



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

## EXHIBIT “H” PART 2

SUBCONTRACTOR shall comply with the clauses in this Exhibit that have been indicated as being incorporated in this subcontract.

**QRL-1-QC-01A, GENERAL QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTED PROGRAM**

In accordance with CONTRACTOR’s responsibilities under DOE Order 414.1D, Admin. Chg. 2, *Quality Assurance*, 10 CFR 830 Subpart A, *Quality Assurance Requirements*, and as applicable 10 CFR 71 Subpart H, *Quality Assurance*, the requirements established for SUBCONTRACTOR’s Quality Assurance (QA) Program in this exhibit are derived from the applicable QA requirements of the DOE Order 414.1D, Admin. Chg. 2, *Quality Assurance*, 10 CFR 830 Subpart A, *Quality Assurance Requirements*, and as applicable 10 CFR 71 Subpart H, *Quality Assurance*. The requirements established in this Exhibit are consistent with the applicable requirements of ASME NQA-1, 2008;2009a, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and Part II, as applied to this subcontract. SUBCONTRACTOR’s Quality Assurance (QA) Program is required to be evaluated for the capability of providing items/services in accordance with subcontract technical and quality requirements and is required to be approved by CONTRACTOR prior to the start of work. SUBCONTRACTOR will be notified of approval of their QA Program and CONTRACTOR will maintain the approval documentation. SUBCONTRACTOR will perform all work under this subcontract in accordance with its approved QA Program and must notify CONTRACTOR of any changes made to its QA Program, whereupon CONTRACTOR will determine the need for re-evaluation/re-approval and any need to pause work pending re-evaluation/re-approval. SUBCONTRACTOR’s QA Program shall be subject to ongoing evaluation and monitoring by CONTRACTOR. Documents supplied by SUBCONTRACTOR that contain proprietary information or describe proprietary processes must be clearly marked to prevent disclosure. Definitions of terms used in this Exhibit are found in NQA-1-2008/1a-2009 Part I, Introduction, Terms and Definitions; 10 CFR 830.3, Definitions; DOE O 414.1D, Chg. 2, 6. Definitions.

**QRL-1-QC-01B, GENERAL QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTING TRIAD PROGRAM**

In accordance with CONTRACTOR’s responsibilities under DOE Order 414.1D, Admin. Chg. 2, *Quality Assurance*, 10 CFR 830 Subpart A, *Quality Assurance Requirements*, and as applicable 10 CFR 71 Subpart H, *Quality Assurance*, the requirements established for SUBCONTRACTOR to perform all work for this subcontract in accordance with CONTRACTOR’s DOE approved Quality Assurance (QA) Program meet the applicable QA requirements of the DOE Order 414.1D, Admin. Chg. 2, *Quality Assurance*, 10 CFR 830 Subpart A, *Quality Assurance Requirements*, and as applicable 10 CFR 71 Subpart H, *Quality Assurance*. The CONTRACTOR QA Program and implementing documents are consistent with the applicable requirements of ASME NQA-1, 2008;2009a, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and Part II.

**QRL-1-QC-01C, GENERAL QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTING DEPARTMENT OF ENERGY APPROVED PROGRAM**

In accordance with CONTRACTOR’s responsibilities under DOE Order 414.1D, Admin. Chg. 2, *Quality Assurance*, 10 CFR 830 Subpart A, *Quality Assurance Requirements*, and as applicable 10



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

CFR 71 Subpart H, *Quality Assurance*, the requirements established for SUBCONTRACTOR to perform all work for this subcontract in accordance with SUBCONTRACTOR's DOE approved QA Program meet the applicable Quality Assurance requirements of the DOE Order 414.1D, Admin. Chg. 2, *Quality Assurance*, 10 CFR 830 Subpart A, *Quality Assurance Requirements*, and as applicable 10 CFR 71 Subpart H, *Quality Assurance*. SUBCONTRACTOR's QA Program and implementing documents must be consistent with the applicable requirements of ASME NQA-1, 2008;2009a (or newer), *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and Part II, as applied through the DOE O 414.1D, Admin. Chg. 2, *Quality Assurance*.



