NREL Subcontractor Quality Assurance Plan Guidance

NREL Quality Management Systems and Assurance

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Subcontractor Quality Assurance Plan Guidance

1.0 INTRODUCTION

The purpose of this guidance is to help business, regardless of size, establish a "quality culture". It is becoming important to businesses who want to do business with the Department of Energy (DOE) National Renewable Energy Laboratory (NREL). These businesses need to align with the NREL's quality requirements and the rapidly expanding DOE and NREL quality movement. Hopefully this guidance is found to be both useful and user-friendly. The commitment to quality usually gives a company the competitive advantage in the long term.

Any company that wants to remain in business must satisfy its customers and employees to survive. Given today's economy, all company executives should be asking themselves "*Is my company susceptible to quality issues*?" Quality equals risk management and should be approached from a strategic perspective instead of the traditional tactical perspective. For most small businesses the strategic approach is based on business planning. Based on this strategic approach, business planning and quality planning are essentially the same thing. Quality planning and implementation can have profound implications for company performance. Small businesses, to a certain extent, do have some advantages over larger businesses because small businesses can move more quickly to implement innovative ideas. Small businesses usually have fewer layers of management, thereby encouraging better communication and work habits. An apparent disadvantage of a small business is the lack of funds, time, and expertise to develop and implement a quality program. The costs of rework or replacement of noncompliance products eventually exceed those of establishing a quality culture in the company. The hard part for any company is to ensure that they walk the talk where quality is concerned. Many quality methodologies or combinations of methodologies are available. The effort to establish or improve the quality program requires a planned and comprehensive effort. The key to be successful is an understanding that the commitment to quality is a long term commitment, not just the "flavor of the day." As Dr. W. Edwards Deming[1] was known to advise, "Just do it!"

Quality can be defined in many ways. Quality can be defined as the degree to which a product or service meets or exceeds a customer's requirements and expectations. Quality can also be defined as the results of several ongoing processes. A simpler, yet effective, way of defining quality is:

a. Say what you are going to do
b. Write down how you are going to do it
c. Do what you say in accordance with how you said you are going to do

Adopting some simple principles of quality management can help a business gain significant competitive advantages over their competition. Quality management adds value while reducing or managing risk.

2.0 NREL QUALITY ASSURANCE PLAN EXPECTATIONS

[1] Dr. W. Edwards Deming was a pioneer in quality and management, who taught the fundamental of the philosophy of quality management to the business leaders of Japan.

"Subcontractors" are those companies that perform work on NREL projects. The Alliance for Sustainable Energy, LLC (Alliance) is the Managing and Operating Contractor for the Department of Energy's National Renewable Energy Laboratory. Most of the NREL subcontracts are managed by the Alliance. The Alliance Subcontractors performing work, providing services, or supplying materials at the NREL are required to comply with the Contractor Requirements Document Section (CRD) of Department of Energy Order 414.1C (DOE O 414.1C), *Quality Assurance*. Working at NREL means that subcontractors are required to develop a Quality Assurance Plan (QAP) that shows how they will implement their quality management processes in order to meet the intent of NREL quality requirements. Quality Assurance Plans may also be referred to as a Quality Assurance Program Description, a Quality Management Plan, a Quality Project Plan, etc. The QAP is expected to be prepared and submitted to NREL for acceptance as established by the solicitation or contract. The accepted QAP along with the associated processes and procedures detail the subcontractor's approach to meet the project objectives and guard NREL against errors and omissions in design or construction, as well as defects in material, equipment, and workmanship.

The QAP is one of the most important aspects to achieve successful completion of contractually prescribed activities. The QAP describes the processes that will be put into place to ensure that the deliverables attained meet the requirements and exhibits an appropriate level of quality. The QAP states the company's quality policy and describes the procedures and processes that will be implemented; the criteria for and areas of application; and roles, responsibilities, and authorities. For task order agreement contracts the QAP may be viewed as the "umbrella" document under which individual projects are conducted. Individual projects, via the task order process, may require a project specific QAP that delineates project specific exceptions or additions to the umbrella QAP.

