

Preparer Note (PN):

This document contains instructions in **dark red colored** text and **blue** hidden text. Do not delete the dark red colored text or any part of sections I thru VIII of this Exhibit since it's intended to be included with the final printed/saved copy. Also, do not modify the page numbering in the footer (except for adding page numbers as indicated by *) since it's designed to be separately numbered from page 1 thru Section VIII of the Exhibit, and then be separately numbered from the Table of Contents (TOC) (re-starting with page 1) thru the end of the Exhibit. You must have the blue hidden text (starting with the Table of Contents) visible in order to effectively/correctly complete this Exhibit however, it's not intended to print. To view hidden text, click on the "¶" (Show/Hide) icon on your tool bar. If that doesn't work, see [How To Set Your Microsoft Word Application To View Hidden Text](#). There is no need to delete the blue hidden text instructions as they will not affect the formatting of the printed document (except for total number of pages in the footer) and will not print unless the application's default setting is changed.

Asterisks highlighted in yellow (i.e., *) have been used throughout this document as placeholders to indicate where information is to be inserted (and the * removed) by the Requester/TSME. This includes but is not limited to the header date, PR# and total page count in the footer of page 1 and page 1 of the TOC. The Solicitation/PO or Subcontract # at the bottom of page 1 of the TOC will be completed by Acquisition Services Management (ASM).

Make sure that after you delete the quality clauses you don't need and retain those you do, update the TOC before releasing this document.

This boxed-in Preparer Note may either be deleted or retained as part of this Exhibit.

INSTRUCTIONS: This Exhibit is to be completed by the Technical SME and optional Quality SME (except for weapons program procurements where QSME signature is mandatory). The completed Exhibit H is signed and converted into Adobe pdf format and attached with the Requisition.

Exhibit H is required for:

- All on-site services (with or without items), regardless of Management Level (ML).
- All ML-1/ML-2, ML-3 item and service procurements, regardless of where work is performed.
- All weapons program (WP) procurements regardless of ML.
- ML-4 item procurements involving stand-alone circuit breakers and fasteners as defined in P840-1, *Quality Assurance for Procurements*.
- ML-4 item procurements involving hoisting, lifting, and rigging equipment as defined in P840-1, *Quality Assurance for Procurements*.

Guidance on the selection of quality clauses for a given item/service is included as hidden text next to each clause. As an example, the QC-27 (S/CI) clause is required for all item procurements (including services with items). QC-22 is required for all ML-1/ML-2 & WP procurements, as is QC-01A (off-site). QC-01B (with appropriate sub-clause box selected) is required for all on-site procurements. QC-36 is required for all Safety Software or Risk Significant Software (as defined in P1040, *Software Quality Management*) and WP procurements of software. QC-25 is required for all WP procurements.

Complete the following sections I thru VII and use this information to complete the remainder of Exhibit H, after which, sign section VIII and scan for submittal with the procurement package.

NOTE TO ASM PROCUREMENT (or WP Processing Personnel): Pages that include sections I thru VIII of the completed Exhibit H are not intended to become part of the subcontract. These sections are intended for planning/documentation purposes only and should be separated from the Exhibit H and retained in the ASM or WP procurement file.

Dated *

I. Originator/Requester Name, Z#, Phone #: ***Technical SME Name, Z#, Phone #:** ***Quality SME Name, Z#, Phone # (if applicable):** ***Generic Item/Service Description:** ***Notes to LANL Procurement Specialist:** This space is either left blank, indicated as "N/A", or applicable notes to the Buyer are listed ***Notes to LANL QPA-DO, MQ-DO, or other LANL organization:** This space is either left blank, indicated as "N/A", or applicable notes to the organization are listed *

ML Designation & Qualification of Subcontractors Designate the Management Level (ML) based on the applicable Master Equipment List, Drawing, Specification, Bill of Materials, etc. or per the requirements of P341, *Engineering Processes Manual* and/or AP-341-502, *Management Level Determination and Identification of Quality Assurance and Maintenance Requirements*. Then select A and/or B, B1, B2, B3, B4, B5, B6, C, C1, D1, or D2 as applicable. In some cases where an Institutional Evaluated Suppliers List (IESL) Supplier is necessary and the procurement is being sent out for competitive bid, both block A and B (with subsequent sub-block) may be selected to plan for both IESL and non-IESL suppliers to compete for procurements. To place an "X" in a check box: either double left click on the box or right click on the box and click on properties; change the default value to "Checked", and click on the OK tab.