## **QRL-1-QC-02A, QUALITY ASSURANCE PROGRAM AND ORGANIZATION REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTED PROGRAM**

SUBCONTRACTOR must implement a Quality Assurance Program in accordance with NQA-1-2008/1a-2009, Requirement 2, Quality Assurance Program, sections 100 through 300, and 500. SUBCONTRACTOR must establish an organization in compliance with NQA-1-2008/1a-2009 Requirement 1, Organization. Where NQA-1-2008/1a-2009 references "this Standard", or "this Part", or "portions thereof", replace that text with "the requirements of this subcontract as specified in the contract documents".

SUBCONTRACTOR must establish management processes to plan, schedule, and provide resources for work for CONTRACTOR such that quality is able to be achieved and delivery timelines are able to be met.

SUBCONTRACTOR must establish and maintain programs and/or procedures to plan and conduct independent assessments to measure the adequacy of work and quality program performance to CONTRACTOR requirements, and to promote improvement in the quality of items and/or services provided to CONTRACTOR. The program must include a process for ensuring that any assessment results are responded to, and action taken where appropriate to enhance quality and/or performance.

SUBCONTRACTOR must establish a process to ensure that organizations which perform independent assessments have sufficient authority, and freedom from line management of the assessed areas, to be able to independently reach conclusions regarding the acceptability and effectiveness of the assessed areas.

SUBCONTRACTOR must establish a process to ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.



## **QRL-1-QC-02B, QUALITY ASSURANCE PROGRAM AND ORGANIZATION REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTING TRAUD PROGRAM**

SUBCONTRACTOR must perform work for this subcontract in accordance with the CONTRACTOR Quality Assurance Program and any applicable local Quality Assurance Plans as defined in SD330, *LANL Quality Assurance Program*. Any items or services procured as a part of this subcontract must be purchased using CONTRACTOR procurement processes and methods of acceptance. SUBCONTRACTOR must perform work for this subcontract in accordance with CONTRACTOR organization requirements as defined in SD312, *LANL Management Models*, and clarified in this subcontract.



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

**QRL-1-QC-02C, QUALITY ASSURANCE PROGRAM AND ORGANIZATION REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTING DEPARTMENT OF ENERGY APPROVED PROGRAM**

SUBCONTRACTOR must perform work for this subcontract in accordance with their DOE approved QA program per the requirements of DOE O 414.1D, Admin. Chg. 2, *Quality Assurance*, and using applicable requirements from NQA-1-2008/1a-2009 (or newer) as implemented through their approved QA program.

**QRL-1-QC-02D, SUPPLEMENTARY QUALITY ASSURANCE PROGRAM REQUIREMENTS**

In addition to the requirements of this Exhibit, SUBCONTRACTOR must implement a Quality Assurance Program in accordance with applicable codes or standards as specified below.

Click or tap here to enter text.

**QRL-1-QC-02E, SUPPLEMENTARY QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTED CALIBRATION PROGRAM**

In addition to the requirements of this Exhibit, SUBCONTRACTOR must implement a QA program that meets the requirements of ISO/IEC-17025, *General Requirements for the Competence of Testing and Calibration Laboratories*, for the performance of calibration of measuring and test equipment (M&TE) provided to CONTRACTOR. If SUBCONTRACTOR is procuring these calibration services from a sub-tier subcontractor, then they must flow this requirement down to that supplier.

**QRL-1-QC-03, DESIGN**

SUBCONTRACTOR must implement a QA program which meets the applicable requirements of NQA-1-2008/1a-2009 Requirement 3 for any design activities providing inputs to items and/or services provided to CONTRACTOR. SUBCONTRACTOR must implement the applicable requirements of NQA-1-2008/1a-2009 Part II, Subpart 2.7 for any software design activities and/or any software used in support of design activities. SUBCONTRACTOR must develop shipping, handling, and storage requirements for items and/or assemblies they design in accordance with the applicable requirements of NQA-1-2008/1a-2009 Part II, Subpart 2.2.

SUBCONTRACTOR must establish a process to ensure that SUBCONTRACTOR:

- designs items and processes affecting the quality of items or services supplied to CONTRACTOR using sound engineering/scientific principles and appropriate standards.
- design activities are in accordance with any standards or requirements included or referenced in this subcontract.
- incorporates applicable requirements and design bases in design work and design changes for items and/or services delivered to CONTRACTOR.
- incorporates any requirements or design bases included or referenced in this subcontract.

