EFCOG Contractor Guide 2007-1, Rev. 0
March 1, 2007
Quality Assurance Subgroup, Integrated Safety Management Working Group

"Attributes of an Effective Quality Improvement Process"

Implementing DOE Order 414.1B Management/Criterion 3

TABLE OF CONTENTS

1.0 INTRODUCTION

To enhance the Department of Energy (DOE) Contractor performance and effectively implement DOE policies and orders, a consistent interpretation of policies and orders is required. Contractors should invoke the necessary programs and procedures and provide systems for continually pursuing quality improvement. Contractors should exhibit a culture that establishes and implements processes to detect and prevent quality problems. The culture must emphasize problem prevention, problem correction, and continuous improvement. This strategy usually exhibits characteristics (or elements) of worker involvement, goal setting, measurement, feedback, and teamwork.

Contractors desire to raise awareness and provide a basis for improved contractor-client communications relative to quality improvement and within budget constraints by:

- Establishing consistent performance evaluation criteria
- Standardizing interpretation of policy, orders, requirements and there implementation
- Increasing DOE and Contractor Management synergy by resolving legacy issues evidenced in the current work environment
- Improving definition of performance expectations and quantification of leading and lagging metrics

1.1 Purpose

The purpose of this document is to clarify and standardize criteria for evaluating contractor performance relative to Quality Improvement, Criterion 3. Contractors through this Guide will be able to effectively assess their specific processes and performance relative to QA Criterion 3, Quality Improvement.

This document will assist the user in obtaining DOE customer concurrence to:

- Establish and implement processes to detect and prevent quality problems
- Identify, control, and correct items, services, and processes that do not meet established requirements
- Identify the causes of problems and include prevention of recurrence as part of corrective action planning

- Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement
- Acknowledging, evaluating and implementing best practices in support of continuous improvement

1.2 Scope

The EFCOG ISM Working Groups QA Subgroup Task Team on Policy and Program Requirements developed this document to provide more definitive criteria to assist the DOE and contractors in implementing an Effective Quality Improvement Process.

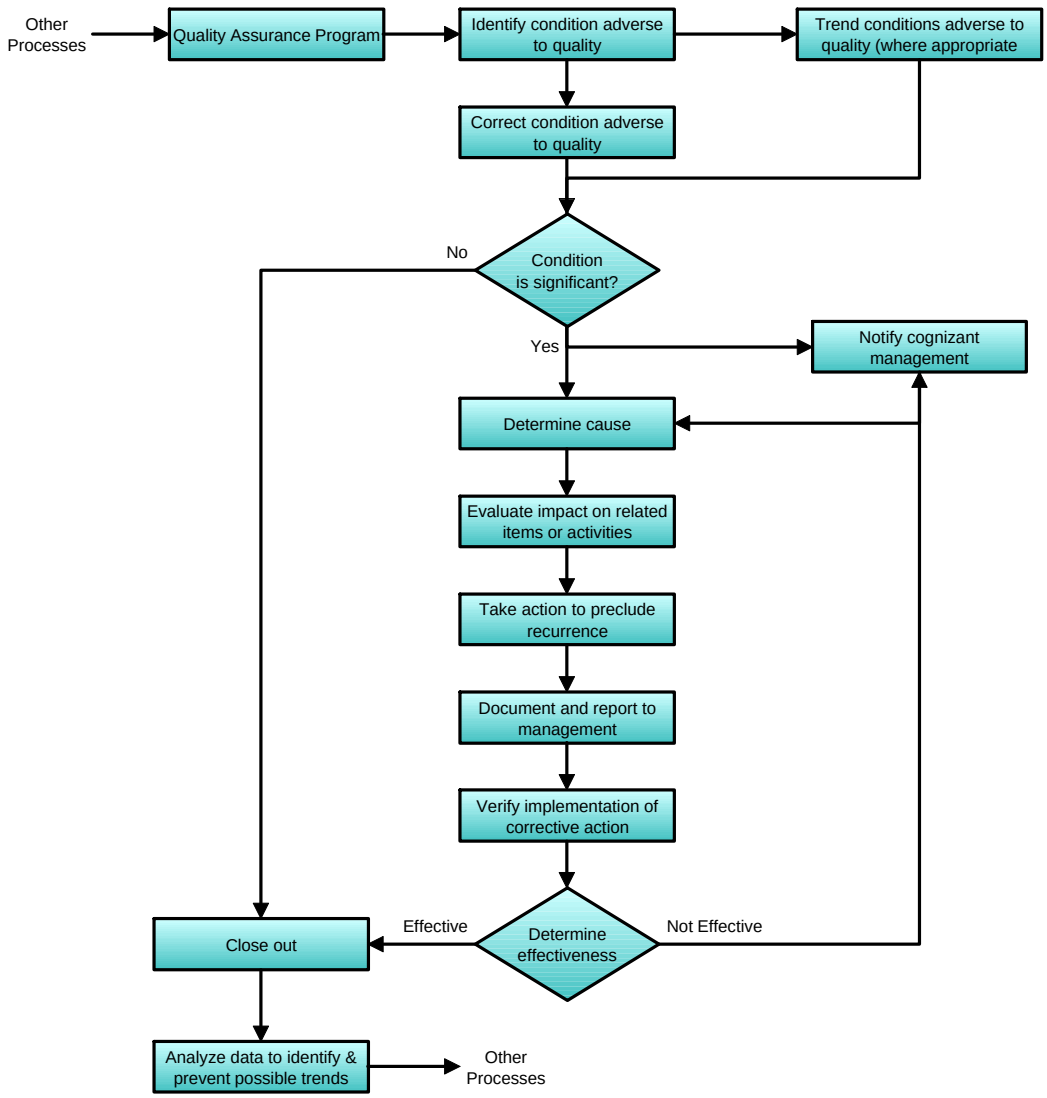
The QA Program (QAP) should focus on properly and safely accomplishing the organization's mission. Therefore, every component and employee of the organization is included within the QAP's scope. The scope also describes the organizational structure, functional responsibilities, levels of authority, and interfaces.