Management Level **ML-1** **ML-2** **ML-3** **ML-4**

- A.** Proposed Subcontractor(s) is/are listed on the Institutional Evaluated Suppliers List (IESL) for the approved items/services. Required (where supplier is listed on the IESL) for ML-1/ML-2 (including 3rd party Commercial Grade Dedication; CGD), Safety Software, weapons program (WP) procurements, and calibration services for instruments enrolled in the LANL Standards & Calibration Lab (S&CL) program.
- B.** Proposed Subcontractor(s) is/are not listed on the Institutional Evaluated Suppliers List (IESL) for the approved items/services or if listed, do not meet the required QA Program evaluation criteria for the proposed item/service. Required (where supplier is not listed on the IESL) for ML-1/ML-2, Safety Software, WP procurements, and calibration services for instruments enrolled in the LANL Standards & Calibration Lab (S&CL) program (also, required for IESL listed Suppliers where QA Program criteria does not satisfy item/service requirements). If block "B" is applicable, you must also select either, B1, B2, B3, B4, B5, and/or B6 below and if indicated, an approved Commercial Grade Dedication (CGD) Package and/or Technical Evaluation & Acceptance (TEA) Plan and/or Compensatory Action Plan must be included with the procurement request unless QPA-DO or MQ-DO/W-DO quality personnel allow otherwise.
- B1. Items and/or Services:** Quality & Performance Assurance (QPA) Division will evaluate the Subcontractor for subsequent IESL listing, prior to award/no later than start of work of subcontract. Complete on-line Form 1953 to request Supplier Evaluation and include copy with iProcurement PR unless QPA-DO allows otherwise.
- B2. Items and/or Services:** Requesting Organization will dedicate items/services per, AP-341-703, *Commercial Grade Dedication*. Required (Technical Evaluation & Acceptance Plan, as a minimum) to be developed

Dated 

and approved prior to processing the procurement unless QPA-DO allows otherwise (B2 listed CGD Process may not be used for WP items/services).

- B3. WP Items and Services Only:** Requesting Organization will complete a Compensatory Action Plan per P840-1 (see Weapons Program Procurements). **Required to be developed and approved prior to processing the procurement unless MQ-DO or W-DO quality personnel allow otherwise.**
- B4. Integrated Contractor Order (ICO) or Transfer (processed by ASM):** Requesting Organization will be obtaining items/services from another DOE/NNSA location (DOE Managing & Operating Contractor) under the controls of their DOE approved QA Program. **Required for all ASM processed ICO's/Transfers between other DOE Complex locations (selection of quality clause QC-01C is all that's required).**
- B5. WP Integrated Contractor Order (ICO) or Transfer or Centralized Procurement Order (not processed by ASM):** Requesting Organization will be obtaining items/services from another DOE/NNSA location (DOE Managing & Operating Contractor) under the controls of their DOE approved QA Program. **Required for all non-ASM processed ICO's/Transfers or Centralized Procurements between other DOE Complex locations (selection of quality clause QC-01C is all that's required).**
- B6. Work performed under controls of LANL QA Program (ref. SD330):** Subcontractor will perform all service work under LANL direction per LANL SD330 quality program requirements and LANL personnel will assure all necessary requirements are followed. ML-1 or ML-2 items cannot be provided by Subcontractor without a LANL generated and approved Commercial Grade Dedication (CGD). **Subject controls are required to be described in the subcontract Exhibit D (Scope of Work) for on-site ML-1 or ML-2 work where the Supplier is not listed on the IESL and a CGD is not being processed *for the service*.**
- C. Institutional Evaluated Suppliers List (IESL) Supplier is optional. For ML-3 or ML-4 items or services that are not WP, not Safety Software, and not calibration services for M&TE enrolled in the S&CL Program. If desired or otherwise required by P840-1, also select C1.**
- C1. Services:** Requesting Organization will develop and implement a Compensatory Action Plan per P840-1. **If applicable, the Plan is required to be developed and approved prior to processing the procurement unless QPA-DO allows otherwise.**
- D. Item/service is listed on ASM document 3400.00.0410, *Goods or Services Requiring Special Review/Approval*, (i.e. Form 410). Select D1 or D2 depending on whether item/service is listed on Form 410. If listed, LANL SME review/approval (e-mail acceptable) is required as part of the procurement package prior to processing procurement.**
- D1. Yes:** Form 410 applies and internal review/approval is provided.
- D2. No:** Form 410 does not apply to this procurement.

