

STATE OF LOUISIANA

US 90 (I-49 SOUTH)
ALBERTSON'S PARKWAY TO
AMBASSADOR CAFFERY
DESIGN-BUILD PROJECT

LAFAYETTE PARISH

STATE PROJECT NO. H.010620
FEDERAL AID PROJECT NO. H010620

REQUEST FOR PROPOSALS

DB SECTION 113
DESIGN-BUILDER'S QUALITY PLAN



DB SECTION 113

DESIGN-BUILDER'S QUALITY PLAN

DB 113-1 GENERAL REQUIREMENTS

Prior to commencement of any design or construction activities, the Design-Builder shall submit a Quality Plan, updated as necessary, to the Louisiana Department of Transportation and Development (LA DOTD) for Approval.

The Quality Plan must address the topics contained in this DB Section 113 in the order listed therein and must meet the specified requirements of this DB Section 113, Section 112 and the LA DOTD's Construction Quality Assurance Program (CQAP).

The Quality Plan must set up a "quality system team" which will be distinct and separate from the design and construction production organization. The quality system team shall report directly to the Design-Builder's management through the Design-Builder's Quality Manager. The Quality Plan shall describe the quality system to be implemented at all levels of the Design-Builder's organization, to include Subcontractors (design and construction) at all levels, including labor only.

Please refer to Part 2 – Design-Build Section 101, Section 101-3, for the definitions of QC and Quality Acceptance.

DB 113-1.1 Quality Plan Submittal

The Design-Builder shall submit its Quality Plan within 60 Calendar Days of Notice to Proceed.

DB 113-1.2 Quality Plan Reviews and Updates

The Design-Builder shall conduct management reviews of its quality system as specified in this DB Section 113.

As Work progresses, the Design-Builder shall update the Quality Plan to reflect current conditions. The Design-Builder and/or the Department's Project Manager may identify the need for revisions to the Quality Plan. The Design-Builder shall submit any revisions or updates to the Quality Plan to the Department's Project Manager for approval within 30 calendar days of the identification of the need for a revision.

In addition, the Design-Builder shall submit its Quality Plan for review by the Department's Project Manager annually within 12 months of Notice to Proceed (NTP) or receipt of the last Approval from the Department's Project Manager even if no revisions have occurred during that 12-month period. The Design-Builder shall submit a conformed copy of the updated Quality Plan with revisions highlighted.

DB 113-1.3 Environmental Mitigation

In developing its Quality Plan, the Design-Builder shall establish appropriate controls in its management, design, construction/installation, and documentation procedures to ensure that environmental mitigation requirements are met and documented.

DB 113-1.4 Organizational Requirements

The Design-Builder shall designate a Quality Manager who shall be classified as one of the Key Personnel and be responsible for overseeing the overall quality program and the preparation, implementation, and update of the Quality Plan for the Design-Builder, including management, design, and construction. The Design-Builder's Quality Manager shall not report to the Design-Builder's Project Manager, but shall be directly responsible to and report to the Joint Venture (JV) board, senior management, or similar level of the Design-Builder's organization not directly responsible for design or construction.

The Design-Builder's Quality Manager shall be present and available for consultation with the LA DOTD's Project Manager and other LA DOTD staff on an on-call basis throughout the duration of the Project. The Design-Builder's Quality Manager shall attend the weekly progress meetings at a minimum and such other meetings as the Department's Project Manager may request, including individual meetings between the Design-Builder's Quality Manager and LA DOTD staff.

The Design-Builder's Quality Manager shall be the primary point of contact to the LA DOTD for all issues relating to the Design-Builder's Quality Plan (preparation, review, implementation, and updates).

The Design-Builder's Design QC Manager, CQCM and CQAM and their respective staffs shall report directly to the Design-Builder's Quality Manager.

See DB Section 112 for responsibilities and qualification requirements of construction QC staff. See DB Section 111 for responsibilities and qualification requirements of design QC staff.

DB 113-1.5 Abbreviations

C/A	Corrective Action
HSPPD	Handling/Storage/Packaging/Preservation/Delivery
P/A	Preventive Action

DB 113-2 QUALITY SYSTEM REQUIREMENTS

DB 113-2.1 Management Responsibility

DB 113-2.1.1 Quality Policy

The Design-Builder's executive management shall define and document its policy for quality, including objectives for quality and its commitment to quality. (In the context of this DB Section 113, "executive management" shall mean those persons to whom the Design-Builder's Project Manager reports and who have overall responsibility for the Design-Builder's performance.) The quality policy shall be relevant to the Design-Builder's organizational goals and the expectations and needs of the LA DOTD. The Design-Builder shall ensure that this policy is understood, implemented, and maintained at all levels of the organization.

The Design-Builder shall have a published statement of its commitment to quality and the organization's quality objectives signed by its responsible executive(s). It shall explain the commitment in terms of the services provided to the LA DOTD and the responsibilities assumed by the Design-Builder to discharge its contracted accountabilities, relative to the LA DOTD's overall responsibility to Stakeholders and the

public-at-large for assuring quality in the constructed facility. The statement shall be made known to and understood by all staff and be included in the Quality Plan.

Executive management's commitment to quality could be demonstrated by the quality policy being signed by the responsible executive(s) and management's direct involvement in verifying the implementation and understanding of the quality policy.

All employees shall be made aware of the Design-Builder's quality policy. The indoctrination on quality policy may be formal and can be accomplished by various means depending on the size of the Project, the structure of the Design-Builder's management staff, and the number of employees.

DB 113-2.1.2 Organization

A) Responsibility and Authority

Executive management shall have the responsibility to plan and determine the overall direction of the Design-Builder and its relationship to the quality efforts. Executive management shall ensure the quality policy is documented and understood by all employees and management shall further ensure the implementation of the quality policy by everyone in the organization.

The quality system shall be an integral part of the overall management system and as such shall be supported and implemented from the top down. On a Design-Build (DB) project, most employees are involved in managing, performing, or verifying work that affects quality. It shall not be the sole domain of the design checkers, QC inspectors, QC or QA personnel. All workers, including design and construction production personnel (including those of Subcontractors), shall be aware of the quality system requirements that govern their respective Work.

A description of the organizational arrangements (such as a chart) shall be available and maintained. All key roles and persons and lines of communication and authority between the Design-Builder and the LA DOTD and their representative(s) and with other organizations involved shall be identified.

The responsibility, authority, and interrelation of personnel who manage, perform, and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to do any of the following:

- 1) Initiate action to prevent the occurrence of any nonconformities relating to the product, process, and quality system;
- 2) Identify and record any problems relating to the product, process, and quality system;
- 3) Initiate, recommend, or provide solutions through designated channels. It shall be everyone's responsibility to report any and all quality and safety problems;
- 4) Verify the implementation of solutions. Verifying the implementation of the solutions to quality problems shall be performed in a timely manner. The verification shall also investigate if the solution to the identified problem created another quality problem; and
- 5) Control further processing, delivery, or installation of nonconforming product

until the deficiency or unsatisfactory condition has been corrected. Controls shall be established, including stopping work, if necessary, once a significant quality problem is identified until the cause of the problem can be identified and the required corrective action can be implemented.