The quality improvement process of the QAP involves four primary steps: Prevention and Detection, Identification and Control, Correction, and Improvement.

Management is responsible for leadership and commitment to quality achievement and improvement within a framework of public, worker, and environmental safety. Management retains the primary responsibility and accountability for the scope and implementation of the QAP. However, every individual in the organization is responsible for achieving quality in his or her activities. Senior management should require and cultivate the achievement and improvement of quality at all levels of the organization and ensure that the QAP is understood and implemented.

This document provides an interpretation of what is needed for an effective Quality Improvement Process.

The chart below portrays a generic process for corrective action. Cognizant management should take an active role in determining/approving what corrective actions will be taken and for verifying the effectiveness of the actions taken.


Other Processes
Quality Assurance Program
Identify condition adverse to quality
Trend conditions adverse to quality (where appropriate
Correct condition adverse to quality
No
Condition is significant?
Yes
Notify cognizant management
Determine cause
Evaluate impact on related items or activities
Take action to preclude recurrence
Document and report to management
Verify implementation of corrective action
Effective
Determine effectiveness
Not Effective
Close out
Analyze data to identify & prevent possible trends
Other Processes

2.0 OVERVIEW

The impetus inspiring the EFCOG to commission a task team to clarify and standardize criteria for evaluating contractor performance was the QA Issue analysis done in the EFCOG QA Subcommittee meetings in November 2003. These same QA issues were also identified in the DOE Quality Assurance Improvement Plan's analysis of the status of QA implementation within the DOE.

Some of the common issues identified were:

- Contractor implementation of existing quality assurance requirements and industry standards is inconsistent and sometimes ineffective;
- The flow-down of quality assurance requirements to all tiers of subcontractors and suppliers is inconsistent with gaps; and,
- The quality assurance roles and responsibilities of personnel involved in design, procurement or receipt inspection are not clearly defined and/or are not being effectively implemented.

The lack of consistency in implementing DOE requirements result in weak programs, inconsistent and/or ineffective implementation and/or multiple interpretations of Quality Assurance (QA) criteria. The lack of detail in expectations for implementing QA requirements prompted this document on "Attributes of and Effective Quality Improvement Process" to be developed to address one of the areas identified as needing more consistent implementation.

The principal measure of an organization's performance is the quality of it's products and services. The QA Order and QA Rule require that an organization develop, document, and maintain an effective QA Program (QAP). The goal of the QAP is delivery of safe, reliable products and services that meet or exceed the customer's requirements, needs, and expectations. To accomplish this goal, the QAP should describe methods for planning, performing, and assessing the adequacy of work, including work assigned to external parties.

Management is responsible for leadership and commitment to quality achievement and improvement within a framework of public, worker, and environmental safety. Management retains the primary responsibility and accountability for the scope and implementation of the QAP. However, every individual in the organization is responsible for achieving quality in his or her activities. Senior management should require and cultivate the achievement and improvement of quality at all levels of the organization and ensure that the QAP is understood and implemented.

