INSPECTION PROCEDURE 37055

ONSITE DESIGN ACTIVITIES

PROGRAM APPLICABILITY: 2512

37055-01 INSPECTION OBJECTIVE

To determine whether the licensee's, architect engineer's and contractor's onsite design activity, including controls for engineering and construction initiated field changes, is conducted in compliance with the technical and quality assurance requirements described in the facility SAR.

Inspection Schedule

Inspection	May Be Started	Must Be Started	Must Be Completed
Initial		6 months after onsite design activity starts	
Subsequent		Every 18 months thereafter	

37055-02 INSPECTION REQUIREMENTS

02.01 Functional Responsibilities for Onsite Design

a. Determine the total extent of the onsite design activity relative to the construction of the facility.

b. Determine the extent to which the licensee has authorized/delegated onsite design for the construction of the facility to the architect-engineer, the constructor, and to other contractors or subcontractors onsite. Note location of each design group.

c. For each of the above organizations (Section 02.01b) conducting onsite design, determine the scope of authority and responsibilities for the activities listed below. Based on information gathered, prepare an inspection plan to complete the other inspection requirements of this procedure.

1. Preparation of design documents.

   (a) Input.

   (b) Field design.

   (c) Fabrication.

2. Design review/verification.

3. Design and field initiated changes and revisions.

4. Design document control.

5. Drawing control and issuance.

6. Interface with the home office and licensee.

7. Quality assurance.

02.02 Design Procedure Review

a. Select QA manual documents and implementing procedures utilized by the QA programs for the principal designer and two other site design groups. Determine the adequacy of the implementation of the QA procedures for site design activities, as applicable per Section 02.01 above. (Refer to Regulatory Guide 1.64 and ANSI N45.2.11.)

b. Determine whether the staff is knowledgeable of the requirements of the QA manual procedures.

c. Determine whether procedures are available for each design activity being conducted by the onsite design groups (licensee, architect-engineer, constructor, contractors, and/or subcontractors) for such items as:

   1. Control of design input (i.e., design criteria and specifications prepared by appropriate "home office" original, or related, design input).

   2. Control of design process relative to:

      (a) Drawings and revisions.

      (b) Specifications and revisions.

      (c) Calculations and recalculations.

      (d) Codes, standards, Regulatory Guides, IE Bulletins.

      (e) Interface with home office and licensee.

      (f) Design verifications.

      (g) Document and drawing control.

      (h) Corrective actions on deficiencies.

02.03 Design Process Review. Examine the onsite design process for two design groups relating to the following areas:

a. New Design/Field Fabrication

1. Determine whether the design groups selected understand the applicable design control procedures.

2. For work just completed, by requesting the designer to discuss the scope of the design relative to the following activities, determine whether such activities are subject to adequate design controls.

(a) Design input.

(b) Design review.

(c) Design approval.

(d) Interface with home office.

3. For work selected in Section 02.03a2 above, have designer verify, for several design parameters selected by the inspector, whether they are within the criteria and/or specifications established by the home office.

4. Determine whether the person doing the design review was independent from the individual who did the design.

5. Determine whether the design verification records are adequate.

b. Design Changes. For at least 2 engineering and 2 construction organization initiated field changes (preferably, those where work has proceeded prior to the change receiving a design verification) determine whether the following aspects are adequate:

1. Reason/need for the change.

2. Change does not appear to compromise original design intent.

3. Change was reviewed subject to controls commensurate with the original design and approved by "other than originator". The review did consider impact on overall design by review of the adequacy of the change, impact on other disciplines, and changes necessary to prior analysis.

4. Design drawings are updated/revised to reflect new design changes.

5. In addition, from the drawing control listing, select five drawings with current revisions in each of the three areas of installation relating to containment, mechanical piping, and electrical cable and:

(a) Verify whether site-retained master-reproducible drawings (vellum, brownline, or microfilm); or, where reproducibles are not available, whether the master "stick set," includes revisions which are consistent with that recorded by the drawing control list.

(b) Review the documentation related to the review and approval of the latest revision and the authorization (or controls) leading to issuance of

the revised drawing for construction or for as-built records and determine whether documentation is adequate.