II. Performance/Technical Requirements and Acceptance Criteria Identified In: To place an "X" in a check box: either double left click on the box or right click on the box and click on properties; change the default value to "Checked", and click on the OK tab.

- A. Scope of Work and Technical Specifications (SOW) For services, complete and attach Exhibit D, *Scope of Work and Technical Specifications* to iProcurement purchase requisition (PR).
- B. LANL Procurement Specification If applicable, attach to iProcurement PR.
- C. Subcontractor Catalog page/cut sheet, quote, part #, model #, etc. If applicable, attach to iProcurement PR.
- D. Inspection Plan (e. g. Form 1952) Required for receipt inspection, attach to iProcurement PR.
- E. Other Attachment (e.g., drawings, reports, etc.) If applicable, attach to iProcurement PR.

III. Receipt Inspection For items only, select the applicable subsection below. Receipt inspections must be performed by QPA qualified and certified inspectors except as otherwise allowed for in Attachment E of P840-1 or by Subcontractors in accordance with a LANL approved Subcontractor QA Program/Plan or by Subcontractor or other LANL personnel per a Compensatory Action Plan (ref. P840-1, Attachment E, section E.5.2). A LANL Form 1952 *Inspection Plan: Request for Inspection and Acceptance / Rejection Criteria* or equivalent is required. To place an "X" in a check box: either double left click on the box or right click on the box and click on properties; change the default value to "Checked", and click on the OK tab.

- A. ML-1, ML-2, or ML-3 items (including weapons program procurements), QPA certified receipt inspectors to perform receipt inspection (*at SM-30 unless arranged otherwise with Warehouse Receiving and/or QPA*).
- B. ML-4 item(s) with receipt inspection required (*weapons program procurements, stand-alone circuit breakers and fasteners, and hoisting, lifting, and rigging equipment as defined in P840-1 or as requested by project or facility management*), QPA certified receipt inspectors to perform receipt inspection (*at SM-30 unless arranged otherwise with Warehouse Receiving and/or QPA*). Note that if receipt inspection is requested for ML-4 items not required by P840-1, an organizational charge number may be requested by QPA for receipt inspection performance.
- C. Subcontractor/other LANL personnel to provide receipt inspection (regardless of ML) in accordance with LANL QPA Division approved Subcontractor QA Program/Plan or approved Compensatory Action Plan.
- D. Specialty item (regardless of ML) to be receipt inspected/verified by programmatic organization or project (or subcontractor) as defined in P840-1, Attachment E (E.5.2) (e.g. explosives, radiological materials, hazardous materials, off-site inspection, software, etc.).
- E. ML-4 item(s) with no QPA receipt inspection required.

IV. Nuclear or Radiological Work Failure of the items and/or services to be furnished under this subcontract may affect nuclear or radiological safety; therefore the Nuclear Hazards Indemnity Agreement (48 CFR 952.250-70) clause (SC-14) may need to be included by the ASM Procurement Specialist in the terms and conditions of this subcontract, depending on the TSME/QSME selection of YES or NO for the below information statement (*required to be "Yes" for all ML-1 and ML-2 procurements, unless an Integrated Contractor Order [ICO] and is likely "Yes" for ML-3 procurements if the ML-3 designation is based on Other Equipment Important to Safety [OEITS] or Radiation Protection*). To place an "X" in a check box: either double left click

on the box or right click on the box and click on properties; change the default value to "Checked", and click on the OK tab.

