



Quality Assurance Program Requirements for Subcontractors, Quality Level – 2 (Enhanced Quality)

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.

QL-2-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 Program in this exhibit are derived from 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 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 the approval documentation will be maintained by CONTRACTOR. 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;2009a Part I, Introduction, Terms and Definitions; 10 CFR 830.3, Definitions; DOE O 414.1D, Chg. 2, 6. Definitions; and 10 CFR 71.4, Definitions.

QL-2-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 meets 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 NQA-1, 2008;2009a, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II.

QL-2-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,



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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 SUBCONTRACTOR's DOE approved Quality Assurance (QA) Program meets 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*. CONTRACTOR'S QA program and implementing documents must be consistent with the requirements of NQA-1, 2008;2009a (or newer), *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II, as applied through the DOE O 414.1D, Admin. Chg. 2, *Quality Assurance*, and using a graded approach.

QL-2-QC-02A, QUALITY ASSURANCE PROGRAM AND ORGANIZATION REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTED PROGRAM

SUBCONTRACTOR must establish an organization structure including defining functional responsibilities, levels of authority, and interfaces for personnel managing, performing, and assessing work for CONTRACTOR. The structure must be such that quality is achieved by those performing the work and verified by persons not responsible for the performance of the work.

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 a program to ensure that management regularly assesses their management and quality assurance processes and corrects problems that hinder the organization from achieving the quality and performance requirements specified by CONTRACTOR.

SUBCONTRACTOR must establish a program to ensure that personnel performing activities affecting the quality of items or services supplied to CONTRACTOR are adequately trained and qualified to perform the work. This program must include the evaluation of activities and establish the minimum qualifications to be able to adequately perform those activities. SUBCONTRACTOR must establish a program to evaluate the need for requiring continued training for personnel performing activities affecting the quality of items or services supplied to CONTRACTOR. This program must also ensure that personnel satisfactorily complete training as required to be allowed to continue performing those activities.

QL-2-QC-02B, QUALITY ASSURANCE PROGRAM AND ORGANIZATION REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTING TRIAD PROGRAM

SUBCONTRACTOR must perform all work for this subcontract in accordance with CONTRACTOR organization requirements as defined in SD312, *LANL Management Models*, and clarified in procurement documents. SUBCONTRACTOR must perform all work for this subcontract in accordance with the CONTRACTOR QA Program and any applicable local Quality Assurance Plans as defined by 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.

QL-2-QC-02C, QUALITY ASSURANCE PROGRAM AND ORGANIZATION REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTING DEPARTMENT OF ENERGY APPROVED PROGRAM



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

QL-2-QC-02D, SUPPLEMENTARY QUALITY ASSURANCE PROGRAM REQUIREMENTS

In addition to the requirements of the procurement documents, SUBCONTRACTOR must implement a Quality Assurance Program in accordance with the codes or standards specified below: (e.g., boiler code, pressure safety code, International Building Code, etc.)



QL-2-QC-02E, SUPPLEMENTARY QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTED CALIBRATION PROGRAM

In addition to the requirements of this Exhibit, SUBCONTRACTOR must implement a Quality Assurance (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 supplier, then they must flow this requirement down to the supplier.

QL-2-QC-02F, SUPPLEMENTARY QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTED TYPE B CONTAINER OPERATION PROGRAM

In addition to the requirements of this Exhibit, SUBCONTRACTOR must implement a Quality Assurance (QA) Program that meets the requirements of 10 CFR 71 subpart H, *Quality Assurance*, for the operation of Type B containers on behalf of CONTRACTOR. Additionally, SUBCONTRACTOR must obtain and maintain a license/Certificate of Compliance to operate Type B containers from the Nuclear Regulation Committee (NRC).

QL-2-QC-03, DESIGN

SUBCONTRACTOR must establish a process to ensure that SUBCONTRACTOR:

- designs items and processes affecting the quality of products 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 products delivered to CONTRACTOR.
- incorporates any requirements or design bases included or referenced in this subcontract.



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SUBCONTRACTOR must establish a process to identify and control design interfaces for design activities affecting products delivered to CONTRACTOR. SUBCONTRACTOR must establish a process for the validation and/or verification of design products affecting the quality of products delivered to CONTRACTOR for adequacy against the requirements of this subcontract. The process must ensure that personnel who perform validation and/or verification activities of design products affecting the quality of products delivered to CONTRACTOR are not the same personnel who performed the design work. SUBCONTRACTOR must ensure that verification and/or validation of work has been performed and the work found to meet any applicable requirements prior to approval and implementation of the design.

