




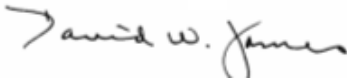
<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 1 of 24



**DW JAMES CONSULTING**  
**855 Village Center Drive #330**  
**North Oaks, Minnesota 55127 USA**

## QUALITY ASSURANCE PROGRAM

### Review and Approval:

	Print Name	Signature	Date
Prepared By:	Thomas M. Kalinowski		6/26/2007
Reviewed By:	Robert A. Snyder		6/26/2007
QA Review By:	Thomas M. Kalinowski		6/26/2007
Approved By:	David W. James		6/26/2007
	President		

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 2 of 24

## **RECORD OF CHANGES**

<b>Revision Number</b>	<b>Date of Revision</b>	<b>Summary of Revision</b>
0	June ?, 2007	Initial issue of manual

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 3 of 24

**TABLE OF CONTENTS**

Purpose..... 4

Scope..... 5

1. Organization..... 5

2. Quality Assurance Program ..... 6

3. Design Control ..... 7

4. Procurement Document Control..... 12

5. Instructions, Procedures and Drawings..... 12

6. Document Control ..... 13

7. Control of Purchased Material, Equipment and Services ..... 14

8. Identification and Control of Materials, Parts and Components ..... 16

9. Control of Special Processes ..... 17

10. Inspection ..... 17

11. Test Control..... 18

12. Control of Measuring and Test Equipment ..... 19

13. Handling, Shipping and Storage..... 20

14. Inspection, Test and Operating Status ..... 20

15. Non-Conforming Materials, Parts and Components ..... 20

16. Corrective Action ..... 21

17. Quality Assurance Records..... 22

18. Audits ..... 23

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 4 of 24

## Purpose

This Quality plan has been developed to ensure that the products and services provided by DW James Consulting, LLC meet applicable regulatory and industry standards and contract requirements. DW James Consulting, LLC is committed to delivering high quality products and services to all of our customers. Quality is an integral part of the planning, design, and implementation of our products and services. This Quality Plan consists of those planned and systematic actions necessary to assure confidence that all Quality related activities will be conducted in a satisfactory manner.

Activities performed as part of the delivery of quality products and services shall be controlled appropriately to ensure that customer, regulatory, and industry requirements are met. Management expects all of the company's employees to take an active role in achieving quality objectives and to inform management of conditions, which require attention. The input of our employees is an important contributor to our success. The Company President shall maintain an open door policy and encourage all employees to report any concerns they may have with Quality related issues.

Some of the functions mandated by this program may be subcontracted to third parties under consulting or associate agreements. DW James Consulting, LLC will retain responsibility to ensure that such functions are completed in accordance with the procedures covered by this Quality plan.

DW James Consulting, LLC has established a Graded Approach to Quality Assurance to efficiently implement quality standards for activities based on importance to quality and safety. Several factors are considered when determining the required level of quality assurance. These factors include; Federal and State Regulations, State Licensing Conditions, customer commitments, contract commitments and worker and general public health and safety issues. Various activities within a process may require a high level of quality assurance due to their impact on quality and safety. Other activities within the same process may have an impact on quality and safety to a lesser degree and therefore, a lower level of quality assurance may apply.

The Quality plan shall ensure that activities affecting quality are accomplished in accordance with the standards relative to the activity's importance to quality and safety and that all prerequisites for the given activity have been satisfied. The Quality plan shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required objective and the need for verification of quality by inspection and testing.

Specific procedures will be developed to describe the detailed steps required to assure quality. These procedures generally include all necessary instructions, including qualifications needed to perform the task. The procedures will also include necessary inspection or testing hold points.

Senior Management of DW James Consulting, LLC has established this Quality Policy as a means of leading the Company toward continuous improvement. The Quality

DW James Consulting. LLC			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 5 of 24

Policy is to be used as a guide for all actions, efforts and strategies of the company's employees. The Quality Policy of DW James Consulting, LLC is as follows:

We are committed to achieving our goal of customer satisfaction by:

- Meeting or exceeding our customer's requirements
- Maintaining high standards for quality, safety and regulatory compliance
- Achieving excellence in all of our efforts
- Establishing clear, consistent and comfortable communications between the Company, the employees and the customer to form a team to deliver the quality product and services that are expected.

