

**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-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 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 reevaluation/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; and 10 CFR 71.4, Definitions.

#### QL-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 NQA-1, 2008;2009a, Quality Assurance Requirements for Nuclear Facility Applications, Part I and Part II.

#### QL-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,

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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 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 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.

#### QL-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, Part I, Requirement 2, Quality Assurance Program, sections 100, 200, 201, 202, the first paragraph of section 300, and section 500. SUBCONTRACTOR must establish an organization in compliance with NQA-1-2008/1a-2009, Part I, 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.

#### QL-1-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.

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#### QL-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 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-1-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-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 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 that supplier.

#### QL-1-QC-02F, SUPPLEMENTARY QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR SUBCONTRACTOR IMPLEMENTED TYPE B CONTAINER MANUFACTURING 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 manufacture of Type B containers provided to CONTRACTOR.

#### QL-1-QC-03, DESIGN

SUBCONTRACTOR must implement a QA program which meets the applicable requirements of NQA-1-2008/1a-2009, Part I, Requirement 3 excluding section 601 Configuration Management of Operating Facilities, 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

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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 including specifying the item classification(s) (e.g., A, B, C, and/or D).

SUBCONTRACTOR must establish a process to ensure that they:

- design 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.
- incorporate applicable requirements and design bases in design work and design changes for items and/or services delivered to CONTRACTOR.
- incorporate any requirements or design bases included or referenced in this subcontract.

SUBCONTRACTOR must establish a process to identify and control design interfaces for design activities affecting items and/or services delivered to CONTRACTOR. SUBCONTRACTOR must establish a process for the validation and/or 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 who perform validation and/or verification activities of designs affecting the quality of items and/or services delivered to CONTRACTOR are not the same personnel who performed the design work. SUBCONTRACTOR must ensure that verification and/or validation of designs have been performed and the designs found to meet applicable requirements prior to approval and implementation of the designs.

# QL-1-QC-04, SUBCONTRACTOR GENERATED PROCUREMENT DOCUMENTS (Quality Supply Chain)

SUBCONTRACTOR must establish and implement a process to determine and flow down appropriate requirements to sub-tier suppliers who will provide items/services that affect the quality of products provided to CONTRACTOR to ensure that technical and quality characteristics and requirements are met. SUBCONTRACTOR must define and flow down to any sub-tier suppliers providing quality affecting items/services, a scope of work to include any technical requirements and the applicable clauses from this exhibit based on the scope of work. The SUBCONTRACTOR's procurement documents must establish and define the items and/or services and documentation to be delivered, and the requirements for sub-tier supplier provided 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 safety related items or services (if safety related items/services are not delineated in contract documents, all items/services must be considered safety related) 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 QL-1-QC-04, QL-1-QC-04A, QL-1-QC-08, and QL-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 QL-1-QC-04A and QL-1-QC-08A instead of QL-1-QC-04 and QL-1-QC-08.

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If the commercial sub-tier supplier is providing items or materials according to a design controlled by SUBCONTRACTOR, SUBCONTRACTOR must implement QL-1-QC-04A and QL-1-QC-08.

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

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

If QL-1-QC-04 is applied to this contract, then this QC is applicable as described in QL-1-QC-04. SUBCONTRACTOR must establish and implement a process to determine and flow down appropriate requirements to sub-tier suppliers who will provide items/services that affect the quality of products provided to CONTRACTOR to ensure that technical and quality requirements are met. SUBCONTRACTOR must define and flow down to any sub-tier suppliers providing quality affecting items/services, a scope of work to include any technical requirements and QA program requirements necessary to ensure the acceptability of sub-tier supplier items and/or services. The SUBCONTRACTOR's procurement documents must establish and 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 affecting the technical or quality requirements of procurement documents must be reviewed in the same manner as the original documents.

#### QL-1-QC-05, CONTROL OF QUALITY AFFECTING ACTIVITIES

SUBCONTRACTOR must establish and implement a process to identify, determine methods for the control of, and verify acceptance criteria for activities that affect the quality of items and/or services provided to CONTRACTOR. This process must meet the requirements of NQA-1-2008/1a-2009. Part I. Requirement 5. Instructions. Procedures, and Drawings. SUBCONTRACTOR must consider at a minimum the activities controlled through this Exhibit as quality affecting. The identification of, methods of control for, and associated acceptance criteria for those activities affecting quality must be documented. 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, Part I, Requirement 2 sections 200, 201, 202, and 300 and documented as part of the identified controls for the 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, Part I, 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, Part I, Requirement 11, Test Control.