QL-2-QC-04, PROCUREMENT DOCUMENTS

SUBCONTRACTOR must establish and implement a process to identify and flow down appropriate requirements to sub-tier suppliers to ensure that technical and quality characteristics and requirements are met. SUBCONTRACTOR must accomplish this by defining the scope of work to include technical requirements that must be met, and quality assurance program requirements necessary to provide reasonable assurance of acceptability. The procurement documents must establish and define the documentation to be delivered, and the requirements for document content. Procurement documents, and changes thereto, must be reviewed by personnel defined in SUBCONTRACTOR's Quality Assurance Program.

QL-2-QC-05, CONTROL OF QUALITY AFFECTING ACTIVITIES

SUBCONTRACTOR must establish processes to ensure that work for this subcontract is performed consistent with technical standards, administrative controls, and any other hazard controls adopted to meet regulatory or contract requirements, and using approved work control documents such as instructions, procedures, drawings, or other appropriate means to ensure the work is satisfactorily accomplished. Such work control documents must establish or reference acceptance criteria for determining if the activities described have been satisfactorily accomplished. The level of detail and instruction must be commensurate with the proficiency of workers and the complexity of the work.

QL-2-QC-06, DOCUMENT CONTROL

SUBCONTRACTOR's quality assurance program shall address configuration control of subcontract requirements, including CONTRACTOR approval of substitutions and configuration control of any provided CONTRACTOR procedures, specifications, or items.

SUBCONTRACTOR must establish a process for identifying and controlling documents that prescribe processes, specify requirements, or establish design. This process must include methods to prepare, review, approve, issue, use, and revise these documents. The process must ensure that current controlled documents are available at the location(s) where the associated work is being performed. A method of ensuring that the correct documents are used must be established and implemented.

QL-2-QC-07, SUPPLIER EVALUATION AND SELECTION

SUBCONTRACTOR must establish and implement a process to evaluate sub-tier suppliers who



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provide items or services affecting the quality of items or services SUBCONTRACTOR provides to CONTRACTOR to ensure that they have adequate technical capability and quality assurance controls in place to be able to meet the technical and quality requirements of SUBCONTRACTOR's contract with CONTRACTOR. These processes must serve to ensure that the sub-tier supplier has the capability and programs in place to meet the requirements for the work they will perform. SUBCONTRACTOR must establish methods to ensure that their sub-tier suppliers continue to provide acceptable items and services, including re-evaluation if necessary and performance monitoring as applicable.

QL-2-QC-08, PRODUCT CERTIFICATION PROGRAM

SUBCONTRACTOR must establish, document, and implement a certification system for the product(s) they provide to CONTRACTOR including procedures for the certification activities and generation of the certificate, and the administrative process for review and approval of the certificate. Certificates must meet the content requirements specified for this procurement; identify the material(s) or products being certified traceable to the items delivered; identify the specific requirements of the procurement that are certified to have been met; identify any approved changes and/or deviations from the contract with CONTRACTOR; and must describe or reference any requirements that have not been met.

QL-2-QC-09, SUBCONTRACTOR OBLIGATION TO VERIFY CONFORMANCE

SUBCONTRACTOR must verify that items or services offered to CONTRACTOR for acceptance comply with the procurement requirements prior to offering them for acceptance. Should SUBCONTRACTOR identify potential negative impacts to the quality of items or services they have provided to CONTRACTOR they must: (1) consider any impacted items as nonconforming and meet the requirements for nonconforming items for this subcontract, and/or (2) notify CONTRACTOR of impacted services within four (4) business days to include a description of the potential impacts and any risk associated.

QL-2-QC-10, 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 SUBCONTRACTOR's product to assure conformance with subcontract requirements. SUBCONTRACTOR must contractually flow this right of access down to any sub-tier suppliers.

QL-2-QC-11, IDENTIFICATION AND CONTROL OF ITEMS

SUBCONTRACTOR must establish and implement processes to establish and maintain traceability of items and components to their specific end use. Methods of identification and/or traceability must be in accordance with any codes, standards, or specifications invoked by the procurement requirements. 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 traceable to the subcontract. This may include permanent labeling or non-



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permanent labels as appropriate and/or defined in this subcontract.

QL-2-QC-12, IDENTIFICATION AND CONTROL OF SPECIAL PROCESSES

SUBCONTRACTOR must establish a process to identify as special processes those processes where the quality of the product 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 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 in accordance with ANSI/ASNT CP-189, *ASNT Standard for Qualification and Certification of Nondestructive Testing Personnel* or other governing code or standard for the type of examination they are performing.

QL-2-QC-13, INSPECTION AND TEST

SUBCONTRACTOR must establish programs to ensure that products delivered to CONTRACTOR are inspected and tested according to the acceptance and performance criteria established in CONTRACTOR procurement documents. Inspections and tests must be performed in accordance with any codes, standards, or specific instructions included or referenced in CONTRACTOR procurement documents. The results of the inspection/test must be documented to include a determination of whether acceptance and performance criteria have been met. Personnel performing inspections/tests to evaluate the acceptability of items or services must not be directly responsible for the performance of the work being evaluated and must have their qualifications to perform the inspection/test certified in writing by an appropriate authority.