- A. YES, failure of the items and/or services to be furnished under this subcontract may affect nuclear or radiological safety. Therefore, include the *Nuclear Hazards Indemnity and Price Anderson Act* clause (SC-14) in the subcontract (to be added by ASM; not part of Exhibit H).
- B. NO, failure of the items and/or services to be furnished under this subcontract will not affect nuclear or radiological safety. Do not include the *Nuclear Hazards Indemnity and Price Anderson Act* clause in the subcontract.

V. **ASME NQA-1** If answered "Yes", the procurement records for the items and/or services to be furnished under this subcontract are governed by ASME NQA-1 (required to be "Yes" for all ML-1 and ML-2 procurements [excluding Accelerator facilities]) and ASM needs to control open NQA-1 related records (i.e. the executed subcontract) in accordance with the requirements of NQA-1 requirement 17 and as described in Acquisition Practice 1046, *Safekeeping of Procurement Records*. Procurement Specialists should contact ASM Records Specialist for guidance.

- A. YES, the procurement records for the items and/or services to be furnished under this subcontract are governed by ASME NQA-1 and records must be stored per NQA-1 Requirement 17.
- B. NO, the procurement records for the items and/or services to be furnished under this subcontract are not governed by ASME NQA-1 and records do not need to be stored to NQA-1 requirements.

VI. **Weapon Material or Weapon-Related Material** These terms have specific definitions from procedure P840-1, *Quality Assurance for Procurements* which are partially repeated here: **Weapon Material**—NNSA nuclear weapons, assemblies, components, piece parts, and associated test and handling equipment (including software). **Weapon-Related Material**—Any material including associated software, test and handling equipment, tooling, and fixtures, being developed and produced for or by the NNSA and intended for use in conjunction with, or in any way related to, weapon development, engineering, production, surveillance, or dismantlement.

These definitions do not include research activities outside the scope of DOE weapon system development phases defined in 56XB, *DOE/NNSA Development and Production (D&P) Manual*.

If the items/services being procured meet the subject definitions and/or are intended for use in one or more of the defined phases of weapon project/system development discussed in the D&P Manual, including weapon system refurbishment and life extension programs (LEP); then the below selected check-box should be marked "Yes"; otherwise, the below selected check-box should be marked "No".

- A. YES, this procurement meets the definition of weapon material or weapon related material items/services and/or is intended for use in a D&P Manual defined phase of weapon system development/maintenance, including refurbishment and LEP.
- B. NO, this procurement does not meet the definition of weapon material or weapon related material items/services and/or is not intended for use in a D&P Manual defined phase of weapon system development/maintenance including refurbishment and LEP.

VII. Safety Software/Risk Significant Software/Weapons Program Software If the items and/or services to be furnished under this subcontract are considered Safety Software or Risk Significant Software as defined in P1040, *Software Quality Management* (stand-alone or embedded in equipment; e.g. Programmable Logic Controllers [PLCs]), or are part of a weapons program (WP) procurement of software, selection of QC-36 is required; unless for Safety Software, a Commercial Grade Dedication allows otherwise or for WP procurements of software, a Compensatory Action Plan allows otherwise. If the subcontractor providing Safety Software, Risk Significant Software designated as ML-1 or ML-2, or WP Software items/services is not on the IESL (with an NQA-1 approved QA Program for Safety Software or NAP-24 QA Program for WP software), then a Commercial Grade Dedication is required per procedure AP-341-703 (or Compensatory Action Plan is required for WP procurement of software). Risk Significant Software does not require an IESL Supplier unless it is designated ML-1 or ML-2. Safety Software procurements require approval of the applicable Facility Design Authority Representative (DAR), Design Authority for Facility Engineering, Facility Responsible Associate Director, or Engineering Services Division Leader.

- A. YES, the items and/or services to be furnished under this subcontract are considered Safety Software or Risk Significant Software as defined in P1040 or are part of a weapons program procurement (as defined in P840-1) of software.
- B. NO, the items and/or services to be furnished under this subcontract are not considered Safety Software or Risk Significant Software as defined in P1040 or are not part of a weapons program procurement (as defined in P840-1) of software.