This document provides an interpretation of what is needed for an effective Quality Improvement Process.

3.0 PART A OF CRITERION 3 - ESTABLISH AND IMPLEMENT PROCESSES TO DETECT AND PREVENT QUALITY PROBLEMS

Just as there are processes to perform the work, processes must be established and implemented to prevent and detect quality problems. In an effective quality program, there are many steps between prevention and detection of quality problems. The first step in quality improvement is the prevention of quality problems.

Detection relates to finding of quality problems associated with items, services, and processes. The QA Rule and the QA Order require items, services, and processes that do not meet established requirements to be identified, controlled, and corrected according to the importance of the problem and work affected. The QA Program must provide methods to identify and control nonconforming items, services, and processes to prevent recurrence.

The customer and/or the stakeholders flow-down defined requirements as definitive contractual obligations. Expectations should be congruent with requirements within the confines of resources, schedules, and funding. Prevention of problems is a proactive approach to continuous improvement and meeting requirements as expected. It requires identifying internal and external factors that affect the organization and its work. Correcting problems after they occur is an undesirable reactive behavior. Preventive action should be used to minimize the number of corrective actions. The QAP should include procedures and processes that ensure effective prevention and detection controls.

3.1 Implementation

Preventive action is applicable to items, services, and processes.

Monitoring and assessment mechanisms must be in place to anticipate changes that could lead to problems. Preventive action falls into two categories, engineered controls and administrative controls. For example, maintenance of equipment is an engineered control. Maintaining equipment and production machinery are examples of ongoing preventive activities. Training or Procedural Requirements are examples of administrative controsl. The preventive action process requires an evaluation of the subject system to identify issues that could prevent an organization from meeting the requirements.

Management, or a process owner, through effective implementation of the QAP will become aware of a potential problem by reviewing data or information. The ways that preventive actions are identified are as varied as the work. Not only can you identify potential problem areas from

trending data, but by looking at changes, good or bad, that have the potential to disrupt the day-to-day operations.

4.0 PART B OF CRITERION 3 - IDENTIFY, CONTROL, AND CORRECT ITEMS, SERVICES, AND PROCESSES THAT DO NOT MEET ESTABLISHED REQUIREMENTS

Items, services and processes that do not meet established requirements need to be identified, controlled, and corrected according to the importance of the problem and the affected work. The information related to quality problems should be tracked and the resultant issues should be prioritized based on the company's established prioritization system. The prioritization process should be based upon various factors including environmental and safety considerations, repetitive nature of the issue, programmatic concerns, fiscal concerns, and regulatory implications. After prioritization, the issues should be tracked and managed through resolution in accordance with the company's Corrective Action/Issue Management system.

4.1 Identifying Quality Problems

Quality problems are deficiencies in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. Such quality problems may be identified by internal organization sources (e.g., workers, customers, suppliers) or by an external source (customer/regulator). Once identified, quality problems must be evaluated to determine significance and documented. The method for determining the significance of a problem and the process for handling problems must be documented in the QAP.

An effective organization is one in which the quality problems are identified through its own internal resources doing introspective assessments. An effective organization also promotes a no-fault environment in which personnel have the mandate, freedom and responsibility to, and are expected to, identify potential quality problems and recommend improvements without fear of reprisal.

Quality problems are conditions adverse to quality and must be identified and documented. Conditions adverse to quality include failures, malfunctions, suspect/counterfeit items, deficiencies, defective items, out-of-control processes, and non-conformances. Where conditions adverse to quality have been identified, the extent to which other items and activities may be affected should also be evaluated so that appropriate action may be taken, including measures to control any affected work in process, if necessary.

Other information that could indicate conditions adverse to quality should be reviewed and evaluated may be generated by internal or external organizations, and, the reviews/evaluations should include conditions

adverse to quality identified in reports such as those resulting from audits, inspections, tests, design reviews, individual observations, adverse trends, operational events and maintenance activities.

A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety, security, cost, schedule or operability. Criteria for classifying conditions adverse to quality as to severity must be established, and as a minimum, should consider the following aspects:

- Impact on health and safety of the public, workers or environment;
- Impact on reliability, availability, or maintainability of the equipment or facility;
- Impact to the facility based on its current life-cycle phase (i.e., operations, transition, D&D, etc.);
- Importance in meeting regulatory commitments;
- Consequence of recurrence of the condition; and,
- The extent to which the adverse condition may apply to other items or activities beyond the specific occurrence where it may have greater impact

In classifying conditions adverse to quality, the review should consider repetition of specific conditions adverse to quality, as well as the relationship or similarity between different conditions, in a manner and at a frequency that ensures that significant quality trends are identified and evaluated for appropriate correction.