QL-1-QC-06, DOCUMENT CONTROL

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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 that specify quality requirements or prescribe activities affecting quality such as procedures, drawings, and work control documents. This process must meet the requirements of NQA-1-2008/1a-2009, Part I, Requirement 6, *Document Control*.

#### QL-1-QC-07, SUPPLIER EVALUATION AND SELECTION

SUBCONTRACTOR must establish and implement a process to evaluate sub-tier suppliers 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 supplier being evaluated will be accepted using clause QL-1-QC-08A, Subcontractor Acceptance of Items/Service (Commercial Supply Chain). These evaluations must ensure that sub-tier suppliers 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 ensure that the sub-tier supplier 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. These on-site evaluations may be performed by SUBCONTRACTOR, CONTRACTOR, or other entities as long as the evaluations can demonstrate the sub-tier supplier's ability to meet the technical and quality requirements for the items and/or services they will provide to SUBCONTRACTOR. 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 objectively demonstrate the sub-tier's ability to meet the requirements of this subcontract.

# QL-1-QC-08, SUBCONTRACTOR ACCEPTANCE OF ITEMS/SERVICES (Quality Supply Chain)

SUBCONTRACTOR must establish and implement processes to evaluate and document the conformance and acceptability of safety related items and/or services provided by sub-tier suppliers that SUBCONTRACTOR will provide to CONTRACTOR for this subcontract (if safety related items/services are not delineated in contract documents, all items/services must be considered safety related). Methods of acceptance for items and/or services must be in accordance with NQA-1-2008/1a-2009, Part I, Requirement 7, Control of Purchased Items and Services, sections 400 – 507 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 II, Subpart 2.2, sections 500 through 503.1.

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

SUBCONTRACTOR must establish and implement processes to evaluate and document the

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conformance and acceptability of safety related items and/or services provided by commercial subtier suppliers which SUBCONTRACTOR will provide to CONTRACTOR for this subcontract (if safety related items/services are not delineated in contract documents, all items/services must be considered safety related). 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 suppliers. 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.

#### QL-1-QC-09, CERTIFICATION PROGRAM

SUBCONTRACTOR must establish, document, and implement a certification system or program 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.

#### QL-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 must be re-inspected, retested, or re-verified as appropriate to verify acceptability. If SUBCONTRACTOR identifies negative impacts to the quality of items or services they have provided to CONTRACTOR, they 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.

#### QL-1-QC-11, 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.

#### QL-1-QC-12, IDENTIFICATION AND CONTROL OF ITEMS

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SUBCONTRACTOR must establish and implement methods to identify and control items that affect the quality of items or services SUBCONTRACTOR will provide to CONTRACTOR for this subcontract. Methods of identification and control must meet the applicable requirements of NQA-1-2008/1a-2009, Part I, Requirement 8, Identification and Control of Items except section 303 bullet (c).

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

#### QL-1-QC-13. 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 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 of special processes must meet the applicable requirements of NQA-1-2008/1a-2009, Part I, Requirement 9, Control of Special Processes. Persons performing Nondestructive Examination (NDE) to verify conformance of items or activities must not be directly responsible for performing the work being verified and must be qualified and certified in accordance with NQA-1-2008/1a-2009, Part I, Requirement 2, sections 300, 400, and 500 and 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-1-QC-14, CONTROL OF INSPECTION

SUBCONTRACTOR must establish and maintain an inspection program to verify the conformance of items or activities to the requirements specified in the subcontract documents. The inspection program must meet the requirements of NQA-1-2008/1a-2009, Part I, Requirement 10, Inspection sections 100, 200, 401, 402, 500, 601, 602, 603, 604, 700, and 800. Sampling plans used to determine acceptance of lots of items must be specified in inspection plans or procedures. Persons performing inspections to verify conformance of items or activities must not be directly responsible for performing the work being verified and must be qualified and certified according to NQA-1-2008/1a-2009, Part I, Requirement 2, sections 300, 302, 400, and 500.

#### QL-1-QC-15, 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 and/or to obtain data used in engineering analyses, calculations, or designs. The testing program must meet the requirements of NQA-1-2008/1a-2009, Part I, Requirement 11, Test Control excluding section 200 (c).

Software used to perform or support the testing of items and/or other software provided under this subcontract must be controlled according to the applicable requirements of NQA-1-2008/1a-2009

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Persons performing tests to verify conformance of items or activities must not be directly responsible for performing the work being verified and must be qualified and certified according to NQA-1-2008/1a-2009, Part I, Requirement 2, sections 300, 302, 400, and 500.