B) Resources

The Design-Builder shall identify resource requirements and provide adequate resources, including the assignment of trained personnel for management, performance of Work, verification activities, and internal quality audits.

The Design-Builder shall have a system for assuring that projects are adequately staffed and that resources are provided adequate training to perform such activities as design reviews (DB Section 113-2.4), verification activities, receiving, in-process and final inspections (DB Section 113-2.10), and internal quality audits (DB Section 113-2.17).

The Quality Plan shall identify the source of staffing (management, professional, technical, and labor) and shall deal with the integration of resources into the specific Contract requirements.

Other resources shall also be addressed, such as, computers, craft tools, equipment, and facilities.

C) Design-Builder's Quality Manager

The Design-Builder's executive management shall appoint a Quality Manager who, irrespective of other responsibilities, shall have a defined authority for the following activities:

- 1) Ensuring that a quality system is established, implemented, and maintained; and
- 2) Reporting on the performance of the quality system to the Design-Builder's management for review and as a basis for improvement of the quality system.

The Design-Builder's Quality Manager shall have direct access to executive management to report on the performance of the quality system and shall not work under the Design-Builder's Project Manager or anyone else responsible for design or construction production.

DB 113-2.1.3 Management Review

The Design-Builder's executive management shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this standard and the Design-Builder's stated quality policy and objectives (*see* DB Section 113-2.1.1). Management reviews shall be held at least at three-month intervals.

Records of such reviews shall be maintained (*see* DB Section 113-2.16). Minutes shall be taken of the review meetings and these minutes shall be maintained as quality records. Copies of minutes shall be provided to the Department's Project Manager on request.

DB 113-2.2 Quality System

DB 113-2.2.1 General

The Design-Builder shall establish, document, and maintain a quality system as a means of ensuring that product conforms to specified requirements. The Design-Builder shall prepare a Quality Plan covering the requirements of this DB Section 113. The Quality Plan shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

The Quality Plan shall cover temporary and permanent components; the Design-Builder; all Principal Participants; and all Subcontractors, suppliers, and vendors (design, construction, and materials) at all tiers.

Specific to construction inspection, materials sampling and testing, process controls, etc. the Design-Builder's Quality Plan will include a Construction Quality Management Plan (CQMP) that meets the requirements of the LA DOTD Construction Quality Assurance Program (CQAP) for design-build projects and DB Section 112. The CQMP will be a component of the Design-Builder's Quality Plan, but should be written to allow it to be a stand-alone document that meets the requirements of the LA DOTD CQAP.

The Quality Plan shall either contain or reference the procedures and documentation structure outline critical to quality.

The Quality Plan shall also establish or reference the procedures that make up the quality system. Should the Quality Plan only reference the procedures, it shall also detail the levels of the documented system, its contents, and the interrelationship of the document types.

There shall be a "road map" within the Quality Plan that is lined up to the applicable element that describes the quality system. This roadmap may be a cross-reference, narrative, chart, index, or some similar method.

The Quality Plan shall detail the role of the Design-Builder, each Principal Participant, the Designer, the Design-Builder's Project Manager, Quality Manager, CQAM, CQCM, and Design QC Managers, and other team members having a significant quality role.

The Quality Plan shall define policies, goals, and objectives of the organization and organizational interfaces.

DB 113-2.2.2 Quality-System Procedures

- A) The Design-Builder shall prepare documented procedures consistent with the requirements of this DB Section 113 and the Design-Builder's stated quality policy.
- B) The Design-Builder shall document standard Work methods in procedures (*see* DB Section 113-2.2.2) and enforce the implementation of these "Best Practices." However, it is inevitable that situations will arise which require a departure from the norm. These conditions shall be anticipated in the procedures and shall allow for control of these activities.
- C) The Quality Plan shall define the liaison and interface between the quality organization and the design and construction arms of the Design-Builder.

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- D) The quality procedures shall, as a primary objective, be written with the intent of gaining employee understanding of the system.
- E) It is the Design-Builder's responsibility to describe to the LA DOTD the rationale for the procedures selected and, if the procedures do not address every provision of this DB Section 113, to explain why the standard is not applicable in a particular situation. The following common pitfalls should be avoided:
 - 1) Too much emphasis placed on creating multiple tiered documents when a simple Quality Plan will suffice;
 - 2) Procedures which are too restrictive;
 - 3) Procedures which are inconsistent;
 - 4) Inordinate emphasis on documentation requirements; and
 - 5) Over commitment to procedures which provide little or no information to assist employees.
- F) The following list of procedures (1 through 22) shall serve as the starting point for defining the Design-Builder's quality management system.
 - 1) A procedure for preparation, control, and distribution of Project Quality Plan;
 - 2) Scope;
 - 3) Key personnel;
 - 4) Organizational/technical interfaces;
 - 5) Design input requirements;
 - 6) Design output requirements (deliverables);
 - 7) Design reviews;
 - 8) Louisiana Department of Transportation and Development participation;
 - 9) Levels of responsibility and authority for the following personnel:
 - a) On-site staff;
 - b) Other local office staff;
 - c) Executive management; and
 - d) The Design-Builder's Quality Manager;
 - 10) A procedure to control, verify, and validate the design;
 - 11) A procedure to control, verify, and validate that construction is performed in accordance with the Contract requirements; the Design-Builder's Project Specifications; and the Design-Builder's plans, including design assumptions and intent;
 - 12) A procedure for document issue, approval, and revision;
 - 13) A procedure for verification, storage, and maintenance of LA DOTD-supplied Materials or Equipment;

- 14) A procedure for the identification of (and, where required by Contract, the traceability of) deliverable items, such as, Design Plans, Project Specifications, Working Plans, and As-Built Plans;
- 15) A procedure for verification and control of computer programs used in design;
- 16) Procedures for inspecting, testing, and calibrating Equipment;
- 17) Procedures for handling nonconformances;
- 18) Procedures for corrective/preventive actions;
- 19) Procedures for handling, storing, packaging, and delivering Contract deliverables;
- 20) Training processes;
- 21) Procedures for internal quality audits; and
- 22) A procedure for management review.
 - a) The Design-Builder shall identify its standard procedures applicable to the Project. The Design-Builder shall develop Project-specific procedures for all elements of the Project that are important to quality for the Project, but are not addressed adequately by its standard procedures. Both types of procedures shall be included in the Project's Quality Plan.
 - b) The Design-Builder shall effectively implement the quality system and its documented procedures. Implementation shall be demonstrated by internal quality audit reports, trending of nonconformances, records of root cause analysis, records of corrective and preventive actions, and/or records of how the LA DOTD's complaints were handled.
 - c) For the purposes of this DB Section 113, the range and detail of the procedures that form part of the quality system depend on the complexity of the Work, the methods used, and the skills and training needed by personnel involved in carrying out the activity. The procedures shall accurately reflect the Work that is to be accomplished and shall benefit the organization/Project.
 - d) Documented procedures may make reference to specifications that define how an activity is performed. Procedures shall describe the process steps of "what" needs to be done and Work instructions shall prescribe "how" it is to be done.

DB 113-2.2.3 Quality Planning

A Project specific Quality Plan is required. There shall be evidence of quality planning that ensures specific Contract/Project requirements have been identified and incorporated into the documented quality system. The LA DOTD's requirements represent the minimum requirements. The Design-Builder shall develop a fully comprehensive plan.