## Scope

This Quality Plan applies to work performed by DW James Consulting, LLC that may be defined as 'Important-to-Safety' by applicable regulatory codes and standards or otherwise treated as such by customer quality plans. These activities are governed by rules set forth in 10CFR Part 20 Appendix G which requires a quality assurance program to assure compliance with 10CFR Part 61.55 and 10CFR Part 61.56, "Waste Classification" and "Waste Characteristics", respectively.

The products and services include but are not limited to the following:

- Radiological characterization of radioactive wastes.
  - Performance of calculations to determine the radionuclide content of the waste components.
  - Development of package plans used for determining the total package content and demonstrating disposal classification in accordance with 10CFR61 and NRC guidance documents.
  - Development of waste description documents used for transport and disposal records.
- Preparation of Radioactive Material / Waste transportation documentation.
- Development of software related to the activities identified in this section.
- Development of Training programs related to the activities identified in this section.

## 1. Organization

1.1. The Managing Members of the LLC share the authority and responsibility for all Company functions. This authority may be delegated to other personnel for selected functions. However, the Managing Members shall retain responsibility for conformance to quality requirements for all delegated activities.

DW James Consulting. LLC			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 6 of 24

- 1.2. Certain positions will have specific responsibilities to ensure proper implementation of the Quality Assurance Program. The individual responsible for implementing Quality Assurance functions shall be different and independent from the individual responsible for developing the product or service to be validated. If the designated Quality Assurance individual is not a Managing Member, then he/she shall report to a Managing Member other than the one responsible for the product or service to be validated.
- 1.3. All personnel performing quality assurance functions shall have the authority and organizational freedom to:
  - 1.3.1. Identify quality problems.
  - 1.3.2. Initiate, recommend, or provide solutions.
  - 1.3.3. Verify the implementation of solutions.
  - 1.3.4. Stop unsatisfactory work until the proper disposition of a non-conformance, deficiency or unsatisfactory condition has been accomplished.
- 1.4. All employees shall participate to ensure Quality functions are effectively implemented.

## **2. Quality Assurance Program**

- 2.1. The DW James Consulting, LLC Quality Assurance Program consists of those planned and systematic actions necessary to assure that all activities will be conducted in a satisfactory manner. Senior Management is responsible for identifying the needs (and expectations) of the customer and directing the application of the appropriate resources to fulfill those needs. Senior Management is also responsible for fostering an attitude of support and encouraging personnel to complete their work in a quality manner.
- 2.2. The Quality Assurance Program takes into consideration the regulatory requirements for activities identified as important-to-safety and safety-related. It also considers the complexity of the activity and the impact on safety, the need for special controls, the demonstration of compliance through inspections and tests and the degree of standardization of the activity or item. The requirements of the Quality Assurance Program are implemented using a graded approach allowing control over items and activities to be commensurate with their importance and level of risk and are not reductions in quality requirements. During the planning of an activity or design on an item, the Quality Assurance Plan requirements will be implemented through procedures.
- 2.3. The Quality Assurance Program is implemented through the use of written procedures that will establish a planned and disciplined method to achieve the identified objectives.

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 7 of 24

- 2.3.1. This document defines the overall approach to achieve quality.
- 2.3.2. Additional procedures, specific to the activities to be executed, will be developed. These procedures shall define the specific Quality Assurance Criteria applicable to the activity
- 2.3.3. Procedures developed for specific activities shall evaluate and consider requirements from the following:
  - A. Regulatory guidance.
  - B. Engineering specifications and standards.
  - C. Company policies and procedures.
  - D. Specific provisions or contractual agreements.
- 2.3.4. Quality Assurance activities include independent verification such as audits, inspections and process oversight to ensure activities affecting our services have been correctly performed.
- 2.4. Individuals performing activities affecting Quality will be trained and evaluated in accordance with applicable standards, procedures or instructions. These individuals shall be approved by appropriate Management as required.
- 2.5. The adequacy and effectiveness of the implementation of the Quality Assurance Program and procedures shall be assessed on an annual basis. This assessment shall be documented.

### **3. Design Control**

- 3.1. Design activities involving systems, components or software that are 'Important-to-Safety' shall be planned, implemented and controlled in accordance with approved procedures to ensure that applicable technical, regulatory and customer requirements are correctly applied. Design activities shall be independently reviewed by an appropriate level of management prior to verify the adequacy of the design.
- 3.2. Design Input.
 

Applicable design inputs shall be identified and documented and their selection reviewed and approved. Design inputs shall provide the necessary level of detail to ensure the design activity can be carried out correctly and provide a consistent basis for making decisions, accomplishing design verification and evaluating changes.

