 or the commitments made in the application. The term “contractor” includes Consultants, Vendors, Suppliers, Fabricators, Constructors, Architect Engineers, and subtier levels of these, where appropriate.

03.04 Documentation. Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

03.05 Early Site Permit. A Commission approval, issued pursuant to subpart A of 10 CFR Part 52, for a site or sites for one or more nuclear power facilities. (such a permit addresses, at a minimum, site suitability issues, environmental issues, and physical characteristics unique to the site which could pose a significant impediment to the development of emergency plans.)

03.06 Inspection. 1) An NRC activity consisting of examination, observation or measurements to determine applicant/contractor conformance with requirements or standards. 2) Applicant/contractor quality control measures consisting of examination, observation or measurements to determine the conformance of materials, supplies, components, parts, appurtenances, systems, processes or structures to pre-determined quality standards.

03.07 ITAAC. Inspections, Tests, Analyses, and Acceptance Criteria which the licensee/applicant must perform and demonstrate conformance with prior to fuel load.

03.08 Limited Work Authorization(s). Two authorizations permitted under § 50.10(e) of the Code of Federal Regulations, and as allowed by § 52.25 and 52.91, are informally termed Limited Work Authorizations (LWA).

LWA-1. Under § 50.10(e)(1), the Director of Nuclear Reactor Regulation may authorize site preparation work, installation of temporary construction support facilities, excavation for nuclear and non-nuclear facilities, construction of service facilities and construction of structures, systems and components which do not prevent or mitigate the consequences of postulated accidents. The Director of NRR may not authorize such work unless the Atomic Safety and Licensing Board presiding over the proceeding on the application has made the findings specified in § 50.10(e)(2). Under § 52.25, a holder of an ESP that contains a site redress plan as described in § 52.17(c) may perform LWA-1 activities without further authorization. Similarly, under § 52.91, if the COL application references an ESP the authorization from the Director of NRR is not required.

LWA-2. Under 10 CFR 50.10(e)(3)(i), the Director of Nuclear Reactor Regulation may authorize the installation of structural foundations for structures, systems and components which prevent or mitigate the consequences of postulated accidents. A LWA-2 may be granted if, in addition to the findings described above for an LWA-1, the Licensing Board determines that there are no unresolved safety issues relating to the work to be authorized that would constitute good cause for withholding authorization.

03.09 Lead Region. The region designated with the authority to make a recommendation to the Director of Nuclear Reactor Regulation that an activity has been satisfactorily completed based on inspections associated with an early site permit or combined license application. The lead region is based on geography and is defined as that region which oversees the location specified in an early site permit or combined license.

03.10 NRC QA Guidance. The term NRC QA guidance refers to guidance endorsed by NRC through issuances of Regulatory Guides and which discusses acceptable methods of implementing portions of 10 CFR Part 50, Appendix B quality assurance program requirements.

03.11 Objective Evidence. Any documented statement of fact, information, or record, either quantitative or qualitative, pertaining to the quality of an item or service based on direct observations, measurements, or tests which can be verified.

03.12 Quality Assurance. Quality Assurance (QA) comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service. Quality Assurance includes quality control.

03.13 Quality Assurance Manual. Quality Assurance Manual (QA Manual) refers to the aggregate collection of internal policies, procedures, and instructions established by each organization delegated QA Program authority and whose objective is to assure acceptable implementation of the Quality Assurance Program.

03.14 Quality Control. Quality Control (QC) comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component or system to predetermined requirements.

03.15 Quality Assurance Program/QA Commitments. The terms Quality Assurance (QA) Program and QA commitments relate to the description of the quality assurance program, or any part thereof, as required by 10 CFR 50.34(a)(7) in each application for a construction permit or combined license for a nuclear power facility. The quality assurance program provides for a systematic management control system to assure the attainment of safety-related and risk significant quality objectives.

03.16 Safety Evaluation Report. The Safety Evaluation Report (SER) summarizes the results of the Commission's regulatory staff's technical evaluation of a docketed application for a combined license (COL), and delineates the scope and acceptability of technical matters considered in evaluating the safety aspects of the proposed facility.

03.17 Standard Design. A design which is sufficiently detailed and complete to support certification in accordance with subpart B of 10 CFR Part 52, and which is usable for a multiple number of units or at a multiple number of sites without reopening or repeating the design review.

03.18 Standard Design Certification, Design Certification, or Certification. A Commission approval, issued pursuant to subpart B of 10 CFR Part 52, of a standard design for a

nuclear power facility. A design so approved may be referred to as a “certified standard design.”

03.19 Surveillance. Surveillance refers to applicant and constructor activities such as reviews, observations, inspections, and audits to ascertain whether QA Program commitments are being correctly implemented, or to ascertain the state of applicant or contractor compliance with instructions and activities contained or described in the QA Manual.

03.20 The Tendered/Docketed Application. As used in this instruction, a tendered COL application includes the information responsive to 10 CFR 52.77, 52.78, and 52.79 and is submitted by the applicant to the Office of Nuclear Reactor Regulation to allow the staff to conduct acceptance reviews of the application before a docket number is assigned, and the responsible Regional Office to perform substantive inspection of applicant activities relating to the implementation of the QA program required to be in the application.

2502-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Office of Nuclear Reactor Regulation (NRR).

- a. Provides overall program direction for the construction inspection program.
- b. Develops and directs the implementation of policies, programs, and procedures for inspecting applicants, licensees, and other entities subject to NRC jurisdiction.
- c. Assesses the effectiveness, uniformity, and completeness of implementation of the construction inspection program.
- d. Ensures that the public is informed of the impacts of the construction inspection program on the review of an application and the decision on whether to issue a combined license.

04.02 Regional Administrator.

- a. Provides program direction for management and implementation of the inspection program elements performed by the regional office.
- b. Ensures that the regional office staff includes adequate numbers of inspectors in the various disciplines necessary to carry out the inspection program described in this chapter.
- c. Makes recommendations to the Director of Nuclear Reactor Regulation regarding acceptance or denial of COL applications. (See Appendix C of this IMC)
- d. Ensures that the public is informed of the results of the construction inspection program.