Dated *

VIII. Approvals: Approvals indicate agreement with completed Sections I thru VII (including the specified ML for which the TSME has ultimate responsibility for determining) and agreement that the appropriate quality assurance requirements for this procurement (selected "QC" Quality Clauses and associated Table of Contents titles) have been included in Exhibit H. Additional QPA-DO approval (as designated by the QPA Division Leader) is only required for ML-1/ML-2 procurements. Signature/approval of the TSME (and QPA-DO electronic approval in iProcurement for ML-1/ML-2) is mandatory (QPA-DO signature line for ML-1 and ML-2 orders can be satisfied by QPA-DO electronic approval in iProcurement). QSME signature is optional and only required as requested by the TSME (except QSME is required for weapons program procurements). Blank signature lines are to be marked as "N/A" (not applicable) as appropriate.

TSME (signature)

Z Number

Date

QSME (signature)
 (only as requested by TSME, otherwise mark as "N/A";
unless weapons program procurement)

Z Number

Date

QPA-DO (signature)
 (only required for ML-1 or ML-2, otherwise mark as "N/A")

Z Number

Date

EXHIBIT “H” QUALITY ASSURANCE REQUIREMENTS

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QC-01A QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR OFF-SITE SUBCONTRACTS (Sept 2014)

In accordance with CONTRACTOR's responsibilities under DOE Order 414.1D, *Quality Assurance* and 10 CFR 830 Subpart A, *Quality Assurance Requirements*, 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 prior to award, and is required to be approved by CONTRACTOR prior to the start of work (as further defined/controlled in the subcontract). SUBCONTRACTOR QA Program approval documentation will be maintained on file with CONTRACTOR. SUBCONTRACTOR will perform all work under this Subcontract in accordance with its approved QA Program and further will notify CONTRACTOR of any quality affecting changes made to its QA Program, whereupon CONTRACTOR will determine need for re-evaluation/re-approval. SUBCONTRACTOR'S QA Program shall be subject to ongoing evaluation and monitoring by CONTRACTOR and shall address configuration control of subcontract requirements, including CONTRACTOR approval of substitutions and configuration control of any provided CONTRACTOR procedures, specifications, or items. SUBCONTRACTOR agrees to provide CONTRACTOR and/or DOE/NNSA the right and access to conduct audits of SUBCONTRACTOR'S quality systems and verify compliance with subcontract requirements as well as the right to conduct inspection and/or testing of SUBCONTRACTOR'S product to assure conformance with subcontract requirements. Any SUBCONTRACTOR proprietary processes must be specifically identified in writing in order to prevent disclosure. Unless otherwise provided for in this subcontract, SUBCONTRACTOR is responsible for including (i.e. flowing down) the quality assurance requirements of this subcontract in its lower-tier subcontracts to the extent necessary to ensure SUBCONTRACTOR'S compliance with these requirements.

It is additionally noted that this subcontract includes items and/or services that are intended to be used in support of the following applications: (as marked with an "X"):

- DOE Safety Class, Safety Significant, or Safety Assessment Document credited Accelerator (i.e. nuclear safety related) applications (ref. [for DOE nuclear facilities] ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications*).
- Weapons Program (i.e. weapon material or weapon related material) applications (ref. QC-1 which has been superseded by NAP 24, *NNSA Weapon Quality Policy*).
- Calibrated Instrumentation (i.e. Accredited Calibration) applications (ref. DOE/AL 56XB, DOE *Development and Production Manual, Chapter 13.2, Metrology Program* and/or ISO 17025, *General Requirements for the Competence of Testing and Calibration Laboratories* [and applicable accreditations; e.g. A2LA, NVLAP, ACLASS, DKD, etc.]).

QC-01B QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR ONSITE SUBCONTRACTS (Sept 2014)

All work activities, including the purchase and inspection of any provided items intended for permanent installation (or spares), items ultimately intended for off-site shipment such as waste containers etc., or calibrated portable Measuring & Test Equipment (M&TE) being used in testing/calibration of permanently installed equipment, will be governed by the following sub-clauses that are marked with an "X":

- In accordance with CONTRACTOR's responsibilities under DOE Order 414.1D, *Quality Assurance* and 10 CFR 830 Subpart A, *Quality Assurance Requirements*, 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 prior to award, and is required to be approved by CONTRACTOR prior to the start of work (as further defined/controlled in the subcontract). SUBCONTRACTOR QA Program approval documentation will be maintained on file with CONTRACTOR. SUBCONTRACTOR will perform all work under this Subcontract in accordance with its approved QA Program and further will notify CONTRACTOR of any