  - 3.2.1. Design inputs include:
    - A. Design basis;
    - B. Performance requirements;
    - C. Regulatory requirements;

DW James Consulting. LLC			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 8 of 24

- D. Customer specifications;
- E. Industry codes and standards;
- F. Technical requirements.

3.2.2. Changes from approved design inputs, including the reason for the changes shall be documented, approved and controlled.

### 3.3. Design Process

Design activities shall be documented to the level of detail necessary to permit the design process to be carried out in a correct manner and to permit verification that the design meets the specified requirements. Appropriate design documents should contain information adequate to support the design, construction / manufacture and operation of the product and include appropriate Quality standards. Measures shall be established for selection and review for suitability of application of materials, parts, equipment and processes. These measures include provisions to assure quality standards are specified and included in design documents. Any deviations for these standards are documented, reviewed and approved.

### 3.4. Design Analysis

Design analysis is performed and documented in accordance with approved procedures. Design analysis reports provide details of (where applicable):

- 3.4.1. The objective of the analysis;
- 3.4.2. Design inputs and their sources;
- 3.4.3. Literature research and background data;
- 3.4.4. Assumptions and designation of those that must be verified as design proceeds;
- 3.4.5. Calculation methodology and calculations;
- 3.4.6. Summary of results and compliance requirements;
- 3.4.7. Identification of computer calculations, including computer hardware and software;
- 3.4.8. Review and approval s specified in procedures.

### 3.5. Design Verification

3.5.1. Design verification is performed to ensure that appropriate requirements and customer needs are translated to the design documents. Design verification is performed in accordance with approved procedures that define responsibilities, methods, and documentation requirements. Independent personnel who have qualifications equal to those of the original design personnel perform design verification. This could include

DW James Consulting. LLC			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 9 of 24

an engineering supervisor who initiated the design provided he/she did not specify a singular design approach or rule out certain design considerations. No individual is ever the verifier for his / her own work or input.

3.5.2. The design verification method is based on regulatory and contractual requirements, level or complexity of the design and “state-of-the-art” considerations. The level of design verification applied complies with the identified requirements. Design verification methods include, but are not limited to:

- A. Formal design reviews;
- B. Alternate calculations;
- C. Qualification testing.

3.5.3. Design verification is usually performed prior to the release of the design output document for production uses or process implementation. This includes resolution of any identified discrepancies. An exception would be cases where insufficient data exists to finalize the design at a point in the project where material procurement or preliminary facility construction must begin. In such cases, unverified portions of the design are identified and controlled. Final design verification is completed prior to reliance on the item or process to perform its function. Appropriate Management shall document completion of design verification.

### 3.6. Design Changes

Changes to final design, field changes, and modifications are justified and subject to design control measures commensurate with those applied to the original design. These measures shall include assurance that the design analyses for the items are still valid. Where changes to previously verified designs have been made, the initial design verification shall be reviewed for the impact of the changes to the original design and the need for any supplementary design verification shall be determined. Changes are approved by the same group or organization responsible for review and approval of the original design documents.

### 3.7. Interface Control

Formal design interfaces are established when multiple organizations (internal or external) participate in the design process. Procedures are written that establish and document responsibility and authority for transmittal, review, approval, release, distribution, and revision of design inputs and design output documents. Transmittals shall indicate the status of design information or of documentation submitted, including any incomplete items that require further actions.

DW James Consulting. LLC			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 10 of 24

### 3.8. Computer Programs

Computer programs (whether generated, transferred, or purchased) used to calculate or develop important-to-safety and safety-related data shall be subjected to documented verifications or validations, including evaluation of program changes. Computer programs may be used for design analysis without individual verification of the program for each application provided:

- 3.8.1. The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed;
- 3.8.2. The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

### 3.9. Software Design

Software design shall follow the pattern of documentation and control for a design process described above.