SUBCONTRACTOR must establish a process to identify and control design interfaces for design



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

activities affecting items and/or services delivered to CONTRACTOR. SUBCONTRACTOR must establish a process for the validation and verification of designs affecting the quality of items and/or services delivered to CONTRACTOR for adequacy against the requirements of this subcontract. The process must ensure that personnel and organizations who perform validation and verification activities of designs affecting the quality of items and/or services delivered to CONTRACTOR are not the same personnel or functions who performed the design work. SUBCONTRACTOR must ensure that verification and validation of designs have been performed and the designs found to meet applicable requirements prior to approval and implementation of the designs. SUBCONTRACTOR must flow the requirements of this clause down to any sub-tier subcontractors who perform design activities for this subcontract.

## **QRL-1-QC-04, SUBCONTRACTOR GENERATED PROCUREMENT DOCUMENTS**

SUBCONTRACTOR must establish and implement a process to determine and flow down appropriate requirements to sub-tier subcontractors to ensure that technical and quality characteristics and requirements are met. SUBCONTRACTOR must define and flow down to any sub-tier suppliers a scope of work to include any technical requirements and the content of the applicable clauses from this exhibit based on the scope of work. The SUBCONTRACTOR's procurement documents must establish and clearly define the items and/or services and documentation to be delivered, and the requirements for documentation content. SUBCONTRACTOR's procurement documents must be reviewed by personnel defined in SUBCONTRACTOR's Quality Assurance Program. Revisions to procurement documents affecting the technical or quality requirements of the documents must be reviewed in the same manner as the original documents.

When SUBCONTRACTOR procures items from a sub-tier supplier that cannot meet the applicable clauses of this exhibit (hereafter referred to as a commercial sub-tier supplier), then the requirements of QRL-1-QC-04, QRL-1-QC-04A, QRL-1-QC-08, and QRL-1-QC-08A must be applied as follows. If the commercial sub-tier supplier is providing items or materials according to a design provided by CONTRACTOR, SUBCONTRACTOR must implement QRL-1-QC-04A and QRL-1-QC-08A instead of QRL-1-QC-04 and QRL-1-QC-08. If the commercial sub-tier supplier is providing items or materials according to a design controlled by SUBCONTRACTOR, SUBCONTRACTOR must implement QRL-1-QC-04A and QRL-1-QC-08.

When SUBCONTRACTOR procures services from a commercial sub-tier supplier, then SUBCONTRACTOR must implement QRL-1-QC-04A and QRL-1-QC-08A instead of QRL-1-QC-04 and QRL-1-QC-08.

## **QRL-1-QC-04A, SUBCONTRACTOR GENERATED PROCUREMENT DOCUMENTS (Commercial Supply Chain)**

If QRL-1-QC-04 is applied to this contract, then this QC is applicable as described in QRL-1-QC-04. SUBCONTRACTOR must establish and implement a process to determine and flow down appropriate requirements to sub-tier subcontractors to ensure that technical and quality requirements are met. SUBCONTRACTOR must define and flow down to any sub-tier suppliers a scope of work to include any technical requirements and QA program requirements necessary to provide reasonable assurance of the acceptability of sub-tier subcontractor items and/or services.



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

The SUBCONTRACTOR's procurement documents must establish and clearly define the items and/or services and documentation to be delivered, and the requirements for documentation content. SUBCONTRACTOR's procurement documents must be reviewed by personnel defined in SUBCONTRACTOR's Quality Assurance Program. Revisions to procurement affecting the technical or quality requirements of the documents must be reviewed in the same manner as the original documents.

## **QRL-1-QC-05, CONTROL OF QUALITY AFFECTING ACTIVITIES**

SUBCONTRACTOR must establish and implement a process to identify, to determine methods for the control of, and to verify acceptance criteria for activities that affect the quality of items and/or services provided to CONTRACTOR. SUBCONTRACTOR must consider at a minimum the activities controlled through this Exhibit as quality affecting. The identification of, the methods of control for, and the associated acceptance criteria for those activities affecting quality must be documented. Activities that are determined to affect quality must be performed consistent with applicable technical standards, specifications, administrative controls, and any other hazard controls adopted to meet regulatory or contract requirements, and according to established and documented instructions, procedures, and/or drawings as appropriate to control the activities. Such instructions, procedures, and/or drawings must include or reference the acceptance criteria for determining if the activities they describe have been satisfactorily accomplished. The level of detail and instruction must be commensurate with, and reference as applicable, the required proficiency of workers, the complexity of the work, and the importance of ensuring consistent and acceptable results. The proficiency of workers and the necessary training and qualifications to perform designated activities affecting quality must be determined in accordance with NQA-1-2008/1a-2009 Requirement 2 sections 200, 201, 202, and 300 and documented as part of the identified controls associated with activities affecting quality. When SUBCONTRACTOR uses inspections as a method of control for quality affecting activities, the inspections must be performed in accordance with the applicable requirements of NQA-1-2008/1a-2009 Requirement 10, *Inspection*. When SUBCONTRACTOR uses tests as a method of control for quality affecting activities, the tests must be performed in accordance with the applicable requirements of NQA-1-2008/1a-2009 Requirement 11, *Test Control*.