05.01 General. Figure 1, “COL Application and Review Timeline,” graphically depicts the licensing process for an application referencing an ESP and standard design. This chapter will initially be applied when an applicant announces the intent to apply for a COL, and will continue to be applied through the review process until the combined licensing decision is made. Initial inspection and assessment activities will support the NRC decision on whether to docket an application, while additional inspections and assessments will support the process for the consideration of the combined license.

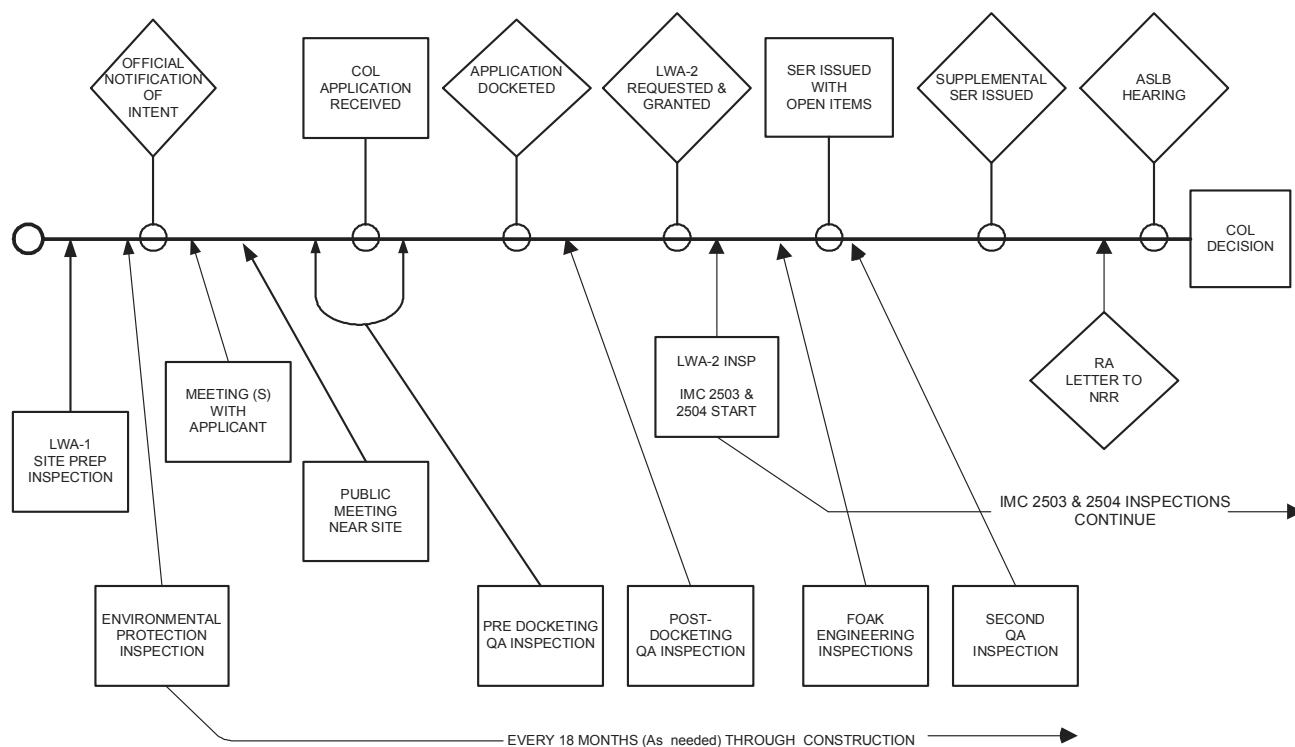


Figure 1. COL Application and Review Timeline

This Manual Chapter provides the NRC guidance for inspection and assessment of an applicant’s quality assurance and design engineering programs during design and procurement activities in the preparation of an application for a COL, and during engineering design activities in preparation for construction of a nuclear power facility. It also provides recommendations for the surveillance of an applicant’s stewardship of the environmental conditions of the reactor site referenced by the COL application. The inspection and review of offsite fabrication and related QA activities for long lead-time, ITAAC-related components, ordered prior to approval of the COL, will be through inspection procedures referenced by IMC 2503 and IMC 2504.

05.02 NRC Meetings with the Applicant. When the NRC receives official notice of an applicant’s intent to prepare or submit an application for a COL, NRR will schedule a public meeting, or series of public meetings, between NRC and the applicant. The meeting(s) will allow the applicant and the NRC to exchange pertinent information related to the project.

The information exchange should include the following:

- a. Primary contacts for each organization along with the responsibilities and objectives of both the applicant and NRC.
- b. Identification of lead region for NRC inspections.
- c. The location(s) where NRC can perform a review of the preparation of the application, as well as the applicant's engineering design activities, QA records, and procurement records.
- d. The applicant's schedule for completion of the application, the schedule for translation of design information into construction plans, drawings, and procedures, and the schedule for procurement of ITAAC-related long lead time structures, systems, and components (SSCs).
- e. NRC plans for a pre-docketing review of the implementation of QA requirements during application preparation and the inspection procedure(s) to be used in the review.
- f. NRC planned post-docketing inspections of QA, design engineering, and procurement activities in support of the review of the application, and the inspection procedures to be used.
- g. The applicant's plans and schedule for site preparation activities and the NRC plans for inspections to assure the acceptable implementation of the QA program and activities to ensure the protection of the environment.

05.03 Public Meeting Near Proposed Site. In addition to the meeting(s) discussed in 05.02 above, the NRC staff intends to hold a public meeting at a location near the proposed project site in order to inform the local population about the project and their opportunities to participate in the decision(s) of the NRC. The NRC staff intends to hold this public meeting prior to the docketing of the application.

05.04 Pre-COL Inspection Activities. An application for a COL may, but need not, reference a standard design certification issued under subpart B of 10 CFR Part 52, or an early site permit issued under subpart A of 10 CFR Part 52, or both.

For an application not referencing an ESP, licensee site activities would be limited to the site exploration activities necessary to obtain the data necessary to satisfy 10 CFR Part 100, 10 CFR 50.30(f), 10 CFR 50.34, including 10 CFR Part 50, Appendix S, 10 CFR 52.47(a)(1) and (2) and, if the design is modular 10 CFR 52.47(b)(3), unless the applicant requests and is granted authorization to conduct LWA activities upon the completion of the environmental reviews. The inspection activities during site exploration will include those listed in IMC 2501.