- 3.9.1. Software design requirements shall be documented and their selection reviewed and approved. Software design requirements shall identify:
  - A. The operating system;
  - B. Function;
  - C. Interfaces;
  - D. Performance requirements;
  - E. Installation considerations;
  - F. Design inputs;
  - G. Constraints of the computer program.
- 3.9.2. Software design shall be documented and shall define the computational sequence necessary to meet the software requirements. This documentation may be combined with the documentation of the software design requirement or the computer program listings resulting from implementation of the software design. Software design documentation shall include as applicable:
  - A. Numerical methods;
  - B. Mathematical models;
  - C. Physical models;
  - D. Control flow;
  - E. Control logic;
  - F. Data flow;

- G. Process flow;
  - H. Data structures;
  - I. Process structures;
  - J. The applicable relationships between data structures and process structures.
- 3.9.3. The software design shall be translated into computer program(s) in accordance with documented procedures.
- 3.9.4. Software design verification shall be performed by competent individuals or groups other than those who developed and documented the original design. Verification results shall be documented. Software verification methods shall include any one or combination of design reviews, alternate calculations and tests performed during computer program development. The level of verification and the methods chosen shall consider and be a function of the following:
- A. The complexity of the software;
  - B. The degree of standardization;
  - C. The similarity with previously proven software;
  - D. The importance to Safety.
- 3.9.5. Computer program testing shall be performed and accomplished in accordance with Section 11, Test Control.
- 3.9.6. Software designed and developed in accordance with this section shall be maintained under configuration management until the software is retired. Configuration management items shall include configuration identification, change control and status control.
- A. A software baseline shall be established at the completion of each activity of the software design process which will define the most recently approved software configuration. Approved changes created subsequent to the baseline shall be added to the baseline. Configuration identification methods shall establish a labeling system that:
    - I. Uniquely identifies each configuration item;
    - II. Identifies changes to configuration items by revision;
    - III. Provides the ability to uniquely identify each configuration of the revised software available for use.
  - B. Changes to software shall be formally evaluated, reviewed and approved. Appropriate verification activities and acceptance testing

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 12 of 24

shall be performed for the change. Appropriate documentation shall be maintained that identifies the change and maintains traceability to the software design requirements. The documentation shall include:

- I. A description of the change;
  - II. The rationale for the change;
  - III. The identification of affected software baselines.
- C. The status of configuration items resulting from software design changes shall be maintained current. Procedures shall establish controls that include a process for maintaining the status of changes that are proposed and approved but not implemented. The controls shall also provide for notification of this information to affected organizations.

#### **4. Procurement Document Control**

- 4.1. Procurement activities for items and services affecting Quality shall be performed in accordance with approved procedures.
- 4.2. Procurement documents shall identify, as applicable, the scope of work, technical requirements, Quality / Safety requirements, right of access, documentation requirements and reporting and disposition of non conformances of the item(s) or service(s) being procured.
- 4.3. Procurement documents for items and services affecting Quality shall be reviewed by appropriately qualified management prior to release. The review shall be adequate to assure compliance with the applicable sections of the Quality Assurance Program, procedures and / or customer requirements.
- 4.4. Changes to procurement documents shall be subject to the same level of review and approval as the original documents.
- 4.5. Selection of sources for Quality related products or services shall be in accordance with Section 7, Control of Purchased Material, Equipment and Services.

#### **5. Instructions, Procedures and Drawings**

- 5.1. Activities affecting Quality shall be performed in accordance with documented instructions, procedures or drawings as appropriate for the activity being performed.
- 5.2. Instructions, procedures or drawings will include or reference appropriate acceptance criteria for determining the activities have been correctly and satisfactorily accomplished.

DW James Consulting. LLC			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 13 of 24

5.3. When applicable, instructions, procedures or drawings will reference related codes, standards, specifications, customer requirements or other procedures.

5.4. Instructions, procedures and drawings will be reviewed, approved and controlled in accordance with Section 6, Document Control.

## 6. Document Control

6.1. Documents that prescribe or affect Quality are controlled in accordance with written procedures to ensure that the documents are adequately prepared, reviewed and issued and that proper revisions are used.

6.2. Document Control procedures will establish the appropriate control measures to assure the following:

6.2.1. Controlled documents are properly identified;

6.2.2. Controlled documents are distributed and issued to the appropriate locations;

6.2.3. Individuals responsible for preparation, review, approval and distribution are identified;

6.2.4. Controlled documents are reviewed for completeness and approval prior to distribution;

6.2.5. Changes to controlled documents are properly reviewed and issued and that obsolete documents are removed from work areas.

6.3. Major changes to controlled documents shall require the same level of review as the original document. The individuals / organizations performing the review shall have access to all pertinent background data or information regarding the change in order to adequately evaluate and approve the change. Major changes are defined as any change that is not identified as a Minor change.

6.4. Minor changes to controlled documents shall not require the same level of review and approval as the original document. Minor changes are defined as:

6.4.1. Inconsequential editorial corrections including spelling and grammar;

6.4.2. Correction of typographical errors.

6.4.3. Correction of references or definitions that do not alter the purpose, scope or requirements of the original procedure.