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quality affecting changes made to its QA Program, whereupon CONTRACTOR will determine need for re-evaluation/re-approval. SUBCONTRACTOR'S QA Program shall be subject to ongoing evaluation and monitoring by CONTRACTOR and shall address configuration control of subcontract requirements, including CONTRACTOR approval of substitutions and configuration control of any provided CONTRACTOR procedures, specifications, or items. SUBCONTRACTOR agrees to provide CONTRACTOR and/or DOE/NNSA the right and access to conduct audits of SUBCONTRACTOR'S quality systems and verify compliance with subcontract requirements as well as the right to conduct inspection and/or testing of SUBCONTRACTOR'S product to assure conformance with subcontract requirements. Any SUBCONTRACTOR proprietary processes must be specifically identified in writing in order to prevent disclosure. Unless otherwise provided for in this subcontract, SUBCONTRACTOR is responsible for including (i.e. flowing down) the quality assurance requirements of this subcontract in its lower-tier subcontracts to the extent necessary to ensure SUBCONTRACTOR'S compliance with these requirements.

It is additionally noted that this subcontract includes items and/or services that are intended to be used in support of the following applications: (as marked with an "X"):

- DOE Safety Class, Safety Significant, or Safety Assessment Document credited Accelerator (i.e. nuclear safety related) applications (ref. [for DOE nuclear facilities] ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications*).
- Weapons Program (i.e. weapon material or weapon related material) applications (ref. QC-1 which has been superseded by NAP 24, *NNSA Weapon Quality Policy*).
- Calibrated Instrumentation (i.e. Accredited Calibration) applications (ref. DOE/AL 56XB, *DOE Development and Production Manual, Chapter 13.2, Metrology Program* and/or ISO 17025, *General Requirements for the Competence of Testing and Calibration Laboratories* [and applicable accreditations; e.g. A2LA, NVLAP, ACLASS, DKD, etc.]).
- The LANL Quality Assurance (QA) Program governs the subject work. All applicable items must be procured by LANL through the LANL procurement process and be receipt inspected by LANL QPA Division with an associated Inspection Plan (i.e. Form 1952) prepared by LANL project personnel, unless an approved LANL Compensatory Action Plan and/or Commercial Grade Dedication (CGD) package allows otherwise.
- LANL developed and approved Compensatory Action Plan and/or Commercial Grade Dedication (CGD) package shall be submitted as a supplement to Exhibit H.
- Staff Augmentation: The LANL QA Program (SD330), which meets the requirements of DOE O 414.1D and 10 CFR 830 Subpart A, applies to this support service subcontract and SUBCONTRACTOR personnel will comply with SD330 when working under this subcontract. A copy of SD330 will be made available upon request. SUBCONTRACTOR personnel are augmenting LANL staff personnel under the direction of LANL supervision.
- For LANL designated ML-4 work only: All work activities associated with this Subcontract have been planned, reviewed, approved, and designated herein by CONTRACTOR under the controls of the LANL Quality Assurance (QA) Program defined in SD330, which is compliant with DOE Order 414.1D and 10 CFR 830 Subpart A. As such, applicable LANL QA Program requirements have been tailored to the scope of work of this Subcontract within the various Subcontract Exhibits for implementation by SUBCONTRACTOR. Thus, SUBCONTRACTOR is performing work under this

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Subcontract in accordance with the graded approach requirements of the LANL QA Program.

Consistent with a graded approach to the LANL QA Program, it is acceptable for SUBCONTRACTOR to directly procure/supply items as necessary in support of the scope of this Subcontract. SUBCONTRACTOR owned/leased Measuring and Test Equipment (M&TE) which requires calibration and is used on-site at LANL for the purpose of determining LANL item/process acceptability, must be coordinated with the LANL Standards & Calibration Laboratory (S&CL), if LANL item/process acceptability determination includes M&TE enrolled in the LANL S&CL program. As defined in LANL procurement quality procedures, any SUBCONTRACTOR supplied stand-alone circuit breakers and fasteners, and/or hoisting, lifting, and rigging equipment intended to be installed at LANL or otherwise remain at LANL for future use (i.e. spares), must have an Inspection Plan (Form 1952) completed by LANL project personnel and receive documented LANL QPA Division receipt inspection approval prior to installation. Unless otherwise provided for in this subcontract, no other exceptions to the LANL QA Program are allowable unless specifically defined in an approved LANL Compensatory Action Plan.