(c) Examine whether the latest drawings and specifications have been released to all constructors (and contractors) and how the issuance is routinely verified.

6. Whether document control (procedures and implementation) provides timely distribution of the latest revision.

7. Whether design changes (Section 02.03b, Items (1) through (5) above) are processed as required by the QA program for design conducted onsite by the appropriate design group.

8. For the design/field change released for work without design verification, determine that the unverified change and related construction was adequately controlled during the unverified period and, if applicable, that the verification was made prior to the installation becoming "irreversible" (i.e., without extensive demolition and rework per NRR/QAB Position #10 and SRP 17.1).

c. Control of Drawings. Select an individual responsible for control or surveillance (whenever possible exclude the auditor) of drawings related to site construction activities and:

1. Ask the individual to identify and briefly review the substance of QA manual provisions relating to assigned activities.

2. Physically examine the adequacy of facilities relating to the storage and control of drawings

3. If different from Section 02.03c, Item 2, above, examine the adequacy of facilities relating to the storage and control of design drawings by two major construction contractors having design responsibilities.

02.04 Design Control by Licensee

a. Surveillance. Select one person for interviewing who is responsible for surveillance of site-design activities, and:

1. Determine whether the licensee has identified each constructor who prepares and/or issues design end-product documents for construction

2. Determine licensee qualification of design control provisions of constructor QA manual documents by a review of records relating to licensee examinations in this regard for two contractors delegated, or otherwise performing, site design activities.

3. Review one record relating to the licensee surveillance (reviews, etc.) of each contractors onsite design activities. If available onsite, review licensee record and results, relating to a review of one design change initiated by each contractor who performs design. Determine whether these records are adequate.

b. Audits. Select one licensee audit report and related documentation for each of the site-related activities listed below, assure the audit verified implementation of the QA elements of the programs functional areas.

1. Verify that audits were conducted of:

   (a) Design control.

   (b) Document control.

   (c) Records.

2. Verify that audited organizations received a copy of the audit report.

3. Determine whether appropriate standards were referenced for measuring performance.

4. Determine whether auditors were selected in accordance with QA manual provisions and necessity for technical expertise.

5. For adverse findings, review means established to ascertain effective corrective action; and verify that reaudits were scheduled/conducted as necessary.

6. If corrective action was recommended by the audit report, examine records of corrective action taken.

7. Record substantive deficiencies in design and hardware which are potentially generic for items delivered to the site by the AE, NSSS or other major vendors and provide this information to VPB, Region IV, per MC 2720.

8. By review of records relative to the resolution of audit findings pertaining to a significant deficiency, determine whether the matter was identified for consideration under 10 CFR 50.55(e) and/or 10 CFR 21 regulations, as appropriate.

9. To the extent identified by audit or inspector findings, select two significant deficiencies and conduct a record review to ascertain whether these matters were handled satisfactorily under 10 CFR 50.55(e) and/or 10 CFR 21.

02.05 Design Control by Contractors. Obtain two field-originated design documents, preferably involving two disciplines, and complete the following requirements:

a. For designs selected:

   1. Determine whether design input is adequately controlled and assured.

   2. Determine whether the design was verified by an independent reviewer.

   3. Determine whether required approval was received.

   4. Evaluate appropriateness of field design.

   5. Evaluate adequacy of documentation and document control.

   6. Determine whether these activities were performed as described by the QA manual.

   7. If electrical, determine whether separation criteria and physical protection were affected.

8. Verify adequacy of installation instructions.

   Where installation procedures do not reference the equipment supplier's installation instruction, review the drawings, specifications, and procedures sufficiently to ascertain whether the manufacturers or suppliers instructions were adequately incorporated into the constructor's installation instructions. Documented approval of discrepancies should be reviewed also.

b. Examine design deviation notices; for drawings selected in Section 02.05a (select 4, 2 for each discipline, if available) and:

   1. Determine whether appropriate control procedures are used.

   2. Determine whether timely resolution and closeout were achieved and whether the resolution resulted in complying to the original design or to a subsequent reviewed and approved field change.