For an application not referencing a standard design certification, a limited work authorization (LWA-2) involving safety-related site activities would not be allowed until after the resolution of certain safety issues related to those activities, as specified in 10 CFR

50.10(e)(3)(ii). The inspection activities for an application not referencing a standard design certification would include additional inspections in the area of engineering and design control.

Appendix A of this manual chapter lists the inspection activities applicable to any COL application. The basic inspection program would apply to an application which references a standard design certification and an early site permit. Appendix A also lists additional inspections which would be required for those applications which do not reference an ESP and/or standard design certification.

05.05 Inspection of the Quality Assurance (QA) Program. The quality assurance program (QA Program) should be consistent with NRC requirements. The QA Program should have translated the FSAR commitments for quality assurance into procedures and instructions for each organization performing and/or verifying the quality objectives established for the design, procurement and construction of safety-related structures, systems and components (SSCs.)

The NRC policy for the review of the QA manual and the inspection of the QA Program implementation and documentation of findings is as follows:

- a. The review of the QA Manual shall be performed by the Division of Inspection and Program Management (DIPM) NRR, in accordance with the Standard Review Plan.
- b. The QA Program implementation inspection at the applicant/contractor offices or site shall be performed by a team led by the lead region for the proposed site in accordance with the inspection procedures listed in Appendix A of this manual chapter.
- c. Significant inspection findings relating to QA implementation should be resolved with the support of DIPM/NRR before the last supplemental SER is issued.

Pre-Docketing Review.

Until the DIPM review of the COL application is complete, when conducting inspection activities before the COL application is docketed, any evaluation of the applicant's quality assurance measures for on-going design and procurement activities shall be against NRC endorsed QA guidance based on 10 CFR Part 50, Appendix B, requirements related to those activities. The applicant may describe an alternative to NRC QA guidance, as long as it meets the requirements of 10 CFR Part 50, Appendix B.

QA commitments in the application may not be used by an inspector as the primary basis for assessing the implemented QA Program. However, an inspector must still review the QA Program to determine if it is being implemented in accordance with the description in the COL application. Inspections, evaluations, and resolution of identified problems prior to docketing shall be in accordance with these and other referenced instructions of MC-2502.

Post Docketing Review.

Until the COL application is finalized, the inspector should continue to rely on appropriate NRC QA guidance to assist in the initial evaluations of the acceptability of QA Program

implementation. An inspector's final determinations regarding acceptance of QA Program implementation shall be based on compliance with FSAR commitments as discussed below. However, the inspector must remain aware of the NRR review process and related correspondence with the applicant since responses to NRR questions may result in amendments to QA commitments.

After the Region has received NRR's assessment of the applicant's QA Program, the inspector shall use FSAR QA commitments, amendments, and applicant responses identified by NRR as acceptable, as the basis for inspection. Inspectors should discuss with NRR any identified deficiencies related to QA Program elements prior to documenting them in an inspection report.

05.06 Enforcement Actions. Enforcement actions associated with the application are not anticipated, but are not precluded, during the COL review. However, the information submitted with the application will be subject to NRC regulations.

An early site permit referenced by the application for a COL is a license. Therefore violations of conditions of an ESP discovered during inspection or review of engineering design or site preparation activities will be subject to enforcement, including notices of violation, civil penalties and orders.

05.07 Applications Referencing Approved QA Topical Reports. For those applications referencing approved QA topical reports relating to either the applicant, and/or subcontractor organizations, the inspection program will be performed as described below.

Inspections conducted after the issuance of the SER shall be based on acceptable FSAR commitments and amendments identified by the SER. Where inspection findings relate to SER-discussed unresolved elements of the FSAR, problem areas should be discussed with NRR prior to documenting a deviation from the FSAR commitments and/or regulatory requirements, as appropriate.

05.08 FOAK Engineering Inspections. The objective of the FOAK Engineering Inspections (see Appendix B for applicability, policy and guidance) is to ensure that the design process for the lead plant of each certified design is effectively implemented in accordance with NRC regulations and the design commitments made in the FSAR and in the Design Control Document (DCD) applicable to its related certified design. The focus of these inspections is on work not covered previously by the design certification process. These inspections will review the translation of high-level certified design information into lower-tier construction/design documents. Such inspections will include a review of the programmatic controls of the design process and a check of a sample of the design verification activities. The inspections of the design control program will assure that the correct design details will be used in the actual construction/fabrication processes. Engineering inspections may also be used to review the bases for any design acceptance criteria (DAC) or ITAAC submitted by the licensee in the application as complete.

FOAK Engineering Inspections will be conducted as early as possible to support the final supplemental SER. However, the inspections should be conducted only when sufficient procurement, construction and installation specifications have been completed and are available for auditing. The planned schedule for implementation of the FOAK engineering

inspections allows the inspection results to be available as input to the NRC staff recommendations for the issuance of the COL. Therefore, from a programmatic standpoint, the provisions of this manual chapter, including all FOAK engineering inspection activities, are intended to have been completed and end with the issuance of the COL. However, other engineering inspections (e.g., for matters subject to Design Acceptance Criteria [DAC]) will continue in accordance with other manual chapter provisions after the COL has been issued.

The engineering inspections described in Appendix B of this manual chapter will be accomplished for the following:

- a. The first plant referencing each of the certified designs.
- b. Any application which does not reference a certified design. In the case of an application which does not reference a certified design, multiple engineering inspections may be necessary to support the licensing review.
- c. Subsequent applications referencing each of the certified designs where siting considerations are different from those of the first plant. Limited scope FOAK engineering inspections will be conducted during the COL review phase and shall be focused on the site-specific portions of the design, such as the service water intake structure and the ultimate heat sink.

In addition to the FOAK engineering inspections, it is expected that design/engineering inspections will be conducted after the COL is issued. For example, engineering inspections will also be conducted in accordance with IMC-2503, "Construction Inspection Program - Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)," for verification of design details used to procure, construct, and install SSCs for which DAC have been or will be established within the ITAAC. Additionally, the inspection of design control measures associated with field changes, will be conducted as a part of the IMC-2504, "Construction Inspection Program - Non-ITAAC Inspections".