Unless otherwise provided for in this subcontract, SUBCONTRACTOR is responsible for including (i.e. flowing down) the quality assurance requirements of this subcontract in its lower-tier subcontracts to the extent necessary to ensure SUBCONTRACTOR'S compliance with these requirements.

QC-01C QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR INTEGRATED CONTRACTOR ORDERS/TRANSFERS (Sept 2014)

SUBCONTRACTOR, who is a DOE Managing & Operating Contractor, will comply with its DOE/NNSA approved Quality Assurance Program, using a graded approach, for all activities associated with this order/transfer. SUBCONTRACTOR shall also comply with any additional requirements as agreed to between CONTRACTOR (LANL) and SUBCONTRACTOR. Unless otherwise provided for in this order, SUBCONTRACTOR is responsible for including (i.e. flowing down) the quality assurance requirements of this order/transfer in its lower-tier subcontracts to the extent necessary to ensure compliance with these requirements. SUBCONTRACTOR shall include with the shipment (as applicable), documentation for the item(s) provided and shall mark all Weapon Program Procurement packaging (i.e. all Weapon Material or Weapon-Related Material) with the CONTRACTOR (LANL) order number and the words "Receipt Inspection Required".

QC-02 DESIGN/CHANGE CONTROL FOR SUBCONTRACTOR PROVIDED DESIGN (May 2008)

SUBCONTRACTOR shall provide a design that is defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Persons other than those who designed the item shall verify design adequacy and accuracy. Design changes shall be governed by controlled measures commensurate with those applied to the original design.

QC-02A DESIGN/CHANGE CONTROL FOR LANL PROVIDED DESIGN (Sept 2014)

SUBCONTRACTOR shall implement the LANL provided design for the work involved. In the case of maintenance and repair work on existing LANL equipment/systems, the LANL provided design includes the current design configuration of existing equipment/systems being worked on. Design questions and design change requests must be transmitted to the CONTRACTOR via formal documents such as Requests for Information (RFI), Field Change Requests (FCR), or Subcontractor Deviation Disposition Request (SDDR). No design changes will be implemented unless formally approved by the CONTRACTOR via Engineering Change Notice (ECN) or other controlled document.

QC-03 QUALIFICATION AND CERTIFICATION OF PERSONNEL AND STAFF (Sept 2014)

SUBCONTRACTOR'S personnel and staff shall have the indoctrination, training, experience, qualifications and certifications necessary for the work to be performed as required by industry standards,

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as well as any additional requirements specified in this subcontract. Qualification and certification records shall be available for review by CONTRACTOR upon request.

QC-04 TRACEABILITY - ITEM (Jun 2011)

SUBCONTRACTOR shall have the capability of tracing items to the raw material from which the item was fabricated. All documentation and records associated with tracing items related to this subcontract shall be available for review by CONTRACTOR upon request.

QC-06 CERTIFICATE OF CONFORMANCE (Mar 2016)

SUBCONTRACTOR shall provide a Certificate of Conformance (C of C) for all items or services procured through this subcontract. Each C of C shall be from SUBCONTRACTOR and/or Manufacturer, shall identify CONTRACTOR'S subcontract number, and state that the item or service described thereon conforms in all respects with subcontract requirements, which may include any applicable specifications, drawings, marking requirements, part/model/serial number identification, or codes/standards that the item is certified to. Where applicable, the C of C shall identify the material by CONTRACTOR'S part/control number consistent with part number information in subcontract documents and/or CONTRACTOR'S specifications. Each C of C shall further identify any approved changes, waivers, or deviations to the item requirements and identify any requirements that have not been met, with a corresponding means/recommendation for resolving the nonconformances. Each C of C shall be signed or otherwise authenticated by an authorized person responsible for this function as described in SUBCONTRACTOR'S quality assurance program (or other representative of SUBCONTRACTOR and/or manufacturer if SUBCONTRACTOR is not required to have a quality assurance program). SUBCONTRACTOR personnel must assure that certificates of conformance are verified for compliance with the technical and quality requirements stated in the subcontract.