   3. If applicable, determine whether PSAR intent was changed by any field design. If so, were PSAR change control procedures followed?

c. Examine and determine the adequacy of constructor's and/or subcontractor's audit report covering site-related design activities, and complete the examinations of audit records listed below for each activity:

   1. Review audit schedule.

   2. Determine whether planned audits were conducted per ANSI N45.2.11/N45.2.12, or as otherwise committed.

   3. Whether the scope and depth of the audit(s) are consistent with the purpose stated for each audit.

   4. For adverse findings, review means established to ascertain effective corrective action and when designated (or otherwise necessary), verify schedule for reaudit.

   5. If immediate action was required by an audit report, determine whether required corrective actions were completed in an adequate manner.

   6. Record substantive deficiencies in design and hardware which are potentially generic for items delivered to the site by the AE, NSSS, or other major vendors, and provide this information to VPB, Region IV, per MC 2720.

   7. By review of records relative to the resolution of audit findings pertaining to a significant deficiency, determine whether the matter was identified for consideration under 10 CFR 50.55(e) and/or 10 CFR 21, as appropriate.

   8. To the extent identified by audit or inspector findings, select two significant deficiencies and conduct a record review to ascertain whether these matters were handled satisfactorily under 10 CFR 50.55(e) and/or 10 CFR 21.

02.06 Installation of OnSite Design

a. Select at least four recent onsite design activities; include two items undergoing installation.

b. By examination of those individuals who performed the activity, determine whether the installation conforms to the drawings and/or other design documents.

c. Observe the work for Items a and b (Section 02.06) and determine adequacy.

37055-03 INSPECTION GUIDANCE

General Guidance

a. The intent of this procedure is to determine whether the licensee's system (procedures/implementation) is working in an effective manner to assure a quality product; therefore, it cannot be performed until onsite design work on a particular system (e.g., soil testing, dewatering foundations, soil stabilization, and/or early concrete work on dams and foundations) is underway. Whether the licensee has an adequate system of procedures should have been determined prior to the start of work. This inspection is to determine that the system is working. Therefore, implementation is the primary concern here.

b. This inspection procedure (IP) should be planned to complement IP 35060, Licensee Management of QA Activities, conducted in the licensee's corporate office both in timing and scope. The IP completed first should provide input to the other. Each inspector involved should be experienced in the interpretation of the requirements for onsite design work as stated in 10 CFR 50 Appendix B; Regulatory Guide 1.64; and ANSI N45.2.11.

03.01 Specific Guidance

Note: The guidance below refers to specific subsections of section 02, above.

02.01a Review PSAR Chapter 17, MC 2511, and previous MC 2512 inspection reports, facility docket file, significant construction deficiency file and docket enforcement correspondence and responses. Note inspections related to IP 35100 and 35020 as related to design work.

02.01b Confirm assignment of onsite design responsibilities with site management. Review organization charts, QA manuals and corporate standards. Discuss SAR items submitted to NRR:QA by the licensee as related to onsite design.

02.01c Review standards and procedures for each design group. Note document control of these procedures.

When significant changes to the QA Program commitments are disclosed by the QA Manual and PSAR reviews or discussions with site management, the inspector will include these in his inspection plan to establish if the licensee took appropriate action to ascertain that the changes were consistent with 10 CFR 50, Appendix B, and that this review was performed in compliance with regulations and commitments for control of changes to the QA program after issuance of the license. The inspector should also assess whether the licensee has taken the initiative to issue changes as necessary to improve the effectiveness of program execution.

02.02 Review and Followup. The selections in this area should include the continued examinations of areas of the program which were changed, such as a result of NRC identified deficiencies.

In accordance with recent rulemaking under 10 CFR 50.54 and 10 CFR 50.55, the licensee is required to perform evaluations of changes to the QA program occurring after CP issuance to maintain compliance with 10 CFR 50, Appendix B. The licensee is also to notify NRC of changes to the QA Program description contained in the SAR within 90 days after implementation thereof. The inspector should remain cognizant regarding the effective date of recent rulemaking, in this regard.

All substantive changes in the basic commitments of the approved QA program which have been in effect for 90 days and have not been reported to NRC shall be recorded and forwarded to the Region for review and a conclusion regarding acceptance and potential for enforcement action. Where changes in the "constructor's" QA program are identified through the inspector's reviews of the QA manual documents and the PSAR, changes which are considered to be in noncompliance to original commitments, and, of course, 10 CFR 50, Appendix B, shall be discussed with the licensee.