05.09 Inspection and Review of Operational Programs. This manual chapter may involve the early inspection and review of operational programs submitted with the COL application. If warranted, program direction and procedures for the inspection of operational programs will be provided in Appendix D of this manual chapter.

2502-06 INSPECTION POLICIES AND GUIDANCE

06.01 Inspection Activities. The Construction Inspection Program - Pre-COL Phase shall normally be completed for each announced, tendered, and docketed application. This program generally consists of meeting with applicant management, inspecting QA Manuals, inspecting design engineering activities, and inspecting QA program implementation.

The inspection of an applicant's activities will be coordinated by the lead region for the announced site. Inspection activities, including those related to subcontractor

implementation of detailed QA/QC program provisions at the site or at engineering and design offices will be led by the lead region in cooperation with the headquarters staff.

The scope of this Pre-COL inspection program, including early management and QA meetings, may be reduced for applications submitted by an applicant who has recently (within the past 36 months) been inspected in accordance with these instructions for a prior application. The reductions in pre-COL inspection scope will be determined on a case by case basis by agreement between NRR and the lead region. The public meeting near the project site prior to the receipt of the application shall not be a part of the reduction in scope.

The inspection procedures used to implement this manual chapter include routine follow-up of inspection results. If inspection results require more comprehensive follow-up to reach resolution, the inspection resources expended may be more than what is identified in the inspection procedure.

06.02 Inspector Qualification. NRC inspectors will be assigned responsibility for those inspection requirements consistent with their qualifications.

06.03 Policy for Requiring Changes to the QA Program. The inspection objective is to assure that a responsive and effective, not excessive, QA program is established. Therefore, an applicant will not be required to develop QA program provisions that are not required by the NRC's regulations.

When an inspector believes that additional development of the implemented QA Program is necessary because both the FSAR's description of a specific activity and the specific activity, as implemented, are deficient, then the findings and supporting information, together with the Regional Office's recommendations, should be discussed with NRR before final resolution.

END

Appendix A, Inspection Procedures to Support COL Issuance
Appendix B, First-of-a-Kind Engineering Inspections
Appendix C, Sample Regional Administrator Letter
Appendix D, Review of Operational Programs

APPENDIX A

Inspection Procedures to Support COL Issuance

A.1 Basic Inspection Program for Review of Applications Referencing a Certified Design and an ESP

A.1 INSPECTION PROCEDURES (IPs)	
NUMBER	TITLE and INSPECTION REQUIREMENT
35005	<i>Pre-Docketing Combined License (COL) Quality Assurance (QA) Inspection</i> - One team inspection to review applicant's design, procurement, and application preparation activities. - Additional inspection(s) may be required to review activities of primary subcontractors at other locations.
35029	<i>Pre-Combined License (COL) Quality Assurance (QA) Inspection of Site Limited Work Authorization (LWA)-1 & 2 Activities</i> - Initial inspection, of LWA-1 activities, timing dependent on applicant's schedule and level of site preparation activities. - Initial and follow-up inspections of LWA-2 activities, as required, depending on timing and content of LWA-2 authorization
35017	<i>Post-Docketing Development of the QA Program for Design and Procurement Activities</i> - One team inspection shortly after the docketing of the application. - One team inspection shortly after the issue of the Draft SER - Additional inspection(s) may be required to review activities of primary contractors at other locations.
35021	<i>Post-Docketing Implementation of COL Quality Assurance (QA) Activities Related to Design, Procurement and Construction</i> - Performed in conjunction with IP 35017
35100	<i>Implementation of Quality Assurance (QA) Program Described in Final Safety Analysis report (FSAR)</i>
35020	<i>Inspection of Applicant's Surveillance of Contractor Quality Assurance (QA) Activities</i> - As needed, to observe applicant oversight of contractors
37802	<i>First-of-a-Kind Engineering Inspections</i> - Team inspection activities of First-of-a-kind (FOAK) engineering [reference - Appendix B of this manual chapter] when sufficient procurement, construction and installation specifications have been completed and are available for audit.
80210	<i>Environmental Protection - Initial and Periodic Inspections</i> - Initial inspection no later than 3 months after notification that site preparation will begin or, just before or just after receipt of application to review site depending on level of site preparation activities - periodic inspections every 18 months until construction complete.

A.2 Additional Inspections for Review of Applications Not Referencing an ESP

These inspection activities would be conducted in addition to the basic inspection program listed in A.1 above for an application submitted without an ESP.

A.2 INSPECTION PROCEDURES (IPs)	
NUMBER	TITLE and INSPECTION REQUIREMENT
35004	<i>Pre-Docketing Early Site Permit Quality Assurance Controls Inspection</i> - Inspect in conjunction with IP 35005
35006	<i>Post-Docketing Early Site Permit Quality Assurance Controls Inspection</i> - Inspect in conjunction with IP 35017 - May be done separately if different sub-contractors are involved with site qualification.
35012	<i>Early Site Permit Quality Assurance Controls Assessment and Conclusion</i> - Completed in time to support licensing decision
45051	<i>Geo-Technical/Foundation Activities Procedure Review</i> - Inspect during licensee site exploration activities.

A.3 Additional Inspections for Review of Applications Not Referencing a Certified Design

This inspection activity would be conducted in addition to the basic inspection program listed in A.1 above for an application submitted without a certified design.

A.3 INSPECTION PROCEDURE	
NUMBER	TITLE and INSPECTION REQUIREMENTS
(IP to be developed)	<i>Inspection to Support Design Reviews for 10 CFR Part 52 Licensing</i> - Team inspection activities to support NRR review of the design.

A.4 Pre-COL Phase - 10 CFR Part 21 Inspection Procedures for all COL Applications

A.4 INSPECTION PROCEDURE	
NUMBER	TITLE and INSPECTION REQUIREMENTS
36100	<i>Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance</i> - Applicant & as required, any consultant or vendor tied to 10 CFR 21 thru the Applicant to be inspected - Once, concurrent with 35017. [Note: While not required - If a consultant/vendor organization is inspected as follow-up to IP 35017, the provisions of IP 36100 will be conducted concurrent with the special follow-up inspection.]