Conditions adverse to quality should be reviewed to determine the existence of trends. The significance of identified trends should be evaluated to determine whether further action is necessary.

Problems, regardless of significance, should be identified, documented, and processed in accordance with a graded approach. This includes minor quality problems that may not follow the more formal processes for quality problem documentation and disposition.

4.2 Controlling Nonconforming Items, Services and Processes

The Quality Assurance PAAA Rule (10CFR830) requires that contractors identify a national or international consensus standard that can provide additional guidance to supplement the QA Rule and DOE Order 414.1 directives. Many contractors have elected to utilize guidance from such national consensus standards to shape and direct their implementation of quality assurance activities and processes. Some of the basic principles to control nonconforming items are summarized herein.

Items that do not conform to specified requirements are controlled to prevent inadvertent installation or use. Controls include provisions for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Further processing, delivery, installation, or uses of a nonconforming item are controlled pending an evaluation and an approved disposition by authorized personnel.

Nonconforming items are identified by legible marking, tagging, or other methods not detrimental to the item, on the item, the container, or the package containing the item.

Nonconforming items are segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other positive precautions are employed to preclude inadvertent use of a nonconforming item including tagging, locking or erecting barriers.

In some cases, it may be necessary to issue a “stop work” order to protect the workers, facility or environment from the potential consequences of continued use of the nonconforming item(s). In these situations, conditions governing the issuance and removal of the stop work order should be documented.

4.3 Correcting Nonconforming Items, Services and Processes

Nonconforming items and conditions are evaluated and recommended dispositions are then proposed. The method, responsibility and authority for the identification, control, review and disposition of nonconforming items must be defined in procedures. There are a number of ways that identified nonconforming conditions can be corrected or dispositioned. For the disposition of items, actions such as “Repair”, “Rework”, “Use-as-is”, or “Reject/Scrap” are typically made and documented.

Technical justification for the acceptability of a disposition resulting in the condition not being returned to its original specification/state must be documented to ensure accurate records of the as-built condition.

Nonconformances to design requirements dispositioned as “Use-as-is” or “Repair” should be subject to design control measures commensurate with those applied to the original design. Required as-built records should be generated to reflect the “Use-as-is” or “Repair” condition.

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

nonconforming items or replacement items must be installed and tested according to the original requirements or approved alternatives.

Personnel who have the responsibility to disposition nonconforming conditions (i.e., Items, services, Processes) must be technically qualified and have the pertinent background data available for their information and use in making a disposition determination.

5.0 PART C OF CRITERION 3 - IDENTIFY THE CAUSES OF PROBLEMS AND INCLUDE PREVENTION OF RECURRENCE AS PART OF CORRECTIVE ACTION PLANNING

The QAP should define the necessity and process to perform Root Cause Analysis (RCA) for conditions adverse to quality. The ASME NQA-1 standard requires RCA to be performed and documented for significant conditions adverse to quality. The QAP should define the criteria for when RCAs are required. For those instances where a formal root cause process is specified as required, but, it is determined to not be appropriate or practical, documented justification is required.

The causes of quality problems are typically included in the circumstances immediately preceding the problem and are often obvious anomalies. It is important for compensatory measures and remedial actions to be implemented to prevent further propagation of the problem. However, remedial action alone does not prevent recurrence of the problem.

In this regard, the Root Cause Analysis (RCA) process is key to identifying the “true” or “underlying” cause(s) of problems, which aids in identifying appropriate corrective actions that can prevent recurrence, and ensure continuous improvement.

The product of a RCA includes identification of a strategy that the organization intends to implement to significantly reduce, or eliminate, the risk of similar quality problems occurring in the future. An RCA focuses primarily on systems and processes that are associated with items and services, not individual performance, and is designed to help identify the full extent of *what, how,* and *why* a quality problem occurred.

The Guidance for Root Cause Analysis is provided in DOE Guideline DOE-STD-NE-1004-92 Root Cause Analysis Document (Appendix IV Reference 5). This provides effective methods for performing RCAs.

It is noted that the selection of the method for performing a cause analysis should be the simplest one that solves the problem. The Events and Casual Factor Analysis process may be best for use unless other methods are considered more applicable.

Generally the baseline conditions that identify process improvements in portions of the quality program, the management system or improvement in any process should be fed back for routine improvement. These in many cases may not need a significant root cause analysis or be formally reportable outside the organization, but are important for improving the processes.