6.4.4. Addition of references or definitions to improve clarity that do not alter the purpose, scope or requirements of the original procedure.

6.5. A list of Controlled Documents shall be maintained describing the titles, control numbers and current revision levels.

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 14 of 24

## **7. Control of Purchased Material, Equipment and Services**

7.1. The purchase and control of Quality related materials, equipment or services shall be performed in accordance with approved procedures.

7.2. Suppliers of Quality related materials, equipment or services shall be evaluated to determine their capability to provide items or services in accordance with the requirements identified in the procurement documents. Management is responsible for determining the qualification requirements and methods for evaluation.

7.2.1. Supplier evaluations will be documented and their acceptability based on one or more of the following criteria as appropriate:

- A. The Supplier's history of providing identical or similar products / services that performs satisfactorily in actual use. The Supplier's history shall reflect current capabilities.
- B. The Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.
- C. The Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel and the implementation of the Supplier's quality assurance program.

7.2.2. Supplier evaluations are not required to be performed by DW James Consulting, LLC if any of the following conditions can be applied:

- A. The supplier is currently on the approved supplier list for similar items or services.
- B. The supplier is currently on the customer's approved suppliers list or has been specifically selected by the customer and the customer has provided documentation attesting to this approval / selection.
- C. The supplier is a nationally recognized manufacturer of test equipment and related calibration services and the calibrations services are verified prior to use of the equipment.
- D. The supplier is a regulatory agency or nationally recognized standards laboratory such as the National Institute of Standards and Technology.
- E. The supplier is certified by a regulatory agency or by a nationally recognized certification source (e.g. AIHA, NVLAP, NELAC, ISO, etc.).

7.2.3. A surveillance of the supplier's activities related to the supply of the Quality item or service may be performed in addition to or in lieu of the

requirements of Section 7.2.1 or 7.2.2. The results of surveillances must be documented. The use or need for a surveillance may be dependent on the following conditions:

- A. The complexity or uniqueness of the item / service and its importance to safety.
- B. The degree to which functional compliance can be demonstrated by receipt inspection and test.
- C. The need for special controls and surveillance over processes and equipment where verification of procurement requirements cannot be determined upon receipt.
- D. Any requirements for in-process hold points to verify continuing compliance with specifications.
- E. The availability of the supplier's quality history and / or the degree of standardization of identical items.

7.2.4. A list of approved suppliers shall be maintained. The list shall identify the supplier and the product / service qualified by the evaluation, the date of approval and the date the approval expires. Suppliers must be re-evaluated at least once every three (3) years.

7.3. Requirements to be met by the supplier are detailed in the procurement documents as specified in Section 4, Procurement Document Control. Delivered goods or services shall be evaluated against the requirements prior to acceptance. The method used for acceptance may be one or a combination of the following as is appropriate for the product / service delivered:

7.3.1. Supplier Certificate of Conformance.

7.3.2. Source Verification or Surveillance conducted in accordance with Section 7.2.3

7.3.3. Receipt Inspection.

7.3.4. Post –installation testing.

7.3.5. Where the procurement involves the supply of services only; any or all of the following may be used for acceptance:

- A. Technical verification of the data produced;
- B. Surveillance and / or audit of the activity;
- C. Review of objective evidence for conformance to the procurement document requirements.

7.4. Materials, equipment or services that do not meet procurement requirements shall not be used or implemented until the non-conformance can be evaluated

DW James Consulting. LLC			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 16 of 24

and an appropriate disposition determined. The evaluation will be performed in accordance with Section 15, Control of Nonconforming Items.

- 7.5. For commercial 'off-the-shelf' items, where specific quality assurance controls for nuclear applications cannot be imposed in a practical manner, additional quality verification requirements shall be performed to verify the acceptability of the item. The quality verification requirements shall be determined based on the design requirements and specifications for the intended use.