APPENDIX B

FIRST-OF-A-KIND ENGINEERING INSPECTIONS

1. APPLICABILITY

This Appendix describes a methodology for performing multi-discipline inspections of first-of-a-kind (FOAK) engineering activities for the lead plant of a certified design. If a COL application does not reference a certified design, the guidance in this Appendix can be used to review design information at a level of detail corresponding to that contained in the “certified” design information identified in this appendix. The applicable provisions of the FOAK Inspections could also be invoked at the discretion of NRC management to provide guidance for the conduct of pre-COL design/engineering inspections of follow-on plants (i.e., all facilities after the lead plant) for each of the certified designs.

NOTE:

Engineering and Design Verification inspections will continue after issuance of the COL and during the construction of the facility. Such inspections are expected to examine and evaluate the Design Acceptance Criteria (DAC), the design change implementation process, and samples of both field changes and the as-built construction details for comparison with the original design and FOAK engineering inspection results. Such post-COL engineering inspection activities are neither addressed by this manual chapter, nor by the inspection procedure, IP 37802, governing FOAK engineering inspections.

2. OBJECTIVES

The FOAK Engineering Inspections are used to ensure that the design process for the lead plant of each certified design is effectively implemented in accordance with NRC regulations and the design information in the Final Safety Analysis Report (FSAR) and in the Design Control Document (DCD) applicable to its related design certification rule. The inspections sample the total design and architectural criteria through to the development of the particular design details for those aspects of the design not covered in the certification of the design. The inspections are used to:

- b. Verify that the design bases and/or high-level certified design information, as specified in the design certification and as supplemented by the relevant COL application commitments, are effectively translated into detailed construction specifications, drawings, calculations, and procedures.
- c. Verify that regulatory requirements are correctly implemented in the design control processes, including change processes, related to a specific design certification rule and to the methods intended for use by a COL applicant in the design, construction, and testing of a licensed facility.

- d. Verify that the correct design input information has been provided to the responsible design organizations.
- e. Verify that design engineers have sufficient technical guidance and experience to perform assigned engineering functions.
- f. Perform all of the above verification processes, on a limited-scope basis, for those follow-on plants of any certified design that possess design features deemed appropriate for a FOAK engineering inspection.

The inspections will include a review of the programmatic controls of the design process which are maintained by the applicant and certified design vendor, as well as a sampling check of design verification activities at design offices, on-site, or at contract locations, as appropriate.

3. BACKGROUND

In the past, the NRC conducted design verification inspections late in the construction process. During the 10 CFR Part 52 licensing process, the NRC intends to conduct design inspections during the pre-COL licensing review for “lead” plants and “follow-on” plants, as appropriate. These design and engineering inspections are conducted under the provisions of Inspection Manual Chapter IMC-2502 and are similar to past engineering design verifications which were performed in accordance with IMC-2530, “Integrated Design Inspection Program.”

SECY-94-294, “Construction Inspection and ITAAC Verification,” contained the following statements in reference to engineering design verifications:

The staff stated that design descriptions and functional system drawings available for review during the design certification and COL application stages are adequate for licensing reviews and final safety determinations, but not for actual construction or construction inspection activities.

The NRC will inspect and review the adequacy of licensee design engineering early in a construction project, possibly beginning soon after receipt of a licensing application; first-of-a-kind engineering for the lead plant of each certified design will be assessed during these inspections.

NRC will also assess the effectiveness of the licensee’s design change process in maintaining the fidelity of high-level certified design information that is translated into construction drawings.

In NUREG-1789, “10 CFR Part 52 Construction Inspection Program Framework Document,” the general organization of the inspection program for 10 CFR Part 52 licenses was discussed. The origin of the FOAK Engineering inspections, as discussed above, and the need for related design/engineering inspection activities, were assessed. This evaluation determined that most FOAK inspections would support a decision on whether to issue a COL and therefore would best be conducted in accordance with the provisions

of IMC-2502. However, the anticipated pace of the licensing review may result in some design engineering inspections being completed after the license is issued.

4. GUIDANCE

General Guidance. A FOAK engineering inspection for the lead plant of a certified design is a comprehensive examination of the development and implementation of the detailed design for a selected system or systems of the facility being inspected. Similar design/engineering inspections, but with a scope limited to new or unique design features, may be conducted for the follow-on plants of each certified design using the same vertical-slice examination process. Conclusions about the overall design process may then be drawn based on the results for the selected sample. The inspection is a multi-discipline review including, as a minimum, areas such as mechanical systems and components, electric power, civil and structural design, and instrumentation and control. Other disciplines, including materials and component engineering, should be considered for addition to the inspection scope, based upon their significance in relation to the selected system sample.

The primary focus of these inspections is on the translation of high-level certified design information into lower-tier construction/design documents. The inspection is an assessment of the design control processes being implemented by the applicant, designer organization(s), and applicable subcontractor(s). The design control program is evaluated by examining the design details that would be used in the actual construction/fabrication processes. If an error is found in the design details, the design process is evaluated to see if the error resulted from an isolated mistake or if it reflects a more fundamental weakness in the design control program. Also, the pervasiveness of a design error or weakness will be evaluated, including an assessment of the extent to which the identified condition applies to other areas of the plant design. Such evaluations, intended to identify any generic weaknesses in the design control program, are to be implemented with an inspection procedure (IP 37802) that is tailored to the objectives of the FOAK engineering inspection process.