It is important to consider causal codes associated with the process improvement considerations rather than only event driven codes needed for the DOE Occurrence Reporting System (ORPS). Focusing on improving the process is a basic consideration and not only for significant events

It is also important to promote a *questioning attitude* and to encourage *investigations of the extent* of the problem and extent of the impacts. As with all corrective action plans, to ensure success, it is critical to:

- Assign a competent lead
- Assign appropriate, available, responsible and qualified personnel
- Develop a realistic action plan
- Ensure top-down approval
- Track progress
- Adapt to unanticipated impacts
- Act on new discoveries in accordance with approved processes

6.0 PART D OF CRITERION 3 - REVIEW OF ITEM CHARACTERISTICS, PROCESS IMPLEMENTATION, AND OTHER QUALITY- RELATED INFORMATION TO IDENTIFY ITEMS, SERVICES, AND PROCESSES NEEDING IMPROVEMENT

Organizations are driven by data. Data is required to objectively measure and validate an organization's performance. In order to improve contractor performance, data must be collected, documented, measured and analyzed.

Many types of data and information are needed for performance measurement and improvement. Performance areas typically include:

- customer satisfaction
- product and service quality
- operations
- competitive comparisons
- suppliers
- employees
- costs

Analysis refers to extracting larger meaning from data and information to support evaluation, decision making, performance improvement, and programmatic refinements within the organization. *Analysis entails using data to determine trends, projections, and cause and effect – that might not be evident without analysis*. Data and analysis support a variety of purposes, such as planning, reviewing overall performance, improving operations, and validating performance with "best practices" benchmarks.

Trend analysis uses measurement data to identify favorable and unfavorable patterns or trends in actual performance as compared to any identified indicator, such as goals, specifications, standards, or past results. Trend analysis is beneficial in recognizing emerging patterns in performance results. Such patterns are often not evident or are so gradual that they cannot be detected unless measurements of events are examined periodically. When changes are planned to improve performance, trend analysis is used to assess the effects of implementing corrective actions by comparing past to present performance. Trend analysis is an important activity for ensuring that improvement gains are sustained over time.

The table below identifies a basic set of common processes used throughout the DOE complex for addressing trend detection, analysis, and negative trend prevention:

Trend Detection, Analysis and Prevention Processes	
Trend Detection & Analysis	**Negative Trend Prevention**
Uses data from the Corrective Action Control and Reporting Process and Preventive Action Control and Reporting Process to identify trends and probable trends. Uses data from any oversight process such as: • Surveillance • Audits • Management Self-Assessments • Independent Assessments • Evaluations • Reviews Validate trend results through objective evidence and disseminate the information. Trends are analyzed and conclusions should be fed to the Lessons Learned Program.	Uses data from deficiency reports to determine possible negative trends. Data source examples include: • Nonconformance Control and Reporting System • Findings (or Issues) Control and Reporting System • Corrective Action control and reporting process Actions are initiated to prevent negative trends from becoming real deviations and non-conformances. Actions should be fed to an improvement process such as Six-Sigma, TQM team building and other problem solving processes. Negative trend information and actions are reported to management for awareness, approval and action.

Organizations that have a continuous improvement culture improve their performance by learning from their own experience and that of others and by sharing the information more broadly. These organizations regularly identify sources of information that are relevant to their work or operations. They analyze these information sources for both good work practices and adverse work practices. They take appropriate action in response to the value of these improvement opportunities.

The Lessons Learned and Best Practice processes establish opportunities for performance improvements within the quality program and product lines. All personnel are encouraged to adopt a systematic approach for using lessons learned and best practices as input to

improving performance. These processes evaluate overall performance and identify and implement actions for improvements.

Self-assessment is the method that organizations use to determine how well they are meeting their performance objectives and to implement needed improvements. The process involves:

- a self-assessment plan
- executing the planned assessments
- analyzing and documenting the assessment results
- implementing appropriate improvement actions based on results

Lessons learned and best practice opportunities can be identified from a number of internal and external sources. They will be incorporated into the assessment plan and can provide substantial value to the organization in improving overall performance.

All areas of an organization can benefit from lessons learned and best practices (both strengths and areas for improvement) by emphasizing improvement and learning as a routine part of their ongoing organizational work processes and project activities.

Organizations identify customers and deliverables (products or services), gather data about past and current performance, set performance goals for improvement, and collect data to measure success in meeting goals. There are a wide range of continuous improvement methodologies available to management.