3.0 GRADED APPROACH

Compliance with and implementation of the NREL QA requirements are based on the concept of graded approach. The concept of graded approach recognizes that a "one size fits all" approach to QA/QC does not work at a site as diverse as NREL. For example, the QA/QC expectations for a painting contract are different from that of a building design contract. The level of effort needed to develop and document a quality process and associated plan should be based on the scope of the activity/contract. Similarly, the level of detail for quality documentation of specific activities/contracts varies according to the complexity of the work being performed and the intended use of the product or service. The subcontractor may submit existing quality-related documents (e.g., quality manual, business manual) with an explanatory introduction when that document meets the intent of the applicable requirements for a QAP. The graded approach must not be used to "grade quality assurance criterion to zero" which has the affect of eliminating all verifications of the requirement ("to get out of work"). Even in the least stringent application, compliance with applicable portions of stated requirements are mandatory unless an exemption is approved through an appropriate process.

Subcontractor should evaluate the NREL QAP elements described below for applicability to the specific contract they are responding to or have been awarded. When a particular element is not relevant, an explanation of why it is not relevant should be provided in the QAP. Also, NREL

may determine that additional quality requirements are useful or necessary for a specific project or contract; these elements should be discussed in the QAP. The QAP must be signed by the appropriate company management and quality personnel indicating approval of the plan.

The level of detail included in the QAP is based on the scope and complexity of the solicitation or contract. The QAP must provide sufficient detail to indicate that the subcontractor meets the intent of the stated QA requirements. For example a large construction project may require a comprehensive quality system in addition to a QAP, whereas smaller projects (e.g., painting, concrete repair) may require less explanation in the QAP. Considerable latitude is allowed to develop and implement individual company processes that meet the needs of NREL, compliance with the requirements is still necessary. As appropriate include a short statement or two and then make reference an existing company procedure, including procedure number and title. The QAP should be written so that NREL representatives may assess the suitability and effectiveness of the subcontractor's quality practices and processes.

4.0 QUALITY MANAGEMENT, QUALITY ASSURANCE AND QUALITY CONTROL

Quality management consists of all the activities that support the management function. This includes the quality policy, objectives, and responsibilities; and implementation of quality planning, quality assurance, quality control, and quality improvement. Quality is verified through checking, reviewing, and monitoring of work activities, with documentation by experienced, qualified individuals who are not directly responsible for performing the work. Quality management consists of quality assurance and quality control.

Quality assurance is an integral part of every activity that is performed at NREL. Quality assurance refers to the activities necessary to ensure that a product conforms to established technical requirements. A quality assurance system can help increase a company's credibility and enable them to compete better with others.

Quality control is the ongoing deliberate process, planned and carried out by the provider of products or services. Quality control ensures that the work is done correctly the first time. It is achieved by qualified individuals focused on preventing problems or errors rather than reacting to them. Quality is controlled by adequate planning, coordination, supervision, and technical direction and by proper definition and a clear understanding of job requirements and procedures.

5.0 NREL QUALITY ASSURANCE ELEMENTS

The following are the nine (9) QA elements required to be addressed in a subcontractor's QAP. Included with each element is guidance (*in italics*) to aid in developing the QAP. Not all of the requirements contained in these 9 elements, nor the guidance will be applicable for every contract.

A. Quality Program

State the company quality policy and criteria for the graded approach philosophy. Describe the company quality program. Include descriptions of the following topics:

- ✓ organizational structure, including functional responsibilities and levels of authority
- ✓ the interfaces for managing, performing, and assessing the work
- ✓ the process for developing, maintaining, and managing the quality program
- ✓ the process for scheduling and providing required resources (e.g., personnel, equipment)
- ✓ the communication process ensuring adequate and timely interface with all disciplines and/or parties (e.g., design team, construction team) involved with the project

Guidance

- *The Quality Policy is a written statement that describes the company's commitment to quality, safety, and to meeting customer's requirements. The company's policy statement on quality assurance includes the importance of QA and QC activities to the company and why. It also includes the general objectives and goals of the quality system. The quality statement should commits the company to safely achieving measurable quality results, to continuous improvement, and a safe work place and shall be communicated to customers, suppliers, trade partners, and employees.*
- *Include a statement indicating that all employees shall be responsible for adhering to the quality system policies and procedures.*
- *Describe the company's graded approach for QA/QC (e.g., how the company determines the appropriate level of effort/rigor required to comply with a QA requirement).*
- *An organization chart showing the reporting/connecting relationships between various position titles is a good way of depicting key persons and their roles. The organization chart should display the subcontractor (s) relationships that are relevant to contract. The senior manager(s) responsible for quality assurance should be identified on the organization chart.*
- *Describe the responsibilities for key positions affecting quality. These positions normally include company management, the manager with overall responsibility for the company's quality processes, quality representatives, safety officer, design personnel, supervisors, competent personnel, and inspectors, as applicable.*
- *Describe how the company's quality program was developed and is maintained. Include discussion of the technical activities, programs, processes that are supported by the quality program including required quality controls, where quality oversight responsibility is delegated or assigned, and how internal coordination of QA and QC activities occurs.*
- *Describe the company's process for determining required resources (personnel and equipment) and how the company ensures that they are available (scheduling for the organization and completing of work to meet established requirements).*