The Design-Builder shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a Design-Builder's quality system and shall be

documented in a format to suit the Design-Builder's methods of operation. The Design-Builder shall give consideration to the following activities, as appropriate, in meeting the specified requirements for the Project:

- A) Preparing the Quality Plan;
- B) If the Design-Builder already has a quality management system, blending the unique Project requirements into the quality system by completing the following for this Project:
 - 1) Stating the Project objectives to be obtained;
 - 2) Identifying responsibilities, authorities, and interfaces (both internal and external);
 - 3) Identifying specific procedures, methods, and instructions to be used (standard and Project specific);
 - 4) Identifying inspections, tests, audits, and surveillances to be used;
 - 5) Controlling modifications and change; and
 - 6) Incorporating Project requirements into the standard documents;
- C) Identifying and acquiring any controls, processes, Equipment (including inspection and test Equipment), fixtures, resources, and skills that may be needed to achieve the required quality;
- D) Ensuring the compatibility of the design, production process, installation, service, inspection and test procedures, and applicable documentation. The Design-Builder shall have significant interface obligations and shall describe in its Quality Plan how these obligations shall be met;
- E) Updating, as necessary, QC, inspection, and testing techniques, including the development of new instrumentation;
- F) Identifying suitable verification at appropriate stages;
- G) Clarifying standards of acceptability for all features and requirements, including those which contain a subjective element; and
- H) Identifying and preparing quality records. Quality records are comprised of such documents as audit inspection reports, approved designs, Specifications, Plans, calculations, purchase orders, Design Review records, vendor evaluation reports, cumulative progress reports, and audit reports.

DB 113-2.3 Change Order and Amendment Review

DB 113-2.3.1 General

The Design-Builder shall establish and maintain documented procedures for Change Order and Amendment review and for the coordination of these activities.

The methodology of the review shall be adequately defined and documented in procedure(s). The objective is to ensure that all Contract commitments are reviewed and agreed prior to issue or "execution."

This DB Section 113-2.3 applies to the Contract between the Design-Builder and the LA DOTD.

DB 113-2.3.2 Review

The change review is a process which should begin with the request for change and continues during the Change Order or Amendment preparation. The review process could be "graded" (i.e., different for Change Orders versus Contract Amendments) and could also be different based on the dollar value and legal framework (i.e., specific to the perceived risk of not doing so).

Change review shall take place for each request for Change Order or Contract Amendment.

Before submission of a proposal or the acceptance of a Change Order or Contract Amendment, the proposal shall be reviewed by the Design-Builder to ensure the following:

- A) The requirements are adequately defined and documented. Where no written statement of requirement is available for an order received by verbal means, the Design-Builder shall ensure that the order requirements are agreed before their acceptance. The identification and documentation of the LA DOTD's requirements is required;
- B) The standard also acknowledges that a written statement of requirements may not always be received from the LA DOTD. Where verbal orders are received from an authorized representative of the LA DOTD, the Design-Builder shall ensure requirements are defined, reviewed, and confirmed in writing. In any case, the Design-Builder shall be responsible to ensure the change requirements are understood and have been agreed to by both parties before acceptance;
- C) Any differences between the Contract or accepted order requirements and those in the proposal are resolved. Differences between a proposal and the requested change shall be reconciled and reviewed for impact and action, clearly and mutually agreed; and
- D) The Design-Builder has the capability to meet the Contract or accepted order requirements. The Design-Builder shall have the capability to fulfill the Project Contract requirements before acceptance of the change order or Amendment. This capability can reside in-house, with Subcontractors, or with subconsultants.

DB 113-2.3.3 Amendment to a Contract

The Design-Builder shall identify how an amendment to a Contract is made and correctly transferred to the functions concerned within the Design-Builder's organization.

The Contract review procedure shall include processing all Amendments to the Contract. Amendments and Change Order requests should be subject to an appropriate level of review as the initial Contract. The review shall include impact on Work already performed, schedule, and costs.

DB 113-2.3.4 Records

Change Order and Amendment reviews correspondence, meeting minutes, signed documents, and records of negotiation shall be maintained as Project records. Records of negotiations shall also be attached to a Change Order.

Channels for communication and interfaces with the LA DOTD's organization in these Contract matters shall be established and maintained.

DB 113-2.4 Design Control

DB 113-2.4.1 General

The Design-Builder shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

Design control must be applied to computer programs, spreadsheets, design tables, and other products that provide analytical results which are used to develop or check designs.

The Quality Plan shall detail the roles of the following Design-Builder personnel:

- A) Designer;
- B) Design Manager;
- C) Design Quality Control Manager; and
- D) Responsible Engineer(s).

DB 113-2.4.2 Design and Development Planning

The Design-Builder shall prepare plans for each design and development activity. The plans shall describe or reference these activities and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as the design evolves.

The Project design control procedures shall define the technical interfaces among the different groups which provide input to the design process or receive output. The necessary information shall be documented, transmitted, and regularly reviewed. If not defined in these procedures, a separate description shall be required.

DB 113-2.4.3 Design Input

Design-input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented, and reviewed by the Design-Builder for adequacy. Incomplete, ambiguous, or conflicting requirements shall be resolved with those responsible for imposing these requirements.

The essence of this sub-element is that the Design-Builder determines what information is needed and the available sources for information, reviews all pertinent available data, assures itself that there is sufficient information to carry out its assignment, and resolves with the LA DOTD and other appropriate authorities any actual or apparent conflicts or inconsistencies in the information so gathered. The information, sources, and decisions shall be documented and treated as a quality record (DB Section 113-2.16).

DB 113-2.4.4 Design Output

The Design-Builder shall document design output and express output in terms that can be verified against design-input requirements and validated (*see* DB Section 113-2.4.7).

Design outputs are usually captured in documents such as Plans, reports, and Specifications. The control of these outputs is an integral part of the Design-Builder's document control process.

Output documentation shall be reviewed for compliance with design requirements.

Design output shall comply with the following:

- A) Meet the design-input requirements;
- B) Contain or make reference to acceptance criteria; and
- C) Identify those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g., requirements for operating, storing, handling, maintaining, and disposing).

Design-output documents shall be reviewed before release.

DB 113-2.4.5 Design Review

At appropriate stages of design, documented reviews of the design results shall be planned and conducted. Participants at each Design Review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel as required. Records of such reviews shall be maintained (*see* DB Section 113-2.16).

This element reinforces the principle of qualified staff to perform verification functions. The purpose here is to ensure an unbiased look at the Work output being produced, to verify with a "fresh set of eyes" that the LA DOTD's contractual requirements and needs are being met fully. Reviews shall include consideration of the Project's usability, reliability, maintainability, availability, and operability along with safety, cost, and aesthetics. In reviews it is prudent to address environmental impacts, community impacts, and similar concerns. Note that Design Reviews shall be recorded and retained as quality records. Any computer software used to perform alternative calculations or verify clearances through use of scale models or CADD techniques shall be validated before use for the application made and the validation documented in accordance with DB Section 113-2.16.