QL-2-QC-14, 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 monitor, verify, and/or control the quality of items or services supplied to CONTRACTOR are appropriately selected, controlled, calibrated and/or adjusted, and maintained to ensure adequate accuracy and validity of the data gathered. Traceability must be established between M&TE used to verify quality and its use(s). If M&TE used to verify quality is found to be out of tolerance or otherwise indeterminate, the quality of any items verified since its last acceptable calibration must be re-evaluated. If impacts are found to the quality of products delivered to CONTRACTOR, SUBCONTRACTOR must: (1) consider any impacted items to be nonconforming and meet the requirements for nonconforming items for this subcontract, and/or (2) notify CONTRACTOR of impacted services within four (4) business days to include a description of the potential impacts and any risk associated.

QL-2-QC-15, HANDLING, STORAGE, AND SHIPPING

SUBCONTRACTOR must establish and maintain processes and/or procedures to ensure that items



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are not damaged or lost, and to minimize deterioration during handling, storage, cleaning, packaging, and shipping. 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.

QL-2-QC-16, NONCONFORMING ITEMS

SUBCONTRACTOR must establish and maintain a process to identify, control, evaluate, and resolve nonconformances with items to be provided to CONTRACTOR. Nonconforming items must be controlled by 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 practical, items should be segregated, and when not practical other methods established, documented, and used to control the item(s). Items that have been re-worked must be reexamined in accordance with the original acceptance criteria. Repaired items must be re-examined in accordance with acceptance criteria provided by CONTRACTOR for the repaired condition.

QL-2-QC-17, CORRECTIVE ACTION AND CONTINUOUS IMPROVEMENT

SUBCONTRACTOR must establish, implement, and maintain a process to identify conditions adverse to quality, identify their cause(s), and correct them in a manner that minimizes 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. If a condition adverse to quality has an impact on an item or service provided to CONTRACTOR, SUBCONTRACTOR must: (1) consider any impacted items to be nonconforming and meet the requirements for nonconforming items for this subcontract, and/or (2) notify CONTRACTOR of impacted services within four (4) business days of the potential impacts and any risks that are associated with the impacts. The cause of conditions adverse to quality must be 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 conditions adverse to quality and to minimize recurrence. Completion of corrective actions must be verified as defined in SUBCONTRACTOR's Quality Assurance program.

SUBCONTRACTOR must establish a process for evaluating item characteristics, process implementation, and other quality related attributes of their products, services, and 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.

QL-2-QC-18, 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.



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QL-2-QC-19, QUALITY RECORDS

SUBCONTRACTOR must establish a program to ensure that records of activities or attributes affecting the quality of item(s) or services delivered to CONTRACTOR are documented, retained, and as required by procurement documents, delivered to CONTRACTOR. The program must ensure that records are legible, complete, accurate, and traceable to the items or activities they represent. Record requirements must be established in quality affecting procedures and documents and must include provisions for the minimum content and the review and authentication of the records. Once generated, records must be stored in a retrievable manner that will protect them from loss, damage, or destruction for the minimum duration from subcontract completion specified below.

QL-2-QC-20, SUBCONTRACTOR INDEPENDENT ASSESSMENT

SUBCONTRACTOR must establish and maintain programs and/or procedures to plan and conduct 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 that perform independent assessments have sufficient authority and freedom from line management of the assessed areas, to be able to reach conclusions regarding the acceptability and effectiveness of the assessed areas.

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

QL-2-QC-21, 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 a process for CONTRACTOR to communicate any potential errors to SUBCONTRACTOR for their evaluation.

QL-2-QC-22, SUSPECT/COUNTERFEIT ITEM PREVENTION

SUBCONTRACTOR must establish and implement programs and/or processes to ensure that products they provide to CONTRACTOR do not contain Suspect/Counterfeit Items (S/CI), and to identify and inform CONTRACTOR should any S/CI be identified while performing work under this subcontract. These programs and/or processes must include as appropriate: inspections and tests to confirm that items are genuine, training of personnel in S/CI prevention processes and controls, and the identification, segregation, and preclusion from use of any S/CI identified pending instruction from CONTRACTOR. For additional requirements regarding S/CI as well as definitions and resources reference clause titled: *Counterfeit/Suspect Materials*, in the General Terms and Conditions for this contract.



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Procurement ID #:

Revision:

Local Tracking # (optional):

Name and Z Number	Signature and Date (electronic preferred)
P-TSME: 	