B. Personnel Training and Qualification

Describe the company personnel training and qualification process. Include descriptions of the following topics:

- ✓ the process for tracking the training and qualification requirements for personnel

- ✓ the process for establishing the minimum professional qualifications for each level of design responsibility in all applicable disciplines
- ✓ the process for establishing the minimum proficiency levels for construction craft

Guidance

- *Describe the process used by the company to establish and document the education and/or qualification requirements for company positions requiring professional licenses, certificates, or other specialized training (e.g., a construction site superintendent). Describe how the company ensures that personnel satisfy the minimum proficiency levels required.*
- *Describe the processes used to identify, ensure, and document that personnel have and maintain the appropriate knowledge, skill, and statutory, regulatory, professional or other certification, accreditations, licenses, or other formal qualification (e.g., records).*
- *Describe the company process used to determine/provide retraining, continuing proficiency training, etc.*

C. Quality Improvement

Describe the company quality improvement process. Include descriptions of the following topics:

- ✓ the process for detecting, reporting, and documenting quality problems associated with services, products, and processes
- ✓ the process for identifying, controlling, correcting and preventing the use of nonconforming items, services, and processes
- ✓ the process for identifying and documenting the cause, extent, and remedial and preventative actions.

Guidance

- *Describe the company's approach towards continuous improvement of company processes, including the roles and responsibilities of company staff. Include a description of the process that eliminates recurring quality problems and indentifying opportunities for improvement.*
- *Describe the company's process for identifying and resolving quality problems (e.g., nonconformances, deficiencies, issues, etc.). Include a description of how quality problems are prevents; promptly identified, including a determination of the nature and extent of the problem; correction of the problem, including timeliness, corrective actions, remedial actions ,and preventive actions; documenting the actions taken; determining the cause of the problem; tracking actions to closure; and processes to determine the effectiveness of the actions. Quality problems may occur at anytime and are dependent upon the type of contract (e.g., during design, during construction, rework, supplying a suspect part, etc.)*
- *Describe the processes used to communicate between the company and lower tier subcontractors to identify and resolve quality problems.*

D. Documents and Records

Describe the company document and data control process and the company records management process. Include descriptions of the following topics:

- ✓ the process for preparing, reviewing, approving, issuing, using, controlling, and revising documents prescribing processes, specify requirements, or establish design
- ✓ the submittal review process
- ✓ the electronic document protection process, including software controls
- ✓ the process to manage the identification, preparation, review, approval, protection, maintenance, and disposition of project records

Guidance

- *Describe the company's process for establishing and documenting the appropriate controls for procedures and records (both printed and electronic)*
- *Undocumented procedures are acceptable in many situations but ensure personnel in the company or sub-tier contractors needing to use them clearly and uniformly understand them. Flow charts and brief process outlines are encouraged wherever practical. These requirements explicitly state when a retrievable document is required by the use of the terms document, defined in, record, or written.*
- *Describe the company's process/procedures for maintaining documents including transmittal, distribution, release control, change control, use requirements, traceability, retrieval, removal of obsolete documentation, and disposition. Documentation includes, but is not limited to, procedures, test results, drawings, reports, etc.*
- *Describe the process for scheduling and managing submittals, including those of designers of record, consultants, architect-engineers, subcontractors, offsite fabricators, suppliers, and purchasing agents. Include a description of the process for reviewing, approving and managing submittals and the submittal register/log.*
- *Describe the process for controlling the identification), retention (including retention times), access, preservation (including protection from damage, loss, and deterioration) and disposition of contract/project records.*

E. Work Processes

Describe the company's work control process. Include descriptions of the following topics:

- ✓ the process for ensuring consistency with technical standards, administrative controls, and other hazard controls
- ✓ the process for identifying, labeling, controlling, packaging, storing, shipping, and protecting items, including customer property
- ✓ the process for identifying, controlling, calibrating (when necessary), adjusting, and maintaining equipment used to collect data or take measurements for the project

Guidance

- *Describe or reference the processes, including the roles, responsibilities, and authorities for ensuring that work is performed according to approved planning and technical documents.*