In addition to conducting Design Reviews, design verification may include the following activities:

- A) Performing alternative calculations;
- B) Comparing the new design with a similar proven design, if available;
- C) Undertaking tests and demonstrations; and
- D) Reviewing the design-stage documents before release.

DB 113-2.4.6 Design Verification

Design verification is the process of ensuring specified requirements have been met.

At each stage of design development the Design-Builder shall verify that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (*see* DB Section 113-2.16).

The Design-Builder shall establish and the Quality Plan shall include procedures for verifying and documenting that the design output meets the design input requirements. Verification shall include independent checks, tests, and/or reviews.

Verification shall be performed under the direction of the Design-Builder's Design Quality Control Manager.

Designs provided by subconsultants shall be independently verified and documented under the direction of the Design-Builder's Design QC Manager prior to their acceptance and incorporation into the Work of others.

DB 113-2.4.7 Design Validation

The Design-Builder shall perform design validation to ensure that the Project conforms to defined user needs and/or requirements.

Design validation is the process of ensuring "requirements for a specific intended use are fulfilled." In other words, design validation is conformity with the user's needs rather than only specified requirements. In most cases, the Design-Builder cannot determine if the LA DOTD's "needs" have been fulfilled until the Project is complete and operational.

Design validation seeks to ensure that the final product conforms to the LA DOTD's needs. Design validation follows successful design verification. Validation may only be applicable for electronic, electrical, and/or mechanical components of a Project. Validation is normally performed under defined operating conditions. Validation is normally performed on the final product, but may be necessary in earlier stages prior to Project completion.

Multiple validations may be performed if there are different intended uses.

DB 113-2.4.8 Design Changes

After a design is complete and the Work is ready to be executed, is being executed, or is complete all subsequent design changes and modifications shall be identified, documented, reviewed, and approved by authorized personnel before their implementation.

The Design-Builder shall establish and include in the Quality Plan procedures how design changes are initiated, reviewed, approved, implemented, and recorded in order to maintain configuration control. Changes may originate at the request of the LA DOTD, internal and external design organizations, and site or field personnel.

The persons authorized to approve design changes shall be identified in the procedures. The mechanism for changes in the design can be detailed as part of the procedure for the original Work or addressed in a specific design change procedure(s). It is important that any proposed changes should be reviewed and approved by the Responsible Engineer that produced the original Work. The degree and nature of control on design changes shall be at least equivalent to that under which the original Work was accomplished. Changes shall be responsive to the design input and shall be verified and approved. An administrative system shall be in place to ensure that approved changes are documented and provided to holders of the original material in a timely manner. Also, there shall be a documented process that ensures that superseded information is removed from use when the updated document or record is received.

A master list of currently effective documents shall be maintained to reflect design changes approved. A listing of the design changes shall be communicated to the construction site on a timely basis consistent with the progress of construction activities. Under no circumstances shall Work be performed without current knowledge of the approved design changes to be incorporated into the Work product.

DB 113-2.5 Document and Data Control

DB 113-2.5.1 General

The Design-Builder shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this DB Section 113-2.5 including, to the extent applicable, documents of external origin such as standards and the LA DOTD's plans.

The Design-Builder shall be responsible for the establishment and implementation of documented procedures for ensuring all documents essential to the quality of the delivered product or service are properly controlled. This shall include, but is not limited to, contracts, Plans, Specifications, master drawing lists or equivalent documents, critical procedures and Work instructions, quality system manuals, Project quality plans, and data (e.g., computer data bases and computer files).

Procedures should recognize that there is a finite life to electronic storage media. Consideration should be made for those "documents" which only exist in the electronic media.

DB 113-2.5.2 Document and Data Approval and Issue

The Design-Builder shall be responsible to see that the documents and data are reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

The Design-Builder shall be responsible for establishing, documenting, maintaining, and implementing a procedure which clearly defines the process for document review, resolution of comments, and approval authority.

Quality management system documentation shall also be controlled to ensure its proper authorization and distribution.

No construction Work activities shall be accomplished using unreleased, unauthorized, or outdated design documents.

This control shall ensure the following:

- A) The pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed; and
- B) Invalid and/or obsolete documents are promptly removed from all points of issue or use or otherwise assured against unintended use in the following ways:
 - 1) Superseded, revised, and voided documents shall be removed from all Work areas and the employees whose Work is governed by those documents shall be informed of the changes to ensure compliance to the new or revised requirements;
 - 2) A master document list or equivalent shall be maintained to identify the status and current revision of all controlled documents. The master list or equivalent shall be controlled and be available to all holders of controlled documents; and
 - 3) Any obsolete documents retained for legal and/or knowledge-preservation

purposes are suitably identified. Superseded, revised, and voided documents can be maintained for legal and/or historic information. However, the documented procedure must describe the method of identifying and storing these documents in a manner that ensures they are not inadvertently used by an unknowing individual. There shall also be a record retention plan for the Design-Builder.

DB 113-2.5.3 Document and Data Changes

The Design-Builder shall identify and include in the Quality Plan the process for the initiation, review, and approval of all document changes prior to issuance of those changes.

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval unless specifically designated otherwise. If this is not possible then the designated approval authority shall have adequate background and experience upon which to base the decision. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval.

Where practical, the nature of the change shall be identified in the document or the appropriate attachments.

DB 113-2.6 Procurement and Purchasing

DB 113-2.6.1 General

The Design-Builder shall establish and maintain documented procedures to ensure that purchased services and products conform to specified requirements.

The Design-Builder shall be responsible for establishing, documenting, and maintaining procedures for the evaluation and selection of suppliers, vendors, and subcontractors. The procedures shall detail the requirements for all important activities, such as, preparation of purchase orders; contracts for services; bid lists; and vendor quality requirements, including, pre-award audits, in-process inspections, and product acceptance.

DB 113-2.6.2 Evaluation of Subcontractors, Suppliers, and Vendors

The Design-Builder shall perform the following functions:

- A) Evaluate and select Subcontractors on the basis of their ability to meet subcontract requirements, including the quality system and any specific QC requirements;
- B) Control the evaluation and selection of suppliers, vendors, and Subcontractors. Procedures, rather than just a statement of policy in the Quality Plan, shall be used;
- C) Describe the evaluation and selection process for suppliers, vendors, and Subcontractors of all tiers and describe the priority of quality in the evaluation and selection criteria in the Quality Plan;
- D) Define the type and extent of control exercised by the Design-Builder over Subcontractors. This shall be dependent upon the type of services or products; the impact of subcontracted Work on the quality of final product; and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of Subcontractors; and

- E) Establish and maintain quality records of acceptable Subcontractors (*see* DB Section 113-2.16). Records shall be maintained to document the selection, control exercised over, performance, delivery, and quality of all Subcontractors.

The methods the Design-Builder elects to use to control the delivery of the subcontracted service or product may include, but are not limited to the following:

- 1) Design Reviews;
- 2) Shop inspections;
- 3) Receiving inspections;
- 4) Witnessed inspection hold points;
- 5) Issuance of a certificate of compliance or analysis;
- 6) Testing and approval of a prototype or sample;
- 7) Provision and approval of a Quality Plan prior to contract award; and
- 8) Quality system audits.

The procedures shall detail how Subcontractors (including consultants) will be reported to the LA DOTD (DB Section 108-2.3.4).