## **QRL-1-QC-06, DOCUMENT CONTROL**

SUBCONTRACTOR's QA Program must address configuration control of subcontract requirements, including CONTRACTOR approval of substitutions and configuration control of any provided CONTRACTOR procedures, specifications, or other requirement documents.

SUBCONTRACTOR must establish and implement a process to identify and control documents including procedures, drawings, work control documents. This process must define the processes to prepare, review, approve, revise as necessary, and distribute controlled documents. The personnel responsible for those tasks and the required levels of authority for document approval must also be defined. The process must ensure that controlled documents are available in the appropriate revision at the location(s) where the associated work is being performed. The process must establish and implement a method of ensuring that the correct documents and revisions are used to perform work.

## **QRL-1-QC-07, SUPPLIER EVALUATION AND SELECTION**



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

SUBCONTRACTOR must establish and implement a process to evaluate sub tier subcontractors who will provide items and/or services affecting the quality of items and/or services SUBCONTRACTOR will provide to CONTRACTOR. The remaining requirements of this clause are not applicable if items from the sub tier being evaluated will be accepted using clause QRL-1-QC-08A, *Subcontractor Acceptance of Items/Service (Commercial Supply Chain)*. These evaluations must ensure that sub tier subcontractors have adequate technical capability and quality assurance controls in place to be able to provide items and/or services which meet the applicable technical and quality requirements of this contract prior to procuring items/services from those sub-tier suppliers. The process must provide reasonable assurance that the sub-tier subcontractor has the capability and programs in place to meet the requirements for the work they will perform. Evaluations of sub-tier suppliers must be documented and must be conducted through an on-site evaluation of the sub-tier's capabilities and quality program. Once SUBCONTRACTOR has established a documented history of a sub-tier supplier's ability to successfully provide items/services that meet specified requirements, an evaluation may be conducted via a review of the sub-tier supplier's quality records if the records can objectively demonstrate the sub-tier's ability to meet the requirements of this subcontract.

**QRL-1-QC-08, SUBCONTRACTOR ACCEPTANCE OF ITEMS/SERVICES**

SUBCONTRACTOR must establish and implement processes to evaluate and document the conformance and acceptability of items and/or services provided by sub tier subcontractors that affect the quality of items or services SUBCONTRACTOR will provide to CONTRACTOR for this subcontract. Methods of acceptance for items must be in accordance with NQA-1-2008/1a-2009, Part I, Requirement 7, *Control of Purchased Items and Services*, sections 400 – 600 as selected by SUBCONTRACTOR for each procurement and as applicable. When SUBCONTRACTOR uses receiving inspection as a method of acceptance, SUBCONTRACTOR must meet the applicable requirements of NQA-1-2008/1a-2009, Part I, Subpart 2.2, sections 500 through 503.3.

**QRL-1-QC-08A, SUBCONTRACTOR ACCEPTANCE OF ITEMS/SERVICES (Commercial Supply Chain)**

SUBCONTRACTOR must establish and implement processes to evaluate and document the conformance and acceptability of items and/or services provided by commercial sub tier subcontractors which affect the quality of items or services SUBCONTRACTOR will provide to CONTRACTOR for this subcontract. Methods of evaluating and documenting the conformance and acceptability of such items/services must be according to NQA-1-2008/1a-2009, Part II, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*, sections 500 – 700, and section 800 excluding bullet (c). SUBCONTRACTOR must develop a dedication plan for each item, group of like items, or service to be accepted from sub-tier subcontractors. If critical characteristics and their acceptance criteria are specified in this contract, then dedication plans must use those critical characteristics and acceptance criteria. If the contract does not specify critical characteristics and acceptance criteria then SUBCONTRACTOR must use the specified or referenced design criteria to identify the critical characteristics and use the design parameters to determine the acceptance criteria and tolerances. Definitions for dedications are provided in NQA-1-2008/1a-2009, Part II, Subpart 2.14, section 101.