#### QL-1-QC-16, 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 selected, controlled, calibrated and/or adjusted, and maintained to ensure accuracy and validity of the data gathered. The program must meet the requirements of NQA-1-2008/1a-2009, Part I, Requirement 12, Control of Measuring and Test Equipment. Traceability must be established between: (1) M&TE used to verify quality and its use(s), and (2) the item(s) 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 SUBCONTRACTOR identifies potential negative impacts to the quality of items or services they have provided to CONTRACTOR during evaluation of M&TE past uses, they 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. SUBCONTRACTOR must generate and retain records of calibration and M&TE use such that the records can be used to demonstrate conformance to applicable subcontract requirements.

#### QL-1-QC-17, 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. These processes and/or procedures must meet the requirements of NQA-1-2008/1a-2009, Part I, Requirement 13, Handling, Storage, and Shipping sections 100, 300, 400, 500, 600, and, when SUBCONTRACTOR is providing items they have designed, section 200. In addition the processes and/or procedures must meet the applicable requirements for storage, handling, and shipping from NQA-1-2008/1a-2009, Part II, Subpart 2.2 based on either the below indicated classification (e.g., A, B, C, and/or D) for the item(s) provided under this subcontract as well as any specific requirements specified or referenced below, or on SUBCONTRACTOR's design requirements when SUBCONTRACTOR both designs and manufactures the item(s). Special handling tools/equipment are defined as equipment that is not available from a commercial source as a catalog or standard designed item, or equipment for which no generally accepted consensus standard exists.

#### QL-1-QC-18, ITEM STATUS CONTROL

SUBCONTRACTOR must establish and maintain processes to ensure that the status of items or components provided under this subcontract are identified either through marking or labeling of the items or in documents traceable to the items. These processes must ensure that required

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inspections and tests are performed and that items are not inadvertently installed, used, or operated without required inspections and tests having been performed and passed. The processes 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.

#### QL-1-QC-19, 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. Nonconforming items must be controlled by the SUBCONTRACTOR pending an approved disposition by CONTRACTOR to prevent inadvertent installation or use. 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 must be 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.

#### QL-1-QC-20, 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. 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. The cause of conditions adverse to quality 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 or previously delivered to CONTRACTOR. Corrective actions must be established and documented to resolve conditions adverse to quality 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.

#### QL-1-QC-21, SUBCONTRACTOR OBLIGATION TO RESPOND TO CORRECTIVE **ACTION REQUEST**

When SUBCONTRACTOR is notified by CONTRACTOR of a corrective action request,

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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.

#### QL-1-QC-22. QUALITY 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 in accordance with NQA-1-2008/1a-2009, Part I. Requirement 17, Quality Assurance Records sections 100, 200, 300, 601, 602, and 603. Fire rated cabinets used to store records must be certified by an accredited organization. If SUBCONTRACTOR identifies the need to make change(s) to records previously submitted to CONTRACTOR, they must submit the changed document(s) CONTRACTOR within seven (7) days.

In addition, SUBCONTRACTOR must generate and maintain records for the performance of the quality assurance program activities described in this Exhibit such as Supplier Evaluation and Selection (QL-1-QC-07) and acceptance of items/services (QL-1-QC-08 / 08A) activities.

Quality records associated with this subcontract must be stored by SUBCONTRACTOR in accordance with NQA-1-2008/1a-2009, Part I, Requirement 17, Quality Assurance Records, section 800 for a minimum duration from subcontract closure 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.

#### QL-1-QC-23, AUDIT PERFORMANCE

SUBCONTRACTOR must establish, document, and maintain programs and/or procedures to perform audits using qualified and certified personnel in accordance with NQA-1-2008/1a-2009. Part I. 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 NQA-1-2008/1a-2009, Part I, Requirement 18.

#### QL-1-QC-24, 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 subcontract, then dedication plans must use those critical characteristics and acceptance criteria. If the subcontract 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

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tolerances. Definitions for dedications are provided in NQA-1-2008/1a-2009, Part II, Subpart 2.14, section 101.

#### QL-1-QC-25, 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.

#### QL-1-QC-26, 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 400 - 500, and section 800 bullets (c) and (d) as specified in subcontract documents. Definitions for dedications are provided in NQA-1-2008/1a-2009, Part II, Subpart 2.14, section 101.

#### QL-1-QC-27, 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 if any S/CI be identified while performing work under this subcontract. These programs and/or processes must include as appropriate: the identification of technical and quality assurance requirements in sub-tier procurement documents, inspections and tests to confirm technical and quality requirements are met and that items are genuine, training of personnel in SC/I 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 subcontract.

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# **Quality Assurance Program Requirements for** Subcontractors, Quality Level - 1 (Nuclear Quality)

Institutional Quality & Performance Assurance Division

Revision:

Local Tracking # (optional):	
Name and Z Number	Signature and Date (electronic preferred)
P-TSME:	

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