DB 113-2.6.3 Procurement and Purchasing Data

Procurement and purchasing documents shall contain data clearly describing the service or product ordered, including where applicable:

- A) The type, class, grade, or other precise identification;
- B) The title or other positive identification and applicable issues of Specifications; Plans; process requirements; inspection instructions; and other relevant technical data, including, requirements for approval or qualification of product, procedures, process Equipment, and personnel; and
- C) The title, number, and issue of the quality system standard to be applied.

The Design-Builder shall review and approve procurement/purchasing documents for adequacy of the specified requirements prior to release.

The documented procedure shall identify how and by whom procurement and purchasing documents are reviewed, how comments are resolved, and who in the organization has the authorization for final approval of the document.

DB 113-2.6.4 Verification of Purchased Service or Product

- A) Design-Builder Verification at Subcontractor's Premises

Where the Design-Builder proposes to verify a purchased product or service at the Subcontractor's premises, the Design-Builder shall specify verification arrangements and the method of product release in the procurement/purchasing documents.

The procurement/purchasing document shall include any requirement for the organization performing verification at its Subcontractor's facilities. The method of verification and release of the product or service shall be specified in advance. This may also mean the purchase order or Specifications carry specific instructions on how the process verification will be performed to assure the final product will meet all of the procurement/purchasing requirements.

- B) The Louisiana Department of Transportation and Development Verification of Subcontracted Product or Service

Where specified in the Contract, the Design-Builder or the LA DOTD's representative shall be afforded the right to verify at the Subcontractor's premises and the Design-Builder's premises that subcontracted product or service conforms to specified requirements. Such verification shall not be used by the Design-Builder as evidence of effective control of quality by the Subcontractor.

When specified in the Contract Documents, the LA DOTD shall have the right of access to the Design-Builder and/or Subcontractor facility to inspect, audit, or otherwise verify the specified procurement/purchasing requirements are being fulfilled. The right of access may be extended to authorized personnel and contracted third parties. The Design-Builder is obligated to perform verification actions regardless of what the LA DOTD does. The LA DOTD's verification may not be substituted for the Design-Builder's actions.

Verification by the LA DOTD shall not absolve the Design-Builder of the responsibility to provide acceptable product or service nor shall it preclude subsequent rejection by the LA DOTD.

The Subcontractors shall be responsible for fulfilling all of the specified procurement requirements regardless if the LA DOTD, Design-Builder, or agent thereof performed any tests or inspections. The Design-Builder shall provide the LA DOTD an acceptable product or service regardless of the extent of the LA DOTD's verification. Even if the LA DOTD has performed verification actions at the Design-Builder's facilities, the product may still be rejected if it is not acceptable.

DB 113-2.7 Control of Louisiana Department of Transportation and Development-Supplied Items

The Design-Builder shall establish and maintain documented procedures for the control of verification, storage, and maintenance of any LA DOTD-supplied items provided for incorporation into the supplies or for related activities. Any such item that is lost, damaged, or is otherwise unsuitable for use shall be recorded and reported to the LA DOTD (*see* DB Section 113-2.16).

One of the most significant products provided to the Design-Builder by the LA DOTD is design information in the form of Plans and Specifications as well as proprietary information, and these items shall be protected with the same vigilance as any hardware items supplied. Any apparent deficiency or ambiguity shall be identified to the LA DOTD for its necessary action.

The technical characterizations of the site, such as, the boring log or soil report data supplied by the LA DOTD for consideration in designing the structural system for the product are examples of the LA DOTD-supplied products for the structural consultant.

When such items are encountered documented procedures shall exist which detail the receipt/acceptance, storage, and maintenance (preservation) of these items.

When items are considered inadequate for the task required documented procedures shall detail the process used to report such deficiencies to the LA DOTD.

DB 113-2.8 Product Identification and Traceability

Where appropriate, the Design-Builder shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery, and installation.

This means that the Design-Builder shall establish and maintain documented procedures whereby items of Work for which records are to be kept shall be identifiable. Examples of this on a construction site include the numbering of concrete pours in a structure or the establishment of a grid matrix for identifying columns.

The Design-Builder shall include the document title, the unique number, the LA DOTD's name, the Design-Builder's name, the preparer's name, and the date and revision number on all Project deliverables.

The filing and retrieval of operating manuals, certificates of compliance and/or analysis, heat numbers, inspection status, and nonconforming product shall be traceable to the items. Records shall be kept that identify the installed location of the Equipment.

Where and to the extent that traceability is a specified requirement, the Design-Builder shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (*see* DB Section 113-2.5).

The intent of this DB Section 113-2.8 is to ensure the Design-Builder can effectively identify the root cause of a problem and implement effective corrective and preventive actions to resolve and prevent future occurrences of the problem.

DB 113-2.9 Process Control

The Design-Builder shall plan and control the Work and prepare a documented process plan defining how Work is to be carried out. Documentation may be in the form of a narrative, flow chart, or control points.

The Design-Builder shall identify and plan the production, installation, and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

- A) Documentation of procedures defining the manner of production, installation, and servicing where the absence of such procedures could adversely affect quality. This requirement deals with the planning and control of all Work processes other than design control processes that are critical to the adequacy of the delivered Project;

- B) Establishment and documentation of the method(s) for scheduling, monitoring, and reporting on the status of each significant aspect of the design or other Project tasks. The methods shall be consistent with the size and complexity of the effort. Such schedules shall identify required inputs from others and submittals to the LA DOTD and to relevant government authorities;
- C) An assessment by the Design-Builder of this requirement. The key phrase of this requirement is "where the absence of such procedures could adversely affect quality";
- D) Use of suitable production, installation, and servicing Equipment and a suitable working environment;
- E) Compliance with reference standards/codes, quality plans, and/or documented procedures. Referenced standards shall be available to the people at the location where the Work is to be performed to ensure compliance to the specified requirements;
- F) Monitoring and control of suitable process parameters and product characteristics;
- G) The approval of processes and Equipment, as appropriate. Procedures shall identify who has the responsibility, authority, and expertise for the approval of various processes to ensure their adequacy;
- H) Criteria for workmanship which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples, or illustrations); and
- I) Suitable maintenance of Equipment to ensure continuing process capability.

DB 113-2.10 Inspection and Testing

DB 113-2.10.1 General

The Design-Builder shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the Project are met. The required inspection and testing and the records to be established shall be detailed in the Quality Plan or documented procedures, and shall be consistent with DB Section 112 and LA DOTD's Construction Quality Assurance Program (CQAP) for design-build projects.

This section shall address inspection/testing methodology, methods of control, documentation, acceptance, and distribution of results.

Written procedures are required. In general, QC inspections shall be performed to written criteria with specified levels of acceptability based on clearly defined accept/reject criteria. Reports shall be signed and dated by QC inspection personnel and results clearly indicated.

The Design-Builder shall establish, document, and maintain procedures for inspection and testing activities.

Quality Control inspection and testing shall be performed in accordance with written procedures developed by the Design-Builder or the proper issue of test procedures issued by industry, government, and/or code bodies available to test personnel.

Verification of compliance with Specifications and/or requirements by means of inspection and testing is required at the following times:

- A) On receipt of Materials;
- B) At intermediate stages; and
- C) When Work is completed.