**QRL-1-QC-09, CERTIFICATION PROGRAM**



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

SUBCONTRACTOR must establish, document, and implement a certification system for the items and/or services they provide including the procedures for the certification activities and generation of the certificate, and the administrative procedures for review and approval of the certificate.

Certificates must:

- a) identify the material(s) or items and/or services being certified traceable to the items delivered;
- b) identify the processes used to certify the materials, items, and/or services;
- c) identify the specific requirements of the procurement that are certified to have been met;
- d) identify any approved changes and/or deviations from the contract, and describe or reference any requirements that have not been met.

## **QRL-1-QC-10, SUBCONTRACTOR OBLIGATION TO VERIFY CONFORMANCE**

Using authorized personnel, SUBCONTRACTOR must verify that items or services offered under this subcontract to CONTRACTOR for acceptance comply with the subcontract requirements prior to offering them for acceptance. Any modifications, repairs, or replacements of items after final inspection/test/verification by SUBCONTRACTOR require re-inspection, retesting, or re-verification as appropriate to verify acceptability.

## **QRL-1-QC-11, PROCUREMENT RECORDS**

SUBCONTRACTOR must generate and maintain records for the performance of their Supplier Evaluation and Selection (QRL-1-QC-07) and acceptance of items/services (QRL-1-QC-08 / 08A) activities as defined in QRL-1-QC-23 and QRL-1-QC-24.

## **QRL-1-QC-12, RIGHT OF ACCESS**

SUBCONTRACTOR must provide CONTRACTOR and/or DOE/NNSA access to SUBCONTRACTOR's facilities and records to conduct evaluations of SUBCONTRACTOR's quality systems and verify compliance with subcontract requirements as well as access to conduct inspection and/or testing of items and/or services to assure conformance with subcontract requirements. SUBCONTRACTOR must contractually flow this right of access down to any sub-tier suppliers.

## **QRL-1-QC-13, IDENTIFICATION AND CONTROL OF ITEMS**

SUBCONTRACTOR must establish and implement processes to establish, maintain and document traceability of materials and components to their specific end use. These processes must implement physical markings of materials and components except where determined impractical or insufficient. When such a determination is documented, additional controls must be established, documented, and implemented such as physical separation or procedural controls. Methods of identification and/or traceability must be in accordance with any codes, standards, or specifications invoked by CONTRACTOR procurement requirements. If materials or components have limited calendar or operating life or cycles, these items must be identified as having limited calendar or operating life or cycles and controls must be established to ensure that only items that have not expired are used. Controls must also be established and implemented for limited calendar or operating life or cycle items as appropriate such as maintenance and, if necessary, replacement of markings and labels



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

and environmental controls. Item(s) or assemblies provided to CONTRACTOR under this subcontract that are not installed by SUBCONTRACTOR must be identified either on the item(s) or on the item packaging such that each item is easily identified as a part of the contract. This may include permanent labeling or non-permanent labels or writing as appropriate and/or defined in this subcontract.

## **QRL-1-QC-14, IDENTIFICATION AND CONTROL OF SPECIAL PROCESSES**

SUBCONTRACTOR must establish a process to identify special processes. A special process is one where the quality of the item or service is highly dependent on the skill of the worker and/or the control of the procedure and for which the quality of the work cannot be readily determined by nondestructive inspection or test. SUBCONTRACTOR must identify any special processes which control or verify the quality of the item(s) or service(s) they will provide to CONTRACTOR and must establish methods to control those special processes to ensure quality is achieved. Methods of control must be documented, must specify the procedures, personnel, and equipment qualification requirements, and must include the conditions necessary such as the equipment, parameters, environment, and calibration requirements. SUBCONTRACTOR must maintain records demonstrating the qualification of personnel, processes, and equipment as applicable to the processes. Persons performing Nondestructive Examination (NDE) must be qualified and certified according to ASME NQA-1-2008/1a-2009, Requirement 2, sections 300, 301, 302, 400, and 500.