- *Describe the process the company implements to ensure that applicable codes, regulations, industry standards, company standards, or manufacturer's instructions are reviewed for changes, and how these changes are communicated to key personnel and appropriate sub-tier contractors and incorporated into the company's quality process/program.*
- *Describe the process for determining work performance and acceptance criteria including those QC activities necessary to assess the work performance.*
- *Describe how data applicable to the contract/project are identified, documented, and controlled.*
- *Describe the processes the company implements to identify, label, control, package, store, ship, and protect items including NREL property and completed work.*
- *Describe the process for developing, installing, testing (including verification and validation), using, controlling and documenting computer hardware and software used to satisfy the contract to ensure it meets technical and quality requirements.*
- *Describe the process for identifying, controlling, and maintaining equipment and instruments that will be required to perform activities. Describe the process for identifying, calibrating, and tracking required measurement and test equipment (M&TE), including the applicable calibration criteria (e.g., a voltmeter that is calibrated annually and performs a self-test every use); and process for determining the required calibration criteria (e.g., precision, accuracy, range) for each piece of M&TE (e.g., manufacturer's criteria).*
- *Describe the software control processes for ensuring that computer programs used for applications such as developing or verifying designs, performing safety analyses, establishing safety envelopes, and performing safety management functions perform as intended and cannot create a safety issue through failure or unexpected impacts.*

F. Design

Describe the company design control process. Include descriptions of the following topics:

- ✓ design review management and performance process
- ✓ design approval, verification and validation process
- ✓ design submittal process
- ✓ design development control process
- ✓ the process to ensure the incorporation of applicable requirements and design bases in design work
- ✓ design change control process
- ✓ design interface (technical and administrative) management process (e.g., tracking, and control)
- ✓ interface and communication management process (e.g., between the design team and the construction team)
- ✓ design and construction configuration management process
- ✓ software quality management, configuration management, and maintenance processes

Guidance

- *Describe the process that will manage design activities including design verification and validation, design review, design approval and sign-off, and design waivers of requirements. Any design-related checklists should be attached to the QAP. Include the process that takes into account applicable codes, standards, specifications, quality characteristics, and regulatory requirements, as appropriate. Identify the design review stages and the outputs that will be reviewed and the reviewers for each stage.*
- *Describe the process that will manage the design inputs and output process, including the acceptance criteria.*
- *Describe the design change control and configuration management processes.*
- *Describe the processes for managing software used to originate or analyze design solutions during the design process, include a discussion regarding backup, security, change control, etc.*
- *Describe the design processes that will be used to avoid procurement and use of suspect or counterfeit items (S/CI) and to ensure engineering involvement in disposition of any S/CIs discovered.*

G. Procurement

Describe the company procurement and subcontracting processes. Include descriptions of the following topics:

- ✓ the process for establishing procurement requirements for items and services
- ✓ the process for ensuring inclusion of the performance specifications provided by the design authority and expectations
- ✓ the process for evaluating and selecting prospective suppliers based on specified criteria
- ✓ the process for determining and flowing down applicable requirements to suppliers and subcontractors
- ✓ the coordination process between subcontractors and lower-tier subcontractors
- ✓ the process for managing and controlling supplier documentation
- ✓ the process for ensuring that approved suppliers continue to provide acceptable items and services
- ✓ the process for identifying potential of suspect/counterfeit items and preventing of their procurement

<u>Guidance</u>

- *Describe the processes that will be used to ensure that items and/or services provided by suppliers meet applicable requirements and expectations. Include the processes for preventing the introduction and/or detection of S/CIs into the project.*
- *Identify the processes used to select and evaluate prospective subcontractor/suppliers, include the requirements flow down through various layers of subcontractors/suppliers and performance verification processes.*
- *Describe the process for developing procurement documents including performance specifications, acceptance criteria, applicable standards and specifications, and deliverables/supplier documents (e.g., submittals, documentation, problem resolution, records retention, etc.)*

- *Describe the processes, including the roles, responsibilities, and authorities pertaining to all appropriate procurement documents, solicitations, and agreements. Include a description of the procurement review and approval process, and the process for resolution of procurement related problems.*

H. Inspections and Acceptance Testing

Describe the company quality control and inspection and acceptance testing processes. Include descriptions of the following topics:

- ✓ the process for establishing QC checkpoints and QC criteria
- ✓ the process for establishing the inspection and test methods for specified items, services, and processes
- ✓ the process for acceptance and performance criteria establishment and use
- ✓ the process for inspection and test results documentation
- ✓ the process for ensuring participation of the customer, statutory and regulatory, and other third parties in the project