## **8. Identification and Control of Materials, Parts and Components**

- 8.1. Controls shall be established to ensure that only correct and accepted items are used or installed in quality related applications. These controls shall be documented in applicable design documents, instructions, procedures or drawings as may be most appropriate for the circumstance. The method of identification may be one or a combination of the following:
- 8.1.1. Item identification such as batch, lot, serial number or part number that is maintained from initial receipt up to and including installation. The identification relates the item to the applicable design or other specification document when possible.
  - 8.1.2. Other means of identification including physical separation or procedural control may be used when item identification is not possible.
  - 8.1.3. Markings may be applied using materials and methods that are clear, legible and do not detrimentally affect the function or service life of the item. Markings may be transferred to each part of an identified item when subdivided. Markings may not be obliterated or hidden by surface treatments or coatings unless other identification methods are first established.
- 8.2. Procedures shall specify methods for identification of items when codes, standards or specification require specific identification or traceability requirements (such as traceability to a specific batch, lot or serial number or to specific inspections, tests or other records).
- 8.3. Items having a limited calendar or operating life or cycle shall be identified and controlled to preclude the use of those items after the shelf life or operating life has expired.
- 8.4. Applicable procedures shall contain provisions for maintenance or replacement of markings and identification due to damage from handling, aging, excessive deterioration due to environmental exposure and for updating records while in storage.

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 17 of 24

## **9. Control of Special Processes**

- 9.1. Special processes that control or verify quality shall be performed in accordance with specific procedures or instructions. Management is responsible for identifying special processes and ensuring that appropriate the appropriate instructions are developed and qualified personnel are used.
- 9.2. Special process procedures or instructions shall specify the following:
- 9.2.1. Conditions necessary for accomplishment of the process;
  - 9.2.2. Proper equipment to be used;
  - 9.2.3. Controlled parameters of the process;
  - 9.2.4. Specified environment;
  - 9.2.5. Calibration requirements;
  - 9.2.6. Acceptance criteria for the process (based on applicable codes and standards and referenced in the procedure).

## **10. Inspection**

- 10.1. Inspection activities required to verify conformance of an item or activity to specified requirements shall be conducted in accordance with approved procedures or inspection plans. Procedures or inspection plans shall identify the following:
- 10.1.1. Characteristics to be inspected;
  - 10.1.2. Methods of inspection;
  - 10.1.3. Acceptance criteria;
  - 10.1.4. Sampling criteria when used shall be based on valid statistical methods.
  - 10.1.5. Method for documenting the inspection (such as checklists or procedures with sign-off steps). Records of inspection shall include at a minimum:
    - A. Item / activity inspected;
    - B. Date of inspection;
    - C. Name of inspector;
    - D. Type of observation;
    - E. Results or acceptability;
    - F. Reference to information or action taken in connection with non-conformances.

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 18 of 24

- 10.2. Personnel performing inspections shall be appropriately trained, qualified and / or certified as required for the activity being inspected.
- 10.3. Personnel assigned to perform quality control functions shall be persons other than those who performed the activity being inspected and shall report to a member of management not responsible for the activity being inspected.

## **11. Test Control**

- 11.1. Tests required to collect data, verify conformance of an item or computer program to specified requirements or to demonstrate satisfactory performance for service shall be planned and executed in accordance with specific procedures or instructions. The procedures or instructions shall specify the following:
- 11.1.1. Characteristics to be tested;
  - 11.1.2. Test methods to be employed;
  - 11.1.3. Prerequisites and provisions for assuring test prerequisites have been met;
  - 11.1.4. Acceptance criteria;
  - 11.1.5. Inspection hold points as applicable;
  - 11.1.6. Methods for documenting test results;
  - 11.1.7. Methods for evaluating test results to ensure test requirements and acceptance criteria have been satisfied.
- 11.2. Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements.
- 11.2.1. Tests for computer programs used for design activities shall assure that the computer program produces correct results.
  - 11.2.2. Tests for computer programs used for operational control shall assure that the computer program demonstrates the require performance over the range of operation of the controlled function.
  - 11.2.3. Procedures shall provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs or empirical data and information from technical literature.
  - 11.2.4. In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 19 of 24

- A. In-use tests shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system.
  - B. Periodic in-use manual or automatic shelf check in-use tests shall be prescribed for those computer programs in which program errors, data errors, computer hardware failures or instrument drift can affect the required performance.
- 11.2.5. Computer Program test results shall be documented and reviewed by the responsible design organization to verify the results meet design criteria.
- 11.3. Personnel performing tests shall be appropriately trained, qualified and / or certified as required for the activity being tested.