One notable method available to organizations for promoting continuous improvement is the development of an employee suggestion award program. In addition to the obvious benefit of receiving constructive suggestions for improvement, such a program strengthens employee involvement and goodwill; both are key elements to a successful continuous improvement program.

ACKNOWLEDGEMENTS

This Guide was prepared with the participation of the DOE Office of Quality Assurance with primary responsibility for QA Program policies. DOE contractors and members of national standards bodies made individual contributions during the review and comment process. The following individuals were directly and substantively involved in the developmental of this Guide.

DOE Lead Chip Lagdon, Director, Office of Quality Assurance Programs

Contractor Lead Dennis Dreyfus., Bechtel National Inc.

Bernadette Sullivan
Bechtel National Inc

Chris Marden
BNFL, Inc.

Larry Cumberland
BWXT Y12

Charles H. Moseley, Jr
BWXT Y12

Rich Mickey
Bechtel Nevada

Mike Nicol
Tetra Tech FW

Craig Barnes
Bechtel Nevada

Rick Steele
Pacific Northwest National Laboratory

Dave Torczon
Los Alamos Site Office

Linda Sickles
Sandia National Laboratory

APPENDIX I - LIST OF ACRONYMS

DOE - Department of Energy

EFCOG - Energy Facility Contractors Group

QA - Quality Assurance

QAP – Quality Assurance Program

RCA - Root Cause Analysis

NQA - Nuclear Quality Assurance

APPENDIX II - CONTRACTOR QUALITY IMPROVEMENT RELATED DEFINITIONS USED THROUGHOUT THE DOE COMPLEX

Acceptance Criteria – Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

Approval – The act of authorized personnel or their designee accepting a document, part, or item.

Audit – A planned and documented activity performed to determine by investigation, assessment, examination, review or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation.

Cause (Causal Factor) – A condition or an event that results in an effect (anything that shapes or influences the outcome). This may be anything from noise in an instrument channel, a pipe break, an operator error, or a weakness or deficiency in management or administration.

Causal Factor Chain (Sequence of Events and Causal Factors) – A cause and effect sequence in which a specific action creates a condition that contributes to or results in an event. This creates new conditions that, in turn, result in another event. Earlier events or conditions in a sequence are called upstream factors.

Contributing Cause – A cause that contributed to a quality problem but, by itself, would not have caused the problem. For example, in the case of a leak, a contributing cause could be lack of adequate operator training in leak detection and response, resulting in a more severe event than would have otherwise occurred. In the case of a system misalignment, a contributing cause could be excessive distractions to the operators during shift change, resulting in less-than-adequate attention to important details during system alignment.

Condition Adverse to Quality – An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, suspect/counterfeit items, and nonconformities. A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability.

Corrective Action – Actions taken to eliminate the causes of an existing nonconformity, deficiency, or other undesirable situation in order to prevent recurrence.

Deficient Items – Those items that have been completed, examined, and accepted and then subsequently discovered to deviate from the project design or code requirements. Items found to be damaged or otherwise unacceptable at

the time of receipt inspection shall be treated as deficient and segregated to prevent inadvertent use.

Deviation – A departure from specified requirements.

Direct Cause: The cause that directly resulted in the quality problem. For example, in the case of a leak, the direct cause could have been the problem in the component or equipment that leaked. In the case of a system misalignment, the direct cause could have been operator error in the alignment.

Graded Approach - The processes of ensuring that the level of analyses, documentation, and actions used to comply with requirements are commensurate with:

- The relative importance to safety, safeguards, and security
- The magnitude of any hazard involved
- The life-cycle stage of a facility or item
- The programmatic mission of a facility
- The particular characteristics of a facility or item
- The relative importance to radiological and non-radiological hazards
- Any other relevant factors

Independent Assessment – Reviews carried out by technically knowledgeable personnel in the area of assessment, who are free from direct responsibilities in the areas they are assessing. Independent assessments focus on improving items and processes by emphasizing line organizations' achievement of quality. Independent assessments include the performance of audits and surveillances.

Management Assessment – Reviews performed by management that focus on how well the integrated quality program is working. Management assessments identify management problems that might exist and could hinder an organization from achieving its objectives in accordance with quality, safety, and environmental protection requirements. Management assessments also identify lessons learned and best practices for incorporating improvements into program and standard work processes.

Monitor – To watch over, observe, or examine a work operation. While results of the observations and examination may be recorded, sign-off responsibility is not included.