The criteria for compliance are defined in the Contract, as are appropriate sampling and testing requirements.

Checkpoints and hold points (Work that must be inspected and approved by the assigned QC inspector before Work can proceed) shall be clearly established and identified on the Project execution schedule or other suitable means. Quality Control inspection procedures, logistics, and reporting of results shall be clearly defined, developed, and implemented.

DB 113-2.10.2 Incoming Product Inspection and Testing

The Design-Builder shall ensure that incoming product is not used or processed (except in the circumstances described in DB Section 113-2.10.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of the specified requirements shall be in accordance with the Quality Plan and/or documented procedures.

The Quality Plan shall include incoming product inspection that shall include, but not be limited to, the following:

- A) Documentation review;
- B) Physical inspection of Materials and/or Equipment;
- C) Identification of items as per the purchase order and shipping list, tag number, or marking;
- D) Verification of quantity and size;
- E) Dimensional checks, when applicable;
- F) Verification of protective coatings, if applicable; and
- G) Examination of item(s) for condition and shipping damage.

The Design-Builder shall maintain an adequate checking and approving procedure to ensure that all its Work, including, the monitoring, testing, and approving of such Work at the head office and on-site, meets the LA DOTD's requirements and the Contract.

In determining the amount and nature of receiving inspection, the Design-Builder shall consider the amount of control exercised at the Subcontractor's premises and the recorded evidence of conformance provided.

DB 113-2.10.3 In-Process Inspection and Testing

The Design-Builder shall provide the following functions:

- A) Inspect and test the product as required by the Quality Plan, CQMP and/or documented procedures; and

- B) Hold product until the required inspection and tests have been completed or necessary reports have been received and verified.

DB 113-2.10.4 Final Inspection and Testing

The Design-Builder shall jointly conduct all final inspection and testing with the LA DOTD in accordance with the Contract requirements and the Quality Plan, CQAP and/or documented procedures to complete the evidence of conformance of the finished Project to the specified requirements.

The Design-Builder shall have documented procedures to ensure that the final observation and testing where applicable have been completed.

Records of final inspection and tests are required to verify compliance to specified requirements has been achieved (*see* DB Section 113-2.16).

The Quality Plan, CQAP and/or documented procedures for final inspection and testing shall require that all specified inspections and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

DB 113-2.10.5 Inspection and Test Records

The Design-Builder shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (*see* DB Section 113-2.13).

Inspection and test records for inspections and tests performed by the Design-Builder, the LA DOTD, and/or a third party shall show whether the product has passed or failed according to defined acceptance criteria. Product that fails inspection becomes nonconforming product. Also, the records shall identify the inspection authority responsible.

DB 113-2.11 Control of Inspection, Measuring, and Test Equipment

DB 113-2.11.1 General

The Design-Builder shall establish and maintain documented procedures consistent with the LA DOTD's Construction Quality Assurance Program (CQAP) for design-build projects to control, calibrate, and maintain inspection, measuring, and test Equipment (including test software) used by the Design-Builder to demonstrate the conformance of product to the specified requirements. Inspection, measuring, and test Equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references, such as test hardware, are used as suitable forms of inspection they shall be checked to prove that they are capable of verifying the acceptability of product prior to release for use during production, installation, or servicing and shall be rechecked at prescribed intervals. The Design-Builder shall establish the extent and frequency of such checks and shall maintain records as evidence of control (*see* DB Section 113-2.16).

Where the availability of technical data pertaining to the measuring Equipment is a specified requirement such data shall be made available when required by the LA DOTD for verification that the measuring Equipment is functionally adequate.

Effective test procedures shall contain comprehensive listings of required Equipment, tools, and apparatus to successfully and conclusively perform the test. Matters of "repeatability" and "reproduceability" shall also be addressed, together with precision of measured results and calibration thresholds of measuring devices.

Comprehensive operations, maintenance, setup, and dimensional arrangements for the measuring, testing devices, and Equipment shall also be included in order to allow for their practical layout and installation at the measuring location. The Design-Builder shall establish, document, and maintain procedures for the control of inspection, measuring, and test equipment. It shall be the Design-Builder's responsibility through its Quality Manager to assess the Subcontractor (*see* DB Section 113-2.6.2) to ensure the required procedures exist and are implemented.

The Design-Builder shall be responsible for ensuring applicable requirements of this DB Section 113 are addressed.

This DB Section 113-2.11 applies to inspection or testing and surveying Equipment. The Quality Plan shall address the following:

- A) Definition of the responsibility and authority for the inspection, measuring, and test Equipment;
- B) Procedures for selecting measurements, determining accuracy and precision required, and obtaining Equipment which meets those requirements;
- C) Disposition of nonconforming Equipment;
- D) Procedures for identification, maintenance, and storage of measuring Equipment;
- E) Record keeping;
- F) Calibration frequency;
- G) Calibration status including indicators;
- H) Disposition of items checked with Equipment found to be out of calibration; and
- I) Traceability of primary and secondary calibration standards.

DB 113-2.11.2 Control Procedure

The Design-Builder shall provide the following function:

- A) Determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring, and test Equipment that is capable of the necessary accuracy and precision;
- B) Identify all inspection, measuring, and test Equipment that can affect product quality and calibrate and adjust them at prescribed intervals or prior to use against certified Equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the Design-Builder shall document the basis used for calibration;

- C) Develop a master calibration listing indicating the inspection and test Equipment that is used. The log shall include at a minimum the identification number, item description, and required frequency of calibration and accuracy requirements. It is not intended that calibration is required for non precision tools and instruments, such as, measuring tapes, concrete slump cones, rulers, and weld radius gauges;
- D) Define the process employed for the calibration of inspection, measuring, and test Equipment, including, details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory;
- E) Identify inspection, measuring, and test Equipment with a suitable indicator or approved identification record to show the calibration status;
- F) Maintain calibration records for inspection, measuring, and test Equipment (*see* DB Section 113-2.16);
- G) Assess and document the validity of previous inspection and test results when inspection, measuring, or test Equipment is found to be out of calibration;
- H) Ensure that the environmental conditions are suitable for the calibrations, inspections, measurements, and tests being carried out;
- I) Ensure that the handling, preservation, and storage of inspection, measuring, and test Equipment is such that the accuracy and fitness for use are maintained; and
- J) Safeguard inspection, measuring, and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

DB 113-2.12 Inspection and Test Status

The inspection and test status of product shall be identified by suitable means which indicate the conformance or nonconformance of product with regard to the inspection and test performed. The identification of inspection and test status shall be maintained as defined in the Quality Plan and/or documented procedures throughout production, installation, and servicing of the product to ensure that only product that has passed the required inspections and tests is dispatched, used, or installed.

The Design-Builder shall establish, document, implement, and maintain an effective system for identifying and implementing the inspection and test status of Project products and services. The system shall utilize a method to identify conforming, nonconforming, indeterminate, downgraded, scrap, and rejected Material.

Lack of nonconformance identification shall not be an indication of acceptance.

DB 113-2.13 Control of Nonconforming Product

DB 113-2.13.1 General

The Design-Builder shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming product and for notification to the functions concerned.