## **12. Control of Measuring and Test Equipment**

- 12.1. Tools, gauges, instruments and other measuring devices and test equipment (M&TE) used for activities affecting quality shall be controlled in accordance with specific procedures.
- 12.2. M&TE shall be calibrated at prescribed time periods or usage and whenever the accuracy of the equipment is suspect.
- 12.2.1. Calibrations shall be performed against certified equipment having known and valid relationships to nationally recognized standards.
  - 12.2.2. If no nationally recognized standards exist, the basis for calibration shall be documented.
  - 12.2.3. Calibration methods and procedures shall follow recognized industry standards (ANSI, ASME, NIOSH) as appropriate.
  - 12.2.4. Calibration intervals shall be defined and based on the type of equipment, stability characteristics, required accuracy, intended use and other conditions affecting capability.
- 12.3. Out of calibration devices shall be tagged, segregated or both and not used until they have been recalibrated. M&TE consistently found to be out of calibration shall be repaired or replaced.
- 12.4. When M&TE is found to be out of calibration, an evaluation commensurate with the significance of the condition shall be performed. The evaluation shall be documented and shall consider the following:
- 12.4.1. Validity of previous inspection or test results.
  - 12.4.2. Acceptability of items previously inspected of tested.
- 12.5. M&TE shall be stored and handled in a manner that will maintain the accuracy of the instrument.

DW James Consulting. LLC			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 20 of 24

- 12.6. M&TE shall be marked or labeled to indicate the status of the instrument and its calibration.
- 12.7. Records shall be maintained of the M&TE's calibration status and capability of the equipment to perform the intended function.
- 12.8. Special calibration and control measures on commercial measuring devices such as rulers, tape measures, levels and other such devices are not required where the normal commercial practices provide adequate accuracy.

### **13. Handling, Shipping and Storage**

- 13.1. Handling, shipping and storage requirement for quality related materials, components or equipment shall be specified in procedures or instructions. The procedures or instructions shall describe the controls necessary to:
  - 13.1.1. Preclude damage, loss or deterioration of the quality aspects of the material, component or equipment.
  - 13.1.2. Identify inspection, test or maintenance requirements and intervals while in storage to ensure performance is maintained.
  - 13.1.3. Establish marking or labeling requirements sufficient to properly identify the material as requiring special controls.
- 13.2. Special handling, preservation, storage, cleaning, packaging and shipping requirements shall be established and reviewed by qualified individuals.

### **14. Inspection, Test and Operating Status**

- 14.1. Procedures or instructions shall be established where necessary to assure the inspection and test status of quality related items, structures, systems and components is identified and documented prior to forwarding them to a controlled storage area or releasing the item for use, operation or installation. The procedures or instructions shall identify:
  - 14.1.1. Status indicators.
  - 14.1.2. Conditions under which status may be changed.
  - 14.1.3. Personnel or positions authorized to change status.
- 14.2. Status may be identified through the use of tags, markings, stamps or travelers.

### **15. Non-Conforming Materials, Parts and Components**

- 15.1. Non-conforming materials parts or components will be controlled to prevent their unintended use or delivery in a quality product. Positive controls will be established to clearly identify the non-conforming material, part or

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 21 of 24

component. These controls may include the use of tags, identification markings or physical segregation of the non-conforming materials.

15.2. Evaluations of non-conforming materials, parts or components will be performed to determine the final disposition. Evaluations shall be documented and should include the following:

15.2.1. Identification of non-conformance specific to the requirement(s) that was not met;

15.2.2. Determination of the impact on the function of the item or service to the original design requirement.

15.2.3. Recommendation and basis for final disposition. Options for disposition may be:

A. Repair or re-work the item to the original specifications.

B. Replace the item with one meeting the original specifications.

C. Use the item 'as is'.

15.2.4. Evaluations of non-conforming items should be performed by the supplier of the item. If the supplier cannot or will not complete the evaluation, then the use of other competent personnel is acceptable.

15.3. Repaired items shall be re-examined in accordance with the applicable procedures and the original acceptance criteria unless the disposition has established alternate criteria.

## **16. Corrective Action**

16.1. The quality assurance program is designed to prevent non-conformances. In the event that a non-conformance or other condition adverse to quality occurs, it must be identified promptly, evaluated and appropriate corrective actions taken.

16.2. Written guidance will be developed to define the requirements for:

16.2.1. Reviewing non-conforming conditions (including customer complaints).

16.2.2. Determining the appropriate individuals, organizations or entities that need to be aware of and informed of the non-conformance.

16.2.3. Investigating and analyzing the causal factors and / or root causes of the non-conformance.

16.2.4. Evaluating the need for corrective actions and the type of corrective actions necessary and appropriate to address the non-conforming condition and prevent recurrence.