## **QRL-1-QC-15, CONTROL OF INSPECTION**

SUBCONTRACTOR must establish and maintain an inspection program to verify the conformance of items or activities to the specified requirements in the procurement documents. The program must establish the processes and methods used to establish and document inspection plans, perform inspections, and document results, and report on the final acceptability of the inspected item(s). Inspection plans must identify characteristics to be inspected, methods of inspection, and the acceptance criteria to be used. Sampling plans used to determine acceptance of lots of items must be approved by CONTRACTOR prior to executing the sampling plan. Inspection records must be maintained which at a minimum identify the item inspection, date of inspection, inspector(s) who performed the inspection, type of observation(s), results or acceptability of the inspection(s), reference to any nonconformance associated with the item(s) inspected. Persons performing inspections to verify conformance of items or activities must be independent from the work being verified and must be qualified and certified according to ASME NQA-1-2008/1a-2009, Requirement 2, sections 300, 302, 400, and 500.

## **QRL-1-QC-16, TEST CONTROL**

SUBCONTRACTOR must establish and maintain a testing program to verify the conformance of item(s) and/or computer program(s) to the requirements specified in the subcontract documents. The testing program must establish the processes and methods used to evaluate and document test plans; methods used to control test parameters; test performance procedures; and methods to document results for tests including reporting on the final acceptability of the item(s) and/or software tested.





# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

For testing of items other than software, test plans must identify required controls such as environmental conditions and the tools and equipment required to be able to conduct the test in such a manner to fulfill test requirements and acceptance criteria as established in the subcontract documents. Procedures used to perform tests must reference or include requirements for; test configuration and test objectives, ensuring that any environmental conditions are met, ensuring that appropriately trained and qualified personnel use appropriately selected and calibrated equipment and tools, and for establishing methods of data acquisition. This may be accomplished in whole or in part by referencing appropriate ASTM methods, equipment instructions, or other methods as appropriate.

For testing of software, a testing program meeting the applicable requirements of NQA-1-2008/1a-2009, Part I, Requirement 11, sections 400, 600, and 602 must be established and implemented in addition to the applicable requirements of this clause.

Test results must be documented and evaluated by a defined responsible authority to ensure that requirements for the test have been met. The program must establish and maintain test records including, at a minimum: item(s) tested, date of test(s), personnel or data recorder who recorded the results of the test(s), type of test(s) and observations performed, the results of the test(s) including the acceptability of the test(s) and item(s) tested, reference to any item nonconformances or test deviations identified, and identification of the person evaluating the test results for compliance to established requirements.

Software used to perform or support the testing of items and/or other software for this subcontract must be controlled according to the applicable requirements of NQA-1-2008/1a-2009 Part II, Subpart 2.7.

Persons performing tests to verify conformance of items or activities must be independent from the work being verified and must be qualified and certified according to ASME NQA-1-2008/1a-2009, Requirement 2, sections 300, 302, 400, and 500.

## **QRL-1-QC-17, CONTROL OF MEASURING AND TEST EQUIPMENT**

SUBCONTRACTOR must establish and maintain a program to ensure that tools, gauges, instruments and other measuring and test equipment (M&TE) used to verify or control the quality of items or services are appropriately controlled, calibrated and/or adjusted, and maintained to ensure accuracy and validity of the data gathered. The program must establish processes to ensure that appropriate M&TE is selected based on the type, range, required accuracy, and tolerances required, and to ensure that any special parameters for the use of the M&TE is met, such as environmental conditions. M&TE used to verify or control quality must be calibrated at specified intervals or whenever its accuracy is suspect. Calibrations must be performed with appropriate equipment that is traceable to recognized national and/or international standards and in accordance with established procedures. Calibration procedures must specify or reference required accuracy, methods to be used, and the frequency of calibration based on the type and stability of the equipment to be calibrated and the required accuracy. M&TE must be appropriately marked or labeled to establish traceability for calibration and to indicate the calibration status. The as found condition of M&TE must be verified prior to calibration and recorded. Traceability must be established between: (1) M&TE used to verify quality and its use(s), and (2) the items verified to the M&TE used. If the quality of an item or service is found to be nonconforming, any M&TE used to verify that quality must be evaluated for conformance. If M&TE used to verify quality is found to be out of tolerance or otherwise indeterminate, the quality of any items or services it was used to verify since its last acceptable calibration must be evaluated. If impacts are found to the quality of items and/or services that have been delivered to CONTRACTOR, the SUBCONTRACTOR must notify CONTRACTOR of



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

those impacts within seven (7) calendar days. SUBCONTRACTOR must generate and retain records of calibration and M&TE use such that the calibration data and information can be used to verify conformance to applicable subcontract requirements.