Any NRC finding based on a FOAK engineering inspection that there is evidence that the verification objectives of the inspection are not being met, or that there is a significant concern to be input into the NRC determination process regarding issuance of a COL, is denoted as a “FOAK Engineering/Design Deficiency”. The identification of a *FOAK Engineering/Design Deficiencies* may or may not entail enforcement actions, depending upon the relationship established between the specific finding and the relevant NRC requirement (e.g., the change process controls promulgated in 10 CFR Part 52 or the requirements of 10 CFR Part 50, Appendix B, Criterion III, “Design Control”). Nevertheless, all such deficiencies will be addressed by the applicant. To the extent possible, the corrective actions or resolution should be defined or in place prior to the issuance of the COL.

a. Implementation. The Office of Nuclear Reactor Regulation (NRR) is assigned both the responsibility and authority for implementing the FOAK Engineering Inspections. The Regional Administrator (RA) has responsibility and authority for the administration and

implementation of the inspection program for power reactors within the region. RAs will assist the Office of Nuclear Reactor Regulation, as needed, with inspection resources from their regional staffs to implement the FOAK Engineering Inspection. The RA with responsibility for the plant subject to a FOAK engineering inspection may be assigned to lead and manage the inspection activities associated with the design/engineering inspection at the certified design lead plant or any follow-on plants. If the management lead for such inspections is retained by NRR, the regional staff will, as necessary, assist in the coordination of design/engineering inspection activities, monitor inspections and findings, and support the management of NRC follow-up actions, including the inspection and resolution of open items and disposition of any enforcement actions.

A FOAK engineering inspection is normally implemented using a programmatic approach. The scope and depth of the inspection for a particular facility is determined using the guidelines provided in (1) through (5) below, as appropriate. The scope of the inspection is defined during the planning and preparation phase and appropriate revisions are made as the inspection progresses.

The planning process includes development of a logic or flow network of the design process. Each fundamental entity within the design organization will be identified. For each of these entities, internal and external design information will be determined. From this network, critical design areas will be identified. Based on the results of the above evaluation, a specific sample set, such as the identified criteria for selected systems will be inspected.

(1) A comprehensive inspection is performed for specific sample system(s) that typically possess a large part or all of the following characteristics:

- essential to plant safety
- a clearly defined design basis, as described in the certified design, with the potential for site-specific impact upon the constructed facility,
- generally representative of safety-related features in other systems,
- design involving internal interfaces between the various functional areas and external interfaces with the certified design vendor, component vendors, and engineering service organizations,
- construction involving the integration of multiple subsystems and/or components, some of which may have already been fabricated by the vendors.

(2) Some inspection will be conducted beyond the sample system(s), as needed, to test specific areas or functions.

(3) Risk information should be considered when selecting the sample system(s) to be inspected.

(4) An evaluation should be performed for any programmatic questions or significant Tier 1 - Tier 2 interrelationships that are documented in the referenced Design Control Document, which could affect design information flow or have an impact on the translation of the design bases into construction details.

(5) The inspection covers the design engineering program and any processes for translating certified design information into construction documents for the verification of areas such as:

- validity of design inputs and assumptions,
- validity of and conformance to design specifications,
- validity of analyses,
- system interface requirements,
- inadvertent effects of changes,
- proper component classification,
- revision control,
- documentation control,
- verification of the design.

b. Level of Effort. A FOAK engineering inspection may be conducted in two phases. Phase 1 is initiated approximately one year before a COL might be issued and is intended to assess the ongoing process for translating the certified design information into detailed construction specifications, drawings, calculations, and procedures. The system(s) selected for sampling and the NRC inspection team composition will influence the level of effort in completing the Phase 1 inspections. The typical Phase 1 FOAK engineering inspection is expected to involve 3 or 4 weeks of on-site inspection effort by 8-10 inspectors. FOAK engineering inspection activities to support an application not citing a certified design will involve additional effort. This includes planning and preparation, conducting inspection activities at multiple locations, meetings, report documentation, and following-up on the licensee's response to the inspection report and findings.

The Phase 2 inspection is implemented enough in time to allow the NRC to consider the inspection results in the determination of whether a COL should be issued. Phase 2 is a less resource-intensive follow-up inspection that focuses on three areas: (1) problems identified during Phase 1, (2) the applicant's corrective actions, and (3) design areas that were not ready for inspection during Phase 1, but which were deemed significant enough to warrant some level of review and verification. Phase 2 of the inspection should involve 12 -16 inspector-weeks of follow-up preparation, inspection, and documentation effort.

Flexibility must be exercised in the completion of the Phase 1 and Phase 2 inspections for any individual plant with its specific FOAK design. For example, for the first plant, if design details (e.g., specifications, drawings, calculations) are available in a sufficient quantity for review at the time that the Phase 1 inspection is conducted and the inspection results are generally favorable, the Phase 2 inspection process may be scaled back at the discretion of NRC management. Similarly, the Phase 1 and 2 inspections of any follow-on plant, which would normally entail a review of the unique design features for a subsequent plant using a certified design, could be combined with other inspections, reduced to a limited design verification effort, or eliminated completely at the discretion of NRC management. Additionally, the need for flexibility in the implementation of Phase 1 and Phase 2 inspections for any plant design will be reflected in the consideration of the unique plant, sample systems, and specific design variables selected for inspection.

5. INSPECTION POLICY

a. Inspection Scope. The inspection will evaluate the all aspects of the process used for translating the high-level certified design information into the detailed design documents for use in construction of the facility.

b. Inspection Timeline. The timing of specific Phase 1 and 2 FOAK engineering inspection activities depends upon the plant design and the facility schedules. Any schedule should meet the inspection objectives and should allow inspection results to be available as an input to the NRC staff recommendations on whether a COL should be issued.

A typical one-year schedule to complete both Phase 1 and Phase 2 activities is outlined below:

FOAK Engineering Inspection Activity	Time Allocation (Weeks)
Team Leader Planning - Applicant Notification - Schedule Preparation - Inspection Team Selection - Information Acquisition - Meetings with Regional Office, Applicant, Certified Design and AE Organizations, as applicable	4
Team Preparation - Team Indoctrination Meeting - Review of Background Material - Preparation of Draft Inspection Plans	1-2
Commencement of Phase 1 Inspection Activities - Site Visit and Certified Design Plant Familiarization - Inspection of Applicant Engineering Organization - Initiation of Inspection of Applicant contract design organizations	2
Inspection Plan Refinements and Additional Review of Background Material	1
Continued inspection of licensee engineering, contract design firms, and other needed inspections (e.g., onsite, design offices, vendors, subcontractors, etc.)	1-2
Documentation of Inspection Results and Completion of the FOAK Engineering Inspection Report	4-6
Licensee Review and Response to the FOAK Engineering Inspection Report	8
Review of Licensee Response and Initial Preparation for Phase 2 Inspection Activities	2
Identification of all FOAK Engineering/Design Deficiencies and Potential Enforcement Findings for transmittal to the responsible Region for followup	2
Total time to complete Phase 1	25-29

