

United States
Environmental Protection Agency
Region 2

**SUPERFUND TECHNICAL ASSESSMENT AND
RESPONSE TEAM III (START)
SITE ASSESSMENT TEAM 2 (SAT 2)
QUALITY MANAGEMENT PLAN (QMP)**

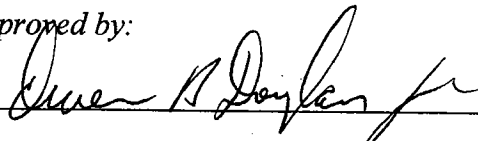
Prepared by:

**WESTON SOLUTIONS, INC.
Region 2
Site Assessment Team 2 (SAT 2)**

December 2005

**SITE ASSESSMENT TEAM
REGION 2
QUALITY MANAGEMENT PLAN
December 2005**

Approved by:


_____ 12-21-05

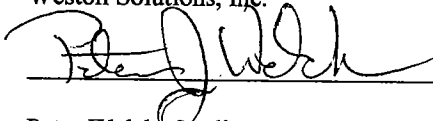
Owen B. Douglass Jr., Ph.D., CIH, Director of Environmental Health & Safety and Quality Assurance Date

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_____ 12/22/05


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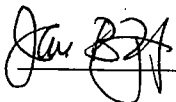
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9.0 ASSESSMENT AND RESPONSE

9.1 AUDITS AND ASSESSMENTS

Audits and assessments are a necessary aspect of quality management. They comprise the “check” step in Deming’s Cycle of Plan – Do – Check – Act. The Deming Cycle is also the cornerstone of Continuous Improvement, which is discussed further below. This is a QA action, i.e., an action that takes place outside the project execution itself. It is an action that follows QC, which is an integral part of the project.

An audit is a planned and documented investigative evaluation of an item, system, process, project, or result to determine the adequacy of and compliance with established contract and/or client requirements, procedures, instructions, drawings, quality assurance plans, and other applicable documents. This type of assessment is termed a “systems audit.”

An audit is a historical assessment of a particular subject insofar as it evaluates the subject’s past “fitness for use.” In assessing the fitness for use, the audit not only determines the subject’s compliance with documented requirements, it also evaluates whether these requirements, processes, or systems are appropriate and sufficient. It should be noted here that legal or contractual requirements must be met until they are changed by the appropriate authority. Audits should be scheduled with sufficient lead-time so that all appropriate records are available at the time of the audit. The scope, including any relevant checklists, shall be provided to the auditees in advance. SAT 2 has forms available to assist in QC and QA audits, assessments, and reviews.

Assessments are conducted with the express aim of determining the status of a particular subject in order to improve objective quality and client (internal and external) satisfaction. Assessments should be fair and impartial, and are not meant to be adversarial or punitive. All assessments (and audits) require:

- Qualified and trained assessment personnel independent from the item, activity, process, project, or program being assessed. The SAT 2 QAO, in general, will serve as lead auditor. The QAO will be responsible for the determination of the qualifications of the assessment team, team training, and the production of assessment plans and reports.
- Assessment Plan.
- Pre-Assessment meeting with group responsible for assessment subject.
- Post-Assessment meeting with assessed group to resolve misunderstandings or to receive additional information.
- Draft Assessment Report to the assessed group to obtain input on omissions or errors in fact.

- Final Assessment Report to the SAT 2 PM and Corporate Quality Assurance Director. The report may include:
 - Description of assessment subject(s).
 - Identification of assessment team.
 - Identification of persons contacted during assessment.
 - Identification of facilities, items, records, protocols, and procedures assessed.
 - Identification of requirements governing the subject(s) assessed.
 - Deficiencies, deviations, or exemplary practice noted during the assessment.
 - Immediate corrective actions taken.
 - Assessment of the effectiveness of corrective actions taken.
- Assessment Close-out wherein the final disposition of each deficiency or finding will be documented. All records of assessments may be submitted to Corporate Quality Management for final archiving. Copies of these records will be submitted as they are generated and not at the close of the assessment process.
- Any disputes encountered as a result of the assessments will be dealt with on the Program level. Should this arbitration fail, involvement of the Corporate Quality Assurance Director will be requested.
- Annual assessment of the SAT 2 Quality System will be performed to ensure adequacy and determine areas for improvement.

The scheduling and implementation of assessments, audits, and surveillance activities is the responsibility of the SAT 2 QAO, in coordination with the SAT 2 PM. A schedule of audits and assessments will be developed by SAT 2 QAO in coordination with the SAT 2 PM.

9.1.1 Management Assessments

WESTON plans and conducts management assessments and/or self-assessments with a focus on the effectiveness of the management systems and the effectiveness of its implementation. This is accomplished by a review of the results of the practices that are in place (e.g., quality improvement team reports, internal audit, and surveillance reports).

Senior management will be responsible for review of the management and self-assessment process, review of the management and self-assessment reports, commentary, and follow-up of any corrective actions determined to be necessary.

9.1.2 Independent Assessments

WESTON recognizes the value of periodic management reviews by staff not associated with the work being reviewed. Planned and periodic independent assessments are scheduled at the Operating Division/Strategic Business Group level. The Operating Division/Strategic Business Group Managers may choose assessment team members from other parts of the corporation or may choose to seek outside expertise.