16.2.5. Records of results and actions taken.

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 22 of 24

16.2.6. Review of corrective actions.

16.2.7. Verification that corrective actions have been implemented.

16.3. Records of conditions adverse to quality and the applicable corrective action shall be maintained and periodically reviewed to identify trends or underlying issues.

## **17. Quality Assurance Records**

17.1. Quality assurance records are those documents that furnish evidence that items or activities meet specified quality requirements. Procedures shall identify the types of quality assurance records generated for the activity, the authentication requirements and the retention requirements for those records.

17.1.1. Quality assurance records include, but are not limited to:

- A. Quality related procedures, instructions or drawings;
- B. Personnel qualifications related to quality functions;
- C. Inspection, test, monitoring or surveillance records for quality functions.
- D. Calibration records for quality M&TE;
- E. Supplier evaluation reports, audits or procurement documents for quality related items.
- F. Design analyses, design reviews and other design-related drawings or documents for quality related components, equipment or software.
- G. Non-conformance reports, evaluations, corrective actions and dispositions for quality related processes, materials, equipment or components.

17.1.2. Quality assurance records shall be legible and traceable to the associated items or activities. Quality assurance records shall accurately reflect the work accomplished or information required.

- A. Corrections to Quality assurance records must be made by authorized personnel and in a manner that does not make the original information illegible.
- B. Corrections to Quality assurance records must be authenticated.

17.1.3. Quality assurance records shall be considered valid records only when stamped, initialed, signed and dated by authorized personnel or otherwise authenticated (e.g. secure electronic signatures with appropriate certificate files).

<b>DW James Consulting. LLC</b>			
Quality Assurance Manual	Revision: 0	Date: June 29, 2007	Page 23 of 24

- 17.2. Records shall be classified as Lifetime or Nonpermanent by the organization responsible for creating the record.
- 17.2.1. Lifetime records are required to be maintained for the life of the particular item while it is installed and fulfilling its quality function or until the records are passed on to the customer as required by applicable Codes, Standards and procurement documents. Lifetime records include those that have significant value in the following:
- A. Demonstrating the capability for safe operation;
  - B. Determining the cause of an accident or malfunction or failure of an item;
  - C. Maintaining, reworking, repairing, replacing or modifying an item;
  - D. Providing required baseline data for in-service inspections.
- 17.2.2. Nonpermanent records are required to show evidence that an activity was performed in accordance with applicable requirements. Retention periods must be established in the applicable procedure, instruction or design analysis.
- 17.3. Quality assurance records shall be stored and maintained in a manner that is retrievable and minimizes the risk of damage or destruction from natural disasters such as winds, floods or fires; environmental conditions such as high and low temperatures or humidity; infestation of insects, mold or rodents. Acceptable methods of storage include:
- 17.3.1. Storage of two (or more) sets of identical records maintained in separate locations.
- 17.3.2. Storage of one set of records in an approved fire-resistant file or vault at a single location.
- 17.3.3. Records may be stored on paper records or electronic media.

## **18. Audits**

- 18.1. Audits are used as tools to ensure that quality processes continue to function as expected and are continually improved.
- 18.1.1. Audits shall be performed in accordance with pre-established written procedures using checklists traceable to applicable standards or requirements. Objective evidence shall be examined for compliance with quality assurance program requirements.
- 18.1.2. Audits are performed by appropriately trained personnel not having direct responsibility in the area(s) being audited.
- 18.1.3. The results of an audit are documented and provided to the management personnel having responsibility for the area being audited

and to the Managing Members for review and corrective action as applicable.

- 18.1.4. Audit responses including evaluations of adverse conditions, cause determination, corrective actions and actions to prevent recurrence of conditions adverse to quality shall be documented and evaluated by the auditing organization.
- 18.1.5. Areas found deficient during audits shall be re-evaluated on a higher priority basis to verify corrective actions have been implemented and are effective. Reasonable time will be allowed to permit the implementation of the corrective action.
- 18.2. Internal audits of the Quality Assurance program component areas are conducted annually and follow a documented schedule. Appropriate time intervals, based on risk, resource availability and functional necessity, are allowed. Other suitable methods of monitoring or measuring the quality of processes may be used where applicable.
- 18.3. External evaluations of material and service suppliers are conducted as necessitated by the level of quality required for the delivered service or product and as described in Section 7, Control of Purchased Items and Services.
- 18.4. Audit records shall include the audit plan, audit reports, written replies and the record of completion of corrective action(s).