## **QRL-1-QC-18, HANDLING, STORAGE, AND SHIPPING**

SUBCONTRACTOR must establish and maintain processes and/or procedures to ensure that items provided under this subcontract are not damaged or lost, and to minimize deterioration during handling, storage, cleaning, packaging, and shipping. SUBCONTRACTOR must establish processes to evaluate and identify items that require unique or extra controls or protective measures due to sensitivity, value, or perishability of items. Items must be marked and/or labeled as necessary to adequately maintain and preserve the item, such as when special environments are present or when an item has special controls in place. SUBCONTRACTOR must identify the need for any special handling tools and/or equipment to meet this requirement and must control those tools and equipment as necessary to include inspecting and/or testing them at specified time intervals or prior to use. Special handling tools are defined as those that meet the description in NQA-1-2008/1a-2009, Part II, Subpart 2.15, *Quality Assurance Requirements for Hoisting, Rigging, and Transporting of Items for Nuclear Power Plants*, section 303, *Special Design Equipment*.

## **QRL-1-QC-19, ITEM STATUS CONTROL**

SUBCONTRACTOR must establish and maintain processes to ensure that the status of items provided under this subcontract are identified either through marking or labeling of the items or in documents traceable to the items. This process must ensure that required inspections and tests are performed and that items are not inadvertently installed, used, or operated without required inspections and tests having been performed. The process must also establish the authority to determine whether a required inspection, test, or other process has been adequately performed and is acceptable. Methods of identification must include physical location of items, tags, labels, markings, shop travelers, stamps, inspection records, or other suitable and documented means.

## **QRL-1-QC-20, NONCONFORMING ITEMS**

SUBCONTRACTOR must establish and maintain a process to identify, control, evaluate, and resolve nonconformances with items and/or services provided under this subcontract. The process must include provisions for providing notification to CONTRACTOR of the nature of the nonconformance as well as recommendations for resolving the issue. Nonconforming items must be controlled by the SUBCONTRACTOR pending an approved disposition by CONTRACTOR. Nonconforming items must be identified by legible and non-detrimental marking or tagging either on the item or its container. When possible, items should be segregated and when not possible other methods established, documented, and used to control the item(s). Items that have been reworked must be reexamined in accordance with the original acceptance criteria. Repaired items must be reexamined in accordance with acceptance criteria provided by CONTRACTOR for the repaired condition. If SUBCONTRACTOR is the designer of the item(s), they must provide evaluations, disposition recommendations, and technical justifications, as applicable, to CONTRACTOR made by personnel with demonstrated competence in the area of evaluation, adequate understanding of applicable requirements, and access to pertinent background information.



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

**QRL-1-QC-21, CORRECTIVE ACTION AND CONTINUOUS IMPROVEMENT**

SUBCONTRACTOR must establish, implement, and maintain a process to identify conditions adverse to quality and correct them in a manner that precludes recurrence. This process must include provisions to determine if a condition adverse to quality may have impact on the quality of an item or service provided to CONTRACTOR. Should a condition adverse to quality have an impact on an item or service provided to CONTRACTOR, SUBCONTRACTOR must notify CONTRACTOR within seven (7) calendar days of the potential impacts to the item/service and any risks that are associated with the impacts. The cause of conditions adverse to quality must be determined and documented, and the cause must be determined and documented when the conditions adverse to quality may have significant impact on the quality of an item or service to be delivered to CONTRACTOR. Corrective actions must be established and documented to resolve the issue and preclude recurrence. Completion of corrective actions must be verified as defined in SUBCONTRACTOR's QA program.

SUBCONTRACTOR must establish a process for evaluating item characteristics, process implementation, and other quality related attributes of their items, services, and/or programs to identify areas which require improvement, or which do not meet requirements of CONTRACTOR procurement documents. This process must ensure that areas identified as needing improvement or not meeting requirements are evaluated for the cause of deficiencies, and that actions are taken to improve performance.