FOAK Engineering Inspection Activity	Time Allocation (Weeks)
Conduct of Phase 2 Inspection Activities (See Note) (preparation, inspection, documentation, followup, enforcement, etc.)	12-16
Total time to complete Phase 1 and Phase 2	37-45

NOTE: Phase 2 should focus on design activities identified by the Phase 1 inspection as either problematic, therefore warranting implementation of corrective measures to be implemented, or indeterminate, warranting further inspection. Phase 2 inspection plans and their implementation should be specifically tailored to areas of concern that are associated with the Phase 1 inspection results. As a general guideline, the overall Phase 2 inspection effort should involve approximately half the number of inspectors as the Phase 1 effort, and less than half the time that was needed to complete Phase 1.

c. Inspection Team Composition. Inspector assignments to the FOAK engineering Inspection shall be based on the expertise needed to implement the scope of the inspection planned for a particular facility. Assigned team members should remain with the team for the duration of each phase of the inspection process with no other duties. While not mandatory, inspector continuity should be maintained between Phase 1 and Phase 2 inspections whenever possible. Since a FOAK engineering inspection is performed at the lead plant of each certified design, consideration should also be given to Regional participation in these team inspections, particularly for a Region where a follow-on plant of the lead certified design is expected to be constructed. If a FOAK engineering inspection will be conducted on a limited scope at follow-on plants, NRC management may delegate such inspections to be performed and controlled as a Regional inspection activity.

Specific inspection and experience needs for a particular team will depend upon the certified design, the system or systems selected in the sample, and the safety and risk significance of specific disciplines [e.g., digital instrumentation and controls (I&C)]. The importance of such factors, along with the availability of NRC inspection resources and the benefits of the participation of a variety of NRC headquarters and regional personnel, will dictate the need for specific contractors on the inspection team.

The participation of an inspector with quality assurance expertise (e.g., from the NRR Plant Support Branch) would be valuable on a FOAK engineering inspection team, particularly for Phase 1 inspections in which any applicant is involved with its first facility construction in accordance with 10 CFR Part 52.

The inspectors assigned Phase 2 inspection responsibilities will be evaluating design areas that may not have received a complete review during Phase 1 as well as checking the adequacy of applicant corrective actions from Phase 1 of the inspection. With the greater emphasis upon corrective actions and limited engineering topics, Phase 2 of the FOAK engineering inspection process could be performed with NRC inspection resources from the Region in which the facility is located, and with less reliance on contractor expertise.

The following team composition is suggested as guidance:

Personnel	Phase 1	Phase2
Team Leader	1	1
Civil /Structural Inspector(s)	1-2	1 w/ materials expertise
Mechanical/ Systems Inspector(s)	1-2	1 w/ component knowledge
Electrical Inspector	1	1 w/ pertinent I&C expertise
I&C Inspector	1	
Materials Inspector	1	
Component Engineering Inspector	1	
Quality Assurance Inspector	1	

d. Inspection Planning and Preparation. The planning and preparation activities for a FOAK engineering inspection apply to both Phase 1 and 2 inspections and involve the Team Leader, as well as all team members. The following points, guidance, and references are general in nature, while the specific details of inspection planning should relate in a meaningful way to the specific facility design that is the subject of the inspection process. Inspection activities to verify that the design bases and high-level certified design information are correctly translated into detailed construction specifications, drawings, calculations, and procedures are dependent upon the state and completeness of such design “daughter” products at the time of the inspection. Therefore, the “completeness” of the design affects not only the sample system(s) selection process, but also other inspection planning activities relating to both Phase 1 and Phase 2 inspection details.

The planning and preparation stage should result in initial inspection plans that detail how the FOAK engineering inspection objectives will be met. It is the responsibility of the Team Leader to integrate the proposed plan/schedule/activities for the various functional areas into an overall team plan and to coordinate the subsequent conduct of team inspection activities. Based upon the in-progress inspection and results, the initial inspection plans may be revised as needed.

Inspection plans should be formulated to address the following functional areas, as a minimum:

- civil and structural,
- mechanical systems,
- electric power,
- instrumentation and control,
- materials, welding, and nondestructive examination
- component design,
- quality assurance (if a QA specialist is designated for team participation)

Before the start of the inspection, the Team Leader should familiarize the team members with the principles of 10 CFR Part 52 design/engineering inspections. The familiarization

should address the background and guidance material, significant items pertinent to Part 52 licensing, and design-related items identified by the regional offices and the Office of Nuclear Reactor Regulation (NRR). The Team Leader will select the sample systems, consistent with the inspection objectives, with input from cognizant NRC staff and with the concurrence of NRC management. However, the entire FOAK engineering inspection team should reach consensus that the selected system(s) will allow for the inspection objectives to be met or provide alternative approaches for meeting those objectives.

Announcement of the sample system(s) to be inspected should not be made until just before the initiation of the inspection to preclude inappropriate biasing of the activities to be inspected. A design work inspection cutoff date should be established for Phase 1 of the inspection. The cutoff date should be the same date as the announcement of the sample system(s) to be inspected. Phase 2 of the inspection can sample continued design work after the selected cutoff date.

The team members should also be briefed on the inspection work products. The briefing should include a discussion of the individual inspector's inspection plans, progress reports, and report outlines; development of findings, particularly FOAK engineering/design deficiencies; and other inspection report inputs. The Team Leader will conduct coordination meetings of all team members, as needed, to discuss the status of inspection activities.

e. Conducting the Inspections. FOAK engineering inspections will be conducted in accordance with the provisions of IP 37802, "First of a Kind (FOAK) Engineering Inspections." This inspection procedure provides the details and instructions for the implementation of all FOAK engineering inspections. Nevertheless, the QA Inspection Procedures identified in Appendix A of this manual chapter, as well as other engineering inspection procedures listed in IMC 2515 (e.g., IP 71111.21, "Safety System Design and Performance Capability") may also provide useful guidance, insights, and references for the successful preparation and conduct of design/engineering inspection activities that are relevant to the inspection process.

f. Management Entrance and Exit Meetings. An entrance interview between the applicant management and all FOAK engineering inspection team members shall be held before starting both the Phase 1 and Phase 2 inspection activities. The senior applicant representatives with responsibility for the inspection areas should be asked to attend this meeting. Regional management with inspection responsibility for the facility should also be represented.