02.02b Interviews with two designers of the lowest level onsite (excluding draftsmen) as well as two "lead" discipline designers and/or supervisors. Determine if training has been sufficient. Examinations of appropriate records may be necessary to verify implementation of manual changes by those who are performing the activity.

02.02c The intent is to do an adequate sampling of QA manuals/procedures which are made available to on-site designers to determine that they are available for use and that all required procedures are included.

Clearly defined procedures should be available describing the control over changes made in the field to facilitate construction. For those cases where design verification cannot be done prior to work proceeding, there should be instructions to provide for adequate control of such cases. Generally, such instructions shall be comparable to that stated by QAB Position 10 or Section 17.1 of the SRP. The QAB Position 10 is repeated below, as follows:

"Verification shall be performed in a timely manner. If other than by qualification testing of a prototype or lead production unit, verification should be completed prior to release for procurement, manufacturing or construction or release to another organization for use in other design activities. In those cases where this timing cannot be met, the design verification may be deferred, providing that the justification for this action is documented and the unverified portion of the design output and all design output documents, based on the unverified data, are appropriately identified and controlled. Construction site activities associated with a design or design change shall not proceed without verification past the point where the installation would become irreversible without extensive demolition and rework. In all cases, the design verification shall be completed prior to fuel load for a plant under construction, or in the case of an operating plant, prior to relying upon the component, system, or structure to perform its safety-related function."

The inspector must remember that the licensee may not be committed under Section 17 of his SAR to QAB #10. However, as QAB #10 represents a clarification of 10 CFR 50, Appendix B, licensee procedures for the timely review of design changes and control over

unreviewed design changes released for construction should be considered inadequate unless comparable instructions exist. Disagreement between the licensee and NRC inspector on this issue should be referred to QAB for review.

02.03a If more than two design groups are active on site, select the two groups working on safety-related items that have not been reviewed as a part of a routine IP or by other inspectors reviewing responses to IEBs, CDRs, or special investigation subjects. Particular attention should be given to the implementation of the interface control system and the independent design verification system.

The independent design verification is frequently performed at the home office (not onsite); however, the inspector should not accept a general statement (in procedures or by site personnel) that this is the case without conducting a random check of issued design that had been prepared by onsite designers to ascertain that the verifier is from the home office. The adequacy of the home office independent designer verification work will be inspected during the inspection of design activities conducted in the licensee's corporate office and/or the LCVIP program (MC 2710).

02.03b Perform these inspections for design or design changes originated in the field. Particular attention should be given to the appropriateness of field design performed (whether or not authorized), timeliness of closeout of design deviation notices, and the checking or verifying of design. Investigate potential ways to initiate design changes that are not authorized, or to not document the closeout action.

It is expected that the inspector will need to verify at least four design changes for each onsite design group; a representative sample of all areas of work (civil, mechanical, etc.) will probably require the inspector to verify more than four design changes per design group. Likewise the inspector is expected to need to review more than five drawings (Section 02.03b4).

See guidance above for Section 02.02c, when assessing comparability to QAB Position 10 for the timely review of design changes and control of unverified design changes and related construction.

02.03c The inspector should locate the drawing control sheet(s) that identifies the most current revision of drawings used for reproduction and, if different, of drawings issued to the construction group. Review the control sheet to see if it provides reasonable status information regarding the construction drawings for the activity. From the listing, select the required number of drawings by number and revision date. Go to the "master" working file and examine the drawings for agreement with the control list. Verify review and approval status and authorization to issue for construction. If voided or out-of-date drawings are in the file determine the reason. If any drawing has interim changes or variations noted on it, establish the meaning of such notations and what, if any, engineering followup is indicated.

02.04 Review the licensee's QA manual program, procedures, and commitments relative to surveillance and audits of design work. Review representative samples of current surveillance and auditing work by the licensee for each onsite design group. Particular attention should be

given to the system provided for tracking items of noncompliance and all level of concerns stated in the reports. Determine whether staff and supervisors of licensee's surveillance work have been trained to identify and report 10 CFR 50.55(e) and 10 CFR 21 items.