Nonconformance – A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Objective Evidence – Any documented statement of fact, other information, or record, quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Preventive Action – An action taken to eliminate the causes of a potential nonconformity, deficiency, or other undesirable situation in order to prevent occurrence.

Procedure – A document that specifies or describes how an activity is to be performed.

Qualification (Personnel) – The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests that qualify an individual to perform a required function.

Quality Assurance – All those planned or systematic actions necessary to provide adequate confidence that an item or a facility will perform satisfactorily in service.

Quality Planning – Quality planning sets down what management wants to accomplish in terms of quality products or services, but also puts in place the processes and resources (people, technology, money, training, and supporting infrastructure) to enable the accomplishment of the objectives.

Quality Policy – Management's statement of the organization's overall intentions and direction with regard to quality

Quality Problem – A collective term that may be a deficiency in:

- An activity, product, service, item characteristic, or process parameter
- A non-compliance with a legal, contractual, or other requirement
- The existence of a substandard condition or a suspect/counterfeit item

Reject – The action taken to eliminate a deficient or nonconforming item from its specified use.

Repair – The process of restoring a deficient or nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still may not conform to the original requirement.

Review – The process of examining, commenting on, and evaluating procedures, drawings, specifications, and related data to determine that they clearly,

accurately, and completely describe the established design and quality requirements.

Rework – The process by which an item is made to conform to original requirements by completion or correction. (e.g., supplying missing documentation, re-machining, re-welding, re-assembling, or other means).

Root Cause – The cause that, if corrected, would prevent recurrence of this and similar quality problems The root cause does not apply to this problem only, but has generic implications to a broad group of possible problems, and it is the most fundamental aspect of the cause that can logically be identified and corrected. There may be a series of causes that can be identified; one leading to another. This series should be pursued until the fundamental, correctable cause has been identified.

Surveillance – The act of monitoring, witnessing, or observing to verify whether an item or activity conforms to specified requirements.

Use-As-Is – Indicates that a nonconformance can be used if the discrepancy will not adversely affect functional requirements.

Verification – The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

APPENDIX III – LESSONS LEARNED

Prior to collecting the information for this publication, a benchmarking exercise was conducted to collect Best Practices relative to self-identifying problem areas and identifying areas for continuous improvement. Additionally, Best Practices were defined for the processes used to identify causes of the problems. Finally, Best Practices were identified to manage the effectiveness of corrective actions that drive the resolution of concerns and drive improvement in the future. After sorting through the issues and consolidating the final list of processes, the following items were highlighted as practices that can clearly improve performance. Along with improved actual performance, some of the practices provide improved methods of communication between customers and contractors by quantifying methods of performance measurement. The list was discussed during this EFCOG effort and modified accordingly.

1.0 Effective Corrective Actions

- Desk Top Guide or User's Handbook - Develop handbook that captures training and process information into one user friendly guidance document
- Quality Reviews – Implement reviews before an issue is officially entered into formal system –
    - Owner develops plan
    - Independent validation reviews
    - Senior manager or designee approvals
    - Issues Management staff reviews and system inputs
- Required Training - Develop training specifically on how to prepare an effective corrective action plan and require it for all independent line verifiers and validators
- Focused Attention to Programmatic Issues - Focus training and management attention more on extent of conditions (previously generic implications) and enduring actions
- Qualified Causal Analysts - Require certification of causal analysts (training plus demonstration of performance)
- Field Verification for Effectiveness - Issues Management staff perform a field verification review on 100% of NTS associated issues. Add a sampling process to require field verification of 5% of issues prior to closure
- Management Field Reviews - Add a requirement for the line organization to include an action plan to conduct an independent field review of all Level A or B issues (more critical issues) 3-6 months following closure.

- Management Assessments - Require annual management assessment by the line organization of effectiveness of corrective actions
- Monitoring Performance - Track and trend effectiveness rate - Presently sustaining an 80% effectiveness rate based on customer reviews, management assessments, and independent assessments
- Consistent Grading with Checklist - Develop effectiveness grading checklist for more consistent grading and finalize with the customer
- Joint Independent Assessments - Initiate joint effectiveness reviews with our customer
- Best Practices - Benchmark a number of sites across the Complex for any lessons learned
- Quantify Success through Metrics - Initiate quantified metric on effectiveness of corrective actions based upon customer reviews, management assessments and independent assessments. Information is reviewed with the customer each month.