There shall be documented procedures to assess nonconformance in the Design-Builder's Work and in the work provided by other contractors, including the LA DOTD. The procedures shall safeguard against use of inaccurate or otherwise inappropriate information or data.

The procedures shall identify the individual(s) responsible for verifying the nonconformance, documenting it, processing the documentation in accordance with the procedures, and determining the effective corrective action/preventive action (*see* DB Section 113-2.14) to resolve the nonconformance.

Procedures shall also cover nonconformances which arise during construction. The procedures shall address the situation where it is discovered that Work does not conform to the requirements after the Work item has previously been subjected to the established checking and approval process. The procedures shall also address Work that is discovered or suspected to contain errors or omissions after delivery to the LA DOTD.

Work shall be immediately brought under control to limit the impact it could have on associated Work where it may have been used as input. Procedures shall include methods to inform those to whom the nonconforming Material had been provided as valid information and to retrieve and isolate from use known copies of the Material until a determination can be made about how to proceed. Nonconformances might be manifested as incorrect plans, errors in calculation (numerical or procedural), survey data that might be based on an incorrect benchmark or route, or even a correct design based on superseded Specifications.

DB 113-2.13.2 Review and Disposition of Nonconforming Product

The Design-Builder shall define the responsibility for review and authority for the disposition of nonconforming product.

A nonconformance shall be defined as any condition in Equipment, Materials, or processes which does not comply with required Plans, Specifications, codes, standards, documentation, records, procedures, or Contract requirements which cause the acceptability of Equipment, Materials, or processes to be unacceptable or indeterminate.

Nonconforming product shall be reviewed in accordance with documented procedures. The review may result in the following:

- A) Rework to meet the specified requirements;
- B) Acceptance with or without repair by consent of the Louisiana Department of Transportation and Development;
- C) Regard for alternative applications; or
- D) Rejection or scrapping.

The procedures shall also address the disposition of nonconforming items and the steps necessary to verify that the nonconformances have been adequately addressed and that the item then be characterized as conforming.

Where required by the Contract, the proposed use or repair of product which does not conform to specified requirements shall be reported for consent by the LA DOTD. The description of the nonconformity that has been accepted and repairs shall be recorded to denote the actual condition (*see* DB Section 113-2.16).

The Design-Builder shall keep and maintain records of nonconforming findings (*see* DB Section 113-2.16). Also, each nonconformance record shall contain all deliberations, retesting, resolution activities, findings, and decisions.

Repaired and/or reworked product shall be re-inspected in accordance with the Quality Plan and/or documented procedures.

Repair shall require the involvement of the LA DOTD, the Designer, and/or an authorized third party to review the condition and determine that although it does not meet the specified requirements, the overall impact is such that the resulting condition is acceptable.

DB 113-2.14 Corrective and Preventive Action

DB 113-2.14.1 General

The Design-Builder shall establish and maintain documented procedures for implementing corrective and preventive action.

This DB Section 113-2.14 encompasses two aspects of dealing with nonconformities. The first is implementation and effectiveness of previously implemented corrective actions.

The second is preventive action, which plays a major role in this requirement. Most procedures addressing corrective action need to include preventive action. The investigation of nonconformances needs to look into three possible causes. They are the product, the process, and the quality system.

These nonconformances may be identified by either internal or external audits or during regular inspections or Design Reviews. The appropriate authority to implement, verify, and review the effectiveness of both preventive and corrective actions shall be identified. Written procedures shall be prepared and implemented to determine the root causes of nonconformances and to revise existing procedures and Work instructions or to establish new ones to prevent the identified situations that cause or allow nonconformances to develop.

Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The Design-Builder shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

DB 113-2.14.2 Corrective Action

The Design-Builder shall maintain and document a procedure for dealing with complaints ensuring the recording, investigating, and determining of the appropriate corrective action, if any, that shall be taken.

The procedures for corrective action shall include the following:

- A) The effective handling of complaints and reports of product nonconformities;
- B) Investigation of the cause of nonconformities relating to the product, process, and quality system and recording the results of the investigation (*see* DB Section 113-2.16);

- C) Determination of the corrective action needed to eliminate the cause of nonconformities;
- D) Application of controls to ensure that corrective action is taken and that it is effective; and
- E) The tracking of complaints and identified nonconformance and the actions taken to resolve them as an indicator of the effectiveness of the quality system.

Determination and implementation of an effective corrective action requires knowing the root cause of the problem and planning the most effective method of resolving the problem.

Follow-up action shall investigate to see if the corrective action resolved the identified problem and also to ensure the corrective action did not have an undesirable effect on another element of the quality system.

DB 113-2.14.3 Preventive Action

The Design-Builder shall establish, document, and maintain procedures for implementing preventive actions.

The procedures for preventive action shall include the following:

- A) The use of appropriate sources of information, such as processes and Work operations, which affect product quality, concessions, audit results, quality records, service reports, and the complaints to detect, analyze, and eliminate potential causes of nonconformities;
- B) Determination of the steps needed to deal with any problems requiring preventive action;
- C) Initiation of preventive action and application of controls to ensure that it is effective; and
- D) Confirmation that relevant information on actions taken is submitted for management review (*see* DB Section 113-2.1.3).

DB 113-2.15 Handling, Storage, Packaging, Preservation, and Delivery

DB 113-2.15.1 General

The Design-Builder shall establish and maintain documented procedures for handling, storage, packaging, preservation, and delivery of product.

The procedures which shall be developed apply to all parties involved on a Project beginning with the Design-Builder writing the Specifications all the way through to the personnel responsible for the start up and turnover of the facility to the LA DOTD. The specific application of the requirements is determined by the function performed: Design-Builder, manufacturer, distributor, vendor, warehousing, Equipment operator, and installer.

The engineer writing the Specifications shall be responsible for identifying any special handling, storage, packaging, preservation, and delivery requirements and assuring the requirements are identified in the appropriate Project documents. Procurement shall be responsible for assuring the vendor, distributor, and/or Subcontractors are aware of the requirements and are also aware of their responsibilities to identify all requirements to their Subcontractors.

Procedures shall be developed and implemented for designating which items require special handling, storage, or maintenance. Development of the handling, storage, packaging, preservation, and delivery procedures and Work instructions are affected by the other elements of this DB Section 113 and therefore should be reviewed for applicability and requirement inclusion.

DB 113-2.15.2 Handling

The Design-Builder shall provide methods of handling products that prevent damage or deterioration.

Handling is any physical or electronic movement. Project Materials are usually handled numerous times from producer to installation and start up. Procedures appropriate to the circumstances shall be developed and implemented to assure handling is done in a manner that prevents damage or deterioration of the material/equipment. There shall be assurances that handling requirements are documented and understood.

The procedures shall cover special handling by people and/or machines.

Special handling clothing and precautions shall be identified for all hazardous materials with assurances that only qualified and trained personnel handle the hazardous material. The handling procedures shall include instructions to follow for decontamination and notification of authorities and responsible parties in the event of an accident.

DB 113-2.15.3 Storage

The Design-Builder shall use designated storage areas or stock rooms to prevent damage or deterioration of product pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.

In order to detect deterioration the condition of product in stock shall be assessed at appropriate intervals.

Items requiring protection shall be identified and protected as necessary to prevent loss, damage, deterioration, or loss of identification.