Guidance

- *Describe the process for establishing inspection/test acceptance criteria.*
- *Describe the process for inspecting, testing, and/or accepting procured items and services in accordance with established acceptance criteria.*
- *Describe the process for inspecting and/or testing in order to verify that the physical and functional aspects of items, services, and work processes meet requirements and are fit for acceptance and use. Include a description of the quality control (QC) processes that will be used, including the process for mandatory hold points. Attach applicable QC checklists to the QAP or reference where they are available.*
- *Describe the process that ensures that inspection/test personnel have the required qualifications.*
- *Describe the process for managing inspection and test records, including the required information, inspection/test data, results and acceptability, and any action taken concerning problems. Include the records protection process.*
- *Describe the process for identifying, calibrating, maintaining, and controlling M&TE used for inspections, tests, monitoring, and data collection. Include processes to manage the use and traceability of the M&TE.*
- *Describe the process for developing, testing, maintaining, and tracking software used for inspection and test processes.*

I. Assessment

Describe the company assessment process. Include descriptions of the following topics:

- ✓ the process for ensuring management assume responsibility for and directly participate in project assessments
- ✓ the independent assessment (e.g., audits) process, including the planning and performance of assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement

Guidance

- *Describe the process for company management self-assessing their organization, functions, and processes to determine how well they meet customer and performance expectations and company objectives.*
- *Describe the process for establishing and implementing independent assessments of the company and the activity. Independents assessments include both compliance-based (e.g., verification of adherence to established requirements) and performance-based (conducted on activities and processes that relate directly to performance expectations) approaches. Independent assessors may be from the same company but did not perform, review, approve or is otherwise related to the work/activity being assessed.*

6.0 QUALITY ASSURANCE PROJECT PLANS

Some contracts with NREL are Task Ordering Agreement (TOA) type contracts. Individual task orders for a Task Order Agreement (TOA) subcontractor may invoke additional quality assurance requirements not included in the original TOA contract including the submittal of a Task Order specific QA Project Plan (QAPP). Examples of additional requirements contained in a Task Order are the inclusion of special training or certification requirements, special inspection or testing requirements, sampling requirements, etc. The QAPP should reference the overarching QAP, if one was accepted as part of being awarded a TOA contract, and then describe how the subcontractor will satisfy compliance with the additional requirements. When no TOA contract level QAP was accepted by NREL, then a QAP will usually be required to be submitted as part of the Task Order.

7.0 DEFINITIONS

Activity – The smallest identified item of work in a project or process.

Assessment – A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

Assurance - Bringing about and installing confidence; being certain or the act of being sure.

Continuous improvement – A recurring process of enhancing the quality processes/system in order to achieve improvements in the overall quality performance consistent with the company's quality policy.

Corrective action – The action taken to eliminate the cause of a detected quality problem.

Graded Approach – The process of ensuring that the levels of analyses, documentation, and/or actions used to comply with requirements are commensurate with 1) the relative importance to safety, safeguards, and security; 2) the magnitude of any hazard involved; 3) the life-cycle stage of a facility or item; 4) the programmatic mission of a facility; 5) the particular characteristics of a facility or item; 6) the relative importance to hazards; and 7) any other relevant factors.

Hazard – The source, situation, or act with a potential for harm in terms of human injury or ill health.

Item – An all-inclusive term used in place of appurtenance, assembly, component, equipment, material, module, part, structure, product, software, subassembly, subsystem, unit, or support system.

Nonconformity – The non-fulfillment of a requirement.

Preventive Action – An action taken to eliminate the cause of a potential quality problem.

Procedure – A document that provides a specified way to carry out an activity or process.

Process – A series of actions that achieves an end result.

Project - A unique process consisting of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including constraints of time, cost, and resources.

Record – A document stating the results achieved or providing evidence of activities performed.

Quality – The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance – Quality assurance, or QA for short, refers to a program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.

Quality Assurance Plan - A document specifying which processes, procedures, and associated resources will be applied by whom and when to meet the requirements of a specific project, product, process or contract.

Quality Control – The process by which entities review the quality of all factors involved in a service, project, or production.

Service – Work, such as design, construction, fabrication, decontamination, environmental remediation, waste management, laboratory sample analysis, software development/validation/testing, inspection, testing, training, assessment, repair and installation or the like.

Supplier – The organization or person that provides a product.

8.0 REFERENCES

Department of Energy Order 414.1C (DOE O 414.1C), *Quality Assurance*

Office of the Secretary of Defense Quality Management Office, *Small Business Guidebook to Quality Management*, August 1998.