2.0 Management Assessment Program

- Formal Schedules - Formalized scheduling system available via Web Page
    - Available via a Web Page
    - Each organization required to input a schedule for the following FY by September 30th
    - Number for each quarter then “baselined” on the last day of previous quarter
    - Allow (and encourage) topic changes but are held to baselined number by our customer
    - Track and trend quarterly schedule performance
- Quantify Success through Metrics - Initiate quantified metric on schedule performance of management assessments across the site based upon actual to planned completions. Information is reviewed with the customer each month. Track and trend schedule performance
- Quality Rating on Documentation - Performance Assurance reviews 100% of all submitted management assessments against five attributes
    - Structure of report per procedure requirements
    - Alignment with primary mission

  - Checklist/plan
  - Thoroughness of Assessment
  - Overall Assessment Value
- Feedback for Continuous Improvement - Provide formal feedback on 10% of graded assessments back to the line organization
- Quantify Success through Metrics - Initiate quantified metric on quality of management assessments from quarter to quarter as a result of the 10% graded checklist for line organization feedback. Information is reviewed with the customer each month. Track and trend attribute performance.
- Required Training for Assessors - Require training for personnel leading management assessments (meet requirement with either of the below):
  - 4-day workshop
  - 1-day Independent Assessment Training
- On-hands Training - Implement workshops as a training tool
  - 4 day workshop (scheduled by organization)
  - Perform an actual assessment for the organization in the workshop
  - Emphasize the five attributes used for grading
- Management Communication on Progress - Provide staff briefings/awareness sessions to organizations as well as individual coaching sessions

3.0 Independent Assessment Program

- Factual Accuracy Consensus - Formalize the factual accuracy process
  - Division Manager involvement
  - Requirements for comment resolution and timeline
  - Ensures factual accuracy of report before finalized
- Required Qualification of Assessors - Require qualification of Lead Assessors based on a graded approach
  - Training course plus minimum number of assessments conducted within specific timeframe
  - Develop equivalency process for qualifying personnel
- Equivalency Table - Equivalency for Lead Assessor qualification to Cover those with required experience from outside specific site

- Formal Schedules - Scheduling system developed and available via Web Page
    - Uses a graded approach based upon the possible significance Available via a Web Page
    - Formal process for developing the annual schedule including input from line organizations and functional area managers
    - Number for each quarter “baselined” on the last day of previous quarter
    - Change request process implemented for schedule change
- Quantify Success through Metrics - Initiate quantified metric on schedule performance of independent assessments across the site based upon actual to planned completions. Information is reviewed with the customer each month. Track and trend quarterly schedule performance

4.0 Issues Management

- Graded Approach to Issues Resolution - Develop a graded approach based upon the possible significance of the violation
    - Process is to be used for resolution of assessment findings as well as events and conditions that are violations of requirements
    - Uses a graded approach based upon the possible significance of the violation
    - Standard checklist developed to grade significance. Based upon what reasonably could happen if issue left unresolved
- Establish Board for Independent Grading of Issues - Issues Management Prioritization and Review Board (IMPRB) for significance determination and ownership assignment
    - Board comprised of knowledgeable personnel from six of the major divisions in the plant plus the chairman (Performance Assurance)
    - All External Assessments and Independent Assessments must be processed through the IMPRB
    - Management Assessments as well as surveillances and walkdowns may go through the IMPRB at the request of the organization or Quality Manager
    - Appeal process defined through the Charter

- Quantify Success through Metrics - Overdue issues/actions/plans tracked and trended over time
    - Overdue issues/actions/plans are tracked and trended over time
    - Reduction of issues open over 24 months tracked and trended over time
    - Increased focus on driving these to closure
- Continuous Improvement for Timely Resolution - Reduce issues open over specified months tracked and trended over time
    - Management Communication of Action Planning – Provide stoplight charts to Senior Management for overdue issues/plans weekly
    - Red-late
    - Yellow-due in 2 weeks
    - Green – due in 1 month

APPENDIX IV – REFERENCES

1. DOE Order DOE O 414.1B, *Quality Assurance*, U. S. Department of Energy, April 29, 2004.

2. DOE Guide DOE G 414.1-2, *Quality Assurance Management System Guide for use with 10 CFR 830.120 and DOE O 414.1*, U. S. Department of Energy, June 17, 1999.

3. 10 CFR Part 830, Subpart A, *Quality Assurance Requirements*, U. S. Department of Energy, January 1, 2003.

4. DOE Manual DOE M 231.1-2, *Occurrence Reporting and Processing of Operations Information*, U. S. Department of Energy, August 19, 2003.

5. DOE Guideline DOE-NE-STD-1004-92, *Root Cause Analysis Guidance Document*, U. S. Department of Energy, February 1992.