Special storage requirements shall be clearly defined for Materials and Equipment which are received on the Project, including, plans, records and operating manuals. A master list shall be maintained indicating applicable purchase orders, including, quantity, product identification, documentation and records required, receiving inspection requirements, and items requiring special storage or maintenance.

Materials shall be segregated to prevent cross contamination or environmental contamination.

Material with limited shelf life shall be identified and procedures developed and implemented to identify means of assuring usage of Material prior to its expiration date. The procedures shall also identify the disposal of Materials that may be toxic or hazardous or might otherwise have an adverse effect on the environment or on unsuspecting humans.

DB 113-2.15.4 Packaging

The Design-Builder shall control packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

Engineering or procurement documents shall specify applicable packaging requirements to ensure no damage, contamination, or deterioration occurs in the course of packaging and transporting the Material and Equipment. Procedures/Work instructions shall clearly define all special packing and packaging and marking process requirements (i.e., export crating, moisture barrier, regulatory requirements, climate control, identification, and all Contract requirements).

Labeling of hazardous materials, special handling instructions, and notification of authorities and the Design-Builder shall be clearly and plainly identified on the packaging.

DB 113-2.15.5 Preservation

The Design-Builder shall apply appropriate methods for preservation and segregation of product when the product is under the Design-Builder's control.

Procedures shall include special unpacking instructions, controlled conditions necessary to prevent or deter deterioration of Material or Equipment, prevention of corrosion and/or contamination, and required servicing.

DB 113-2.15.6 Delivery

The Design-Builder shall arrange for the protection of the quality of product after final inspection and testing. Where contractually specified, this protection shall be extended to include delivery to the destination.

When delivery of Equipment and/or Materials to the job site is the responsibility of the Design-Builder, it shall develop procedures or reference appropriate standards to protect the items during delivery.

DB 113-2.16 Control of Quality Records

The Design-Builder shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the Subcontractor shall be an element of these data.

Records shall be kept of documents which serve as evidence that quality is achieved in Work on the Project. Records shall be adequately identified, filed, and stored. Retention periods and the storage medium of such records shall be established in accordance with Contract requirements.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Quality records shall be made available for evaluation by the LA DOTD as per Contract requirements.

The Design-Builder shall develop and implement procedures to store, retrieve, and dispose of the documents required by the quality management system, including, but not limited to, correspondence, certifications, design calculations, Plans, reports of Design Reviews, and audit reports. In storage, whether active Project files or long term archives, documents that are designated as records shall be originals or reproducible copies and shall be legible, accurate, identified, and indexed so they can be

associated with specific Projects. Documents shall be retrievable in a timely manner. Storage criteria shall be set to specify allowable storage media and ensure physical protection from damage or loss, which could involve duplicate storage facilities for some types of records.

Management shall identify records necessary to provide objective evidence of Contract review, procedure compliance, Design Review (when applicable), training, and completion and acceptance of inspection and testing or to provide traceability of Equipment or items to documentation.

A list of Project-required records shall be developed, retained, and/or turned over to the LA DOTD prior to completing the Work.

DB 113-2.17 Internal Quality Audits

The Design-Builder shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits shall be conducted in accordance with sound auditing principles. The frequency of the audits shall be appropriate to the importance and complexity of a Project or corporate operation but shall at least be on a quarterly basis. Audits shall be initiated early enough in the life of a Project to assure effective QC during all phases. The audits shall include Project management as well as technical Work activities.

Internal quality audits shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The internal quality audit program shall provide verification that the quality system is operating and being implemented as planned. Audits should be conducted on a planned and scheduled basis consistent with the importance of the activities being performed.

The results of the audits shall be recorded (*see* DB Section 113-2.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (*see* DB Section 113-2.16).

The results of internal quality audits shall be reviewed in management review meetings. In accomplishing management review the results of internal audits and their attendant corrective action status shall be reviewed for adequacy and effectiveness.

Auditor qualifications shall be established and documented by the Design-Builder. Staff assigned auditing tasks shall be qualified accordingly with qualification records maintained as quality records. Auditing need not be a full time assignment but staff assigned auditing tasks shall have no direct responsibilities for the function or Work they audit.

Audits shall be carefully planned and executed to avoid or minimize disruption of the audited activity. Results shall be provided promptly to personnel responsible for the audited activity and their management. Corrective action shall be developed to identify the root causes and to institute measures to prevent the types of deficiencies identified in the audit. Corrective actions shall be monitored through

review of documents, surveillance, or follow-up audits. These actions should be conducted in a timely manner to determine the effectiveness of corrective action that is implemented. Records of corrective actions should be kept together with the respective audit records.

Records of internal audits shall be maintained by the Design-Builder.

DB 113-2.18 Training

The Design-Builder shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training, and/or experience, as required. Appropriate records of training shall be maintained (*see* DB Section 113-2.16).

The Design-Builder shall establish documented procedures and records to ensure that the skills and professional judgment of its personnel are developed appropriately for their intended roles through training and/or the recorded accumulation of experience, with systematic reviews of their competence at determined levels, and before any deployment of new roles.

Training shall focus on improving competency and skill for those performing activities that materially impact quality.

Procedures established shall include the following:

- A) Position descriptions defining the requirements of the various positions required in conducting activities affecting quality;
- B) Personnel records documenting each person's experience and current education and training accomplished, both formal and informal, relative to current or projected position assignments;
- C) Documented evaluation of that experience and training, including a determination of what training is required to become fully qualified for the activities to which the person is intended to be assigned;
- D) A documented plan to accomplish the training deficiency;
- E) Records documenting accomplishment of that training; and
- F) Education, experience, and licensure used as a basis for qualifications of individuals, which should be verified.

All qualification and training records are quality records and shall be maintained accordingly (DB Section 113-2.16).

Project personnel shall be trained in all the special Project procedures applicable to their Work.

Craft journeymen with special skills need not be trained but their competency shall be verified and a record maintained of the verification.

DB 113-2.19 Servicing

Where servicing is a specified requirement, the Design-Builder shall establish and maintain documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.

The requirement of this DB Section 113-2.19 is applicable only where it is specified in a Contract.

Should such a requirement exist the Design-Builder shall document procedures which detail the methodologies to be used while performing the service, how compliance to these operations and the LA DOTD's requirements are verified, and the agreed upon method of reporting compliance of service operations to Contract requirements.

With respect to the design perspective this requirement deals with the service rendered to the LA DOTD during the defects liability period, if any.

DB 113-2.20 Statistical Techniques

DB 113-2.20.1 Identification of Need

The Design-Builder shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics consistent with LA DOTD's Construction Quality Assurance Program (CQAP) for design-build projects.

The Design-Builder shall review its operations for activities which may benefit from the use of statistical techniques as a means of establishing a level of control, the maintenance of an existing level of performance, and the verification of performance. The needs assessment could include determining an activity impact on cost, time management/utilization, and quality of deliverables. It could also identify areas where the application of statistics would provide an indication of variation, activities efficiencies, and deviation control.

DB 113-2.20.2 Procedures

The Design-Builder shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified pursuant to DB Section 113-2.20.1.

Should the need for statistical programs be established the Design-Builder shall document procedures detailing the methods to be applied.