9.2 RESPONSE

Where SAT 2 audits or assessments result in findings, observations or deficiencies, they require a response by the parties being audited.

9.2.1 Corrective Action

Corrective Actions are required to ensure that conditions adverse to quality, such as errors in or inappropriateness of reports, failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformance, are promptly corrected. Corrective actions are required as a response to audit, surveillance, or self-assessment findings, and are a useful tool for the resolution of observations. Corrective Actions should be initiated as a result of an observation, finding, or condition in an audit or assessment, and may result in a Continuous Improvement. Use of the *Corrective and Preventive Action Request* form is also a way to initiate and document a Corrective Action request and action. Actions taken will be documented and reported to appropriate levels of management in a timely manner.

9.2.2 Responsibility for Corrective Action

When a non-conformance is identified, the line of responsibility for correction passes to the staff and management of the group having responsibility for the non-conformance.

The WESTON/SAT 2 office having a non-conformance will be responsible for responding to, identifying, recommending, and implementing the recommended corrective action. The respective SAT 2 QAO will be responsible for evaluating effectiveness of corrective action. If the WESTON/SAT 2 office does not agree with the recommendations, the Corporate Quality Assurance Director will decide on the corrective action required.

Documentation of effective corrective action will normally be considered as the completion of the assessment process. Verification of corrective actions, however, may be the subject of a future assessment.

9.2.3 Root Causes

Root cause analysis is the investigation of the fundamental reason for a problem or situation, or, in this case, a finding or an observation. In order to fix or correct an observation or condition noted in an audit or assessment, a root cause analysis should be conducted to determine the basis of the observation or condition. Once the root cause of the condition is determined, the corrective action can be structured to prevent the condition from occurring again. Corrective actions will concentrate on remediation of the specific problems uncovered. Notwithstanding this focus, the quality assessment process should consider potential root causes for further evaluation in the corrective action process. Where root causes are obvious, the corrective action should address their remediation.

Where root causes are not obvious, the SAT 2 QAO may request additional quality assessments or other studies to further evaluate the situation. Root cause studies may result in recommendations to corporate management for changes in policy or practice to mitigate or eliminate quality problems.

9.2.4 Effective Corrective Action Documentation

SAT 2 QAO will be responsible for documenting effective compliance with corrective actions. The *Corrective and Preventive Action Request* Form can be used for this purpose. Completed Corrective Action Reports will be maintained at the Regional level and may be submitted to the Corporate Quality Assurance Director for further distribution, information, and archiving.

The following operating practices assign responsibilities and describe methods for control of the corrective action process: Operating Practice 10-01-004, Identification, Review and Control of Deliverable Documents Samples, Materials, Parts, Components and Deliverables, and Operating Practice 10-01-006, Corrective Action. These and the other Quality Management Operating Practices are located in Appendix 1.

9.2.5 Control of Non-Conforming Items

WESTON has established measures to control reports, samples, materials, deliverables, parts, or components that do not conform to requirements (or where conformance is indeterminate) in order to prevent their inadvertent use or installation. These measures include, as appropriate, procedures for identification and documentation, including follow-up verification for the proper implementation of corrective actions, as well as segregation, disposition, and notification. Non-conforming items are reviewed and either accepted, rejected, repaired, or reworked in accordance with documented procedures.

Upon identification of a non-conforming item, the matter is referred back to the SAT 2 PM, PLPM, and QAO through issuance of the *Corrective and Preventive Action Request* form.

Depending on the nature of the non-conformance, the SAT 2 PLPM in charge of that element is responsible for immediate corrective actions and determination of the root cause of the problem that led to the non-conformance. Preventive actions to the system, if any, will be recommended by the SAT 2 PLPM and implemented by the SAT 2 QAO. All non-conformance reports will remain active until corrections have been made and determined to be appropriate. Close-out of a non-conformance is confirmed by authorization of the SAT 2 QAO.

The documentation regarding non-conformances and their correction will be disseminated to appropriate management and staff level employees to raise awareness and help prevent repeat non-conformances in the future.

Non-conformances include, but are not limited to, rejected and/or deficient final deliverables, to the extent the non-conformance is the result of an omission or material error in contract deliverable, or unapproved process/procedure/policy variances that create an unacceptable business risk to WESTON or could result in a Quality System deficiency.

Non-conforming items will be segregated and appropriately marked to prevent their accidental use. Depending on the nature of the non-conformance, and the item, the non-conformance items will be evaluated and dispositioned by the most efficient means available (e.g., through recycling, repair, alternative use, etc.).

Unapproved process/procedure/policy variances will be addressed by corrective actions, but are not likely to be considered items, products, or deliverables requiring segregation and disposition. It is most probable that they are documents and, as such, the Corrective Action Report will serve as the tag, or marker, and will be attached to the document in question.

For non-document deliverables, each SAT 2 site-specific SAP and site-specific QAPP will define the deliverables and specific methods for non-conformance control, evaluation, and disposition. The Corrective Action Report will define the disposition required.

Operating Practice 10-01-004, Identification, Review and Control of Deliverable Documents, Samples, Materials, Parts, Components and Deliverables, assigns responsibilities and describes methods for control of nonconformance.