**QRL-1-QC-22, SUBCONTRACTOR OBLIGATION TO RESPOND TO CORRECTIVE ACTION REQUEST**

When SUBCONTRACTOR is notified by CONTRACTOR of a corrective action request, SUBCONTRACTOR must respond within thirty (30) calendar days with proposed corrective actions and anticipated completion dates. These will be reviewed by CONTRACTOR for acceptability and tracked to completion.

**QRL-1-QC-23, QUALITY AFFECTING RECORDS**

SUBCONTRACTOR must establish a program to ensure that records of activities or attributes affecting the quality of items and/or services delivered to CONTRACTOR are documented, retained, and as necessary delivered to CONTRACTOR. The program must ensure that records are legible, complete, accurate, and traceable to the items or activities they represent. Methods for making changes to records must be established to ensure adequate review and authentication of the changes. Record requirements must be established in quality affecting procedures and documents and must include provisions for the minimum content and the authentication of the records. Once generated, records must be stored at a predetermined location by authorized personnel in a manner that will protect them from loss, damage, alteration, or destruction for the duration defined in the procurement documents. Use of dual location storage techniques or one-hour fire rated cabinets, which are certified by an accredited organization, are required for records storage. Should SUBCONTRACTOR identify the need to make change(s) to records previously submitted to CONTRACTOR, they must notify CONTRACTOR within seven (7) days with the details of the change(s).



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

**QRL-1-QC-24, RECORDS RETENTION PERIOD**

Quality records associated with this subcontract must be stored by SUBCONTRACTOR for a minimum duration from project completion as specified below and must be retrievable during that period. Quality records include any documentation that demonstrates that items/services provided under this subcontract meet requirements including implementation of SUBCONTRACTOR's QA program.

Specify retention period

**QRL-1-QC-25, AUDIT PERFORMANCE**

SUBCONTRACTOR must establish, document, and maintain programs and/or procedures to perform audits using qualified and certified personnel in accordance with ASME NQA-1-2008/1a-2009, Requirement 2, sections 300, 303-500. These programs and/or procedures must provide for the scheduling, preparation, planning, performance, reporting, and response to audits as described in ASME NQA-1-2008/1a-2009, Requirement 18.

**QRL-1-QC-26, COMMERCIAL GRADE DEDICATION SERVICES**

SUBCONTRACTOR must establish and implement processes for a Commercial Grade Dedication program in accordance with NQA-1-2008/1a-2009, Part II, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*, sections 500 – 700, and section 800 excluding bullet (c) for items/services provided to CONTRACTOR under this subcontract as specified in subcontract documents. SUBCONTRACTOR must develop a dedication plan for each item, group of like items, or service to be dedicated. If critical characteristics and their acceptance criteria are specified in this contract, then dedication plans must use those critical characteristics and acceptance criteria. If the contract does not specify critical characteristics and acceptance criteria then SUBCONTRACTOR must use the specified or referenced design criteria to identify the critical characteristics and use the design parameters to determine the acceptance criteria and tolerances. Definitions for dedications are provided in NQA-1-2008/1a-2009, Part II, Subpart 2.14, section 101.

**QRL-1-QC-27, SOFTWARE ERROR REPORTING**

SUBCONTRACTOR must establish a process to ensure that any errors identified with software provided to CONTRACTOR are communicated to CONTRACTOR within seven (7) calendar days of identification. SUBCONTRACTOR must also establish, maintain, and provide to CONTRACTOR, a process for CONTRACTOR to communicate any potential errors to SUBCONTRACTOR for their evaluation.

**QRL-1-QC-28, COMMERCIAL GRADE TECHNICAL EVALUATION SERVICES**

SUBCONTRACTOR must establish and implement processes for performing technical evaluations for Commercial Grade Dedications in accordance with NQA-1-2008/1a-2009, Part II, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*, sections 300 – 500, and section 800 bullet (c) as specified in subcontract documents. Definitions for dedications are provided in NQA-1-2008/1a-2009, Part II, Subpart 2.14, section 101.



# Quality Assurance Program Requirements for Subcontractors, Quality Risk Level – 1

Institutional Quality & Performance Assurance Division

Procurement ID #: [Click or tap here to enter text.](#)

Revision: 0

	Name, Signature, and Date (electronic preferred)
TSME	
QAR	
P-QSME <sup>1</sup>	

<sup>1</sup> P-QSME signature not required if approval is captured in the procurement system (e.g., Ariba)