For audits Section 02.04b) review PSAR Section 17.1.18, ANSI N45.2.11, N45.2.12, and N45.2.13. Primarily from examinations of audit reports, and related documentation, the inspector should be able to judge from the objective evidence observed in this area whether the licensee is capable of assessing the effectiveness of all elements of the implemented QA program for construction.

Where audits have not been performed to cover certain activities at the site, the inspector should ask to review the schedule of audits for this activity. The inspector(s) may wish to pursue how the licensee is cognizant of the adequacy of the implemented QA program without the performance of audits. Where such measures (reviews, inspections, surveillance of activities and records) are described by the QA manual as a means of evaluating program effectiveness, the inspector may elect to perform examinations in this area, if not previously accomplished as a substitute for the area of the program where audits have not been prepared.

The inspector should expect the scope of licensee audits to vary from detailed examinations of ongoing construction activities, to an overall review of the surveillance, inspection, and audit records generated by the execution of the constructor's QA program. The inspector will want to review the audit plan as well as the report of each audit. Keep in mind that an audit must be formal to the extent that it is planned and scheduled in advance, and reported formally. An audit need not be a prolonged or extensive process. That is, it may be a very brief or very limited audit if appropriate to the particular conditions. Conclusions relating to the adequacy of licensee's surveillance of any one contractor should result from a comprehensive review of his QA program identified surveillance responsibilities and overall records relating to the execution thereof. Inspectors should be alert to evidence of so-called audits which really are QA surveillance or inspection.

When a reaudit is indicated in a report, which appears to be of more than average interest, the inspector should review the report of the reaudit.

02.04(b)(7) Substantive deficiencies which relate to design and hardware supplied by "major" contractors should be recorded, and this information should be forwarded to Region IV for consideration when performing subsequent (generic) inspections of these contractors.

02.04(b) 8 & 9 Generally, a significant deficiency (Criterion XVI) will require a determination on whether it is reportable under 10 CFR 50.55(e) and/or 10 CFR Part 21. Therefore, the QA program should provide for appropriate handling in this regard. (Refer IP 36100, Section 03, Item 4 for additional guidance on 10 CFR 21 aspects.)

02.05 Guidance, references, and concerns as stated for 02.04 are also appropriate for contractors as they are for licensees. In each of the general program inspection areas, it will be necessary for the inspector to identify and enlist the assistance of one or more licensee and

constructor-cognizant individuals, who are representatives of either the quality control or quality assurance organization to answer inspector's questions and to assist him through the process as he inspects. The inspector will need to have a copy of the QA manual procedure or instruction which is used to control the activity to be inspected. By doing this, the inspector will be able to evaluate the knowledge, capability and training needs of each individual and, in addition, evaluate the status and effectiveness of the implemented QA program elements in each area.

For audits by contractors, particular attention should be given to scope and depth of the audit and whether the audit represented a reasonable assessment of the effectiveness of the QA program for control of onsite design.

02.05c6 Substantive deficiencies/deviations which relate to design and hardware supplied by "major" contractors shall be recorded and this information should be forwarded to Region IV for consideration when performing subsequent generic inspections of these contractors.

02.05c7&8 Refer to guidance under 02.04b8 and 02.04b9, above.

02.06 Select recent onsite design activities that have not been inspected to fulfill the requirements of the routine inspection requirements, IP 35061. "In Depth QA Inspection of Performance," nor the inspection of the licensee's responses to IEBs, CDRs, or special investigation subjects.

37055-04 REFERENCES

NRC Regulations/SAR

10 CFR Part 50

10 CFR Part 21

Chapter 17 of SAR (QA)

Technical Chapters of SAR, as appropriate

NRC Guidance

RG 1.28/ANSI N45.2 (QA Program)

RG 1.64/ANSI N45.2.11 (Design)

RG 1.114/ANSI N45.2.12 (Auditing)

RG 1.123/ANSI N45.2.13 (Procurement)

NUREG 0302, Rev. 1 (10 CFR Part 21)

Staff Position

NRR/QAB Interpretation No. 10

END