At the conclusion of each phase of the inspection, the FOAK Engineering Inspection Team Leader and NRC management should discuss their preliminary findings with applicant management at a scheduled exit meeting. For both Phase 1 and Phase 2, 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. Particularly in the latter case, efforts should be made to ensure that the applicant is aware of ongoing inspection results periodically over the course of the inspection.

Communicating inspection observations is also an integral and important part of every inspection, whether done periodically with status meetings or highlighted at the management exit meeting at the conclusion of the inspection. The General Inspection Policies of IMC-2515 provide guidance on which observations and insights to pass on to the applicant during the course of NRC inspections.

g. Inspection Documentation. The team will prepare a Phase 1 inspection report that documents the results of the inspection. The inspection report will conform to the requirements of Inspection Manual Chapter 0613. No disclosure of inspection notes (preliminary or draft inspection report materials developed by design/engineering inspection team members) will be made, except to appropriate NRC staff.

h. Followup and Enforcement. Section 05.06 of IMC-2502 discusses enforcement actions associated with the Pre-COL inspection process. For any *FOAK Engineering/Design Deficiencies* that are identified, the NRC Enforcement Policy may govern the documentation and issuance of the specific findings.

(1) Review of Applicant Response The applicant will be asked to specify what resolution or corrective actions it has taken or plans to take with respect to the deficiencies and unresolved items (if any) in the Phase 1 inspection report.

After the applicant's response is received, team members, or other cognizant personnel, should conduct reviews of the issues and the associated responses. For each inspection item that calls for a response, the evaluation should determine:

- Whether or not the response describes an adequate resolution or if the applicant or NRC needs to do something further to achieve resolution. If additional information or applicant action is deemed necessary, the cognizant team member should coordinate with the Team Leader in providing background information and drafting the request for such additional information or action to the applicant.
- Whether a follow-up inspection is needed. In general, follow-up inspection activities can be performed during the Phase 2 inspection, which should strive for adequate resolution of all Phase 1 inspection open items before the COL is issued. Routine inspection activity (including monitoring the status of open items) is the responsibility of the appropriate regional office.
- Any general comments regarding the response.

Team members should provide a brief summary of their evaluations for those items not needing additional information or reinspection.

The Team Leader will evaluate responses by team members and prepare a letter to the applicant. This letter should request the additional information needed to resolve findings and discuss plans for a reinspection during the Phase 2 inspection.

(2) Reinspection Procedure The applicant will be given written notice stating the specific items to be reinspected during the Phase 2 inspection. The significant areas

of design that were not ready for inspection at the time of the Phase 1 inspection should be included in Phase 2. Issues arising from the Phase 1 inspections should be resolved during the Phase 2 inspection. Generally, the Phase 2 inspection team should have personnel with sufficient expertise to resolve any issues. The Team Leader should coordinate with the applicable regional management before the conduct of any reinspection activities (particularly if the Phase 2 inspection is not controlled and conducted by the cognizant Region) and provide an opportunity for regional participation. This may be particularly helpful for identification of any enforcement issues. A Phase 2 inspection or any reinspection should be documented in accordance with IMC 0613.

(3) Enforcement The focus of engineering inspections performed in accordance with the provisions of this manual chapter is not enforcement, but rather the evaluation of the design processes for FOAK engineering activities and the verification of certified design information at the construction document level. However, after the engineering team evaluation of the applicant's response to the Phase 1 inspection report and before the conduct of Phase 2 inspection activities, the region will be notified of any potential enforcement issues identified, whether developed from *FOAK Engineering/Design Deficiencies* or other regulatory issues. The notification to the region should include a preliminary determination of an appropriate enforcement classification for each issue. The same process should be followed for Phase 2 inspections. The Team Leader is responsible for coordinating with regional management for the follow-up of any enforcement issues and ensuring that appropriate regional tracking numbers are assigned, as required. The Director, Office of Enforcement, will concur with the preliminary enforcement determinations.

During an inspection, situations may be identified where the significance of the matter warrants consideration of prompt action (e.g., NRC order, investigation of wrongdoing, or stop-work consideration). If significant issues arise, the team will inform NRR management and the appropriate regional office promptly. The team's priority will then become the continued assessment of the situation until the matter has been resolved.

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Appendix C

Sample Regional Administrator Letter

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION X,
Address

MEMORANDUM TO: _____, Director
Office of Nuclear Reactor Regulation

FROM: _____,
Regional Administrator

SUBJECT: (SITE NAME) COMBINED LICENSE APPLICATION

(XXX) Corporation, by letter dated (XXXXX), requested a Combined License (COL) for the construction and operation of (XXXX) Nuclear Station, Unit(s) (X), at the (XXX) site, in accordance with Part 52 of Title 10 of the Code of Federal Regulations. We have completed our inspections in accordance with the guidance contained in Inspection Manual Chapter (IMC) 2502 and in close coordination with the staff of the Office of Nuclear Reactor Regulation (NRR). The inspections verified that (XXXX) has implemented programs in conformance with the descriptions contained in the application.

Additionally, the inspections compared statements in the safety evaluation report with (XXXX's) implementation of quality programs in the field preparation for construction and operation, as well as the areas of design engineering, to confirm the accuracy of assumptions used by NRR to form technical positions. Details of the scope and results of our inspections are contained in reports listed in the attachment to this memorandum.

Based on the results of our inspection efforts, we have determined that (XXXX's) programs and activities related to the COL have been completed in conformance with docketed commitments and regulatory requirements [except (list areas of nonconformance).] Within the above inspection scope, we have determined that (XXXX) has/has not met the applicable criteria for design interface and procurement controls for design and construction. We therefore do/do not recommend that (XXXX) be granted a combined license.

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Appendix D

Inspection Procedures for the Review of Operational Programs

TO BE DETERMINED
PENDING NRC'S DECISIONS
ON COMBINED LICENSE APPLICATION GUIDANCE