QC-07 MANUFACTURING, INSPECTION, MAINTENANCE, REPAIR, AND/OR TEST PROCEDURES (Sept 2014)

SUBCONTRACTOR shall upon CONTRACTOR'S request, submit to CONTRACTOR for review prior to manufacturing, inspection, maintenance, repair and/or testing, written procedures, checklists, and/or travelers detailing the activity that will be performed to verify that the items being supplied or worked on conform to the requirements of this subcontract.

QC-08 INSPECTION, EXAMINATION, AND TEST REPORTS (Mar 2016)

SUBCONTRACTOR shall provide to CONTRACTOR, with or prior to each shipment, or as the result of on-site testing/inspection, all reports of inspections and/or tests performed on the items procured/inspected/tested. The reports shall be traceable to the subcontract number, item part/model number, item serial number (where applicable), and/or system description (when items are tested/inspected as part of an overall integrated system).

QC-08A ENGINEERING EVALUATION / ANALYSIS REPORT (Jun 2011)

SUBCONTRACTOR shall provide services to study, evaluate, and/or analyze a given condition as defined by CONTRACTOR within the procurement documents. SUBCONTRACTOR shall provide results of this activity in a peer reviewed, signed written report.

QC-09 SPECIAL PROCESS PROCEDURES (Jun 2011)

SUBCONTRACTOR'S special process procedures as applicable to a work activity shall be made available for CONTRACTOR'S review upon request. Special processes (e.g., welding, brazing, bonding, plating, chemical machining, heat treating, radiographic inspection, ultrasonic testing, pressure leak testing, or waste processing, etc.) shall be performed in accordance with written procedures or instructions. SUBCONTRACTOR shall maintain a system of process sheets, shop travelers, or equivalent means to define the sequence of manufacturing, inspection, installation and test activities to be performed. SUBCONTRACTOR shall provide for the qualification/certification of personnel, prior to their

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assignment, to ensure competence in the use of the special process and associated procedures or specifications. Qualification/certification records of SUBCONTRACTOR personnel who will be performing special process operations shall be available to CONTRACTOR for review upon request. Only those personnel that have been qualified to perform a specific special process shall be used to perform that process.

QC-10 WELDING REQUIREMENTS FOR ON-SITE WELDING AT LANL (Jun 2011)

All on-site welding shall meet the requirements of the LANL Engineering Standards Manual, Chapter 13 – Welding & Joining. A copy of said document will be made available to SUBCONTRACTOR upon request. Prior to performing any welding on-site at Los Alamos National Laboratory (LANL) under this subcontract, all persons who will perform the welding shall provide evidence to CONTRACTOR that they have been previously certified by CONTRACTOR to perform such welding at LANL.

QC-11 ENGINEERING DRAWINGS (Sept 2011)

SUBCONTRACTOR shall provide to CONTRACTOR, with or prior to completion of design deliverables or prior to fabrication if required by the procurement documents, or with or prior to the shipment of any applicable items and traceable to the item shipment, engineering drawings detailing the design of the items/systems required by this subcontract. For specific items, this requirement may be satisfied by inclusion of existing drawings in a technical operations/maintenance manual. Further, drawings may be for design only or for fabrication/construction to occur at a later date and may include, during or after fabrication/construction, any applicable as-built drawings.

QC-12 CERTIFICATION OF CALIBRATION (Sept 2014)

SUBCONTRACTOR shall submit with each instrument/system, a certification that the instrument/system has been calibrated and is ready for use. If separately stated in the procurement documents, such calibrations and associated calibration certificates shall have a pedigree of accreditation (e.g. A2LA, NVLAP, ACLASS, DKD, L-A-B, etc.) specified and provided by the SUBCONTRACTOR. The certification shall contain, as a minimum, the description and/or part/model number of the instrument/system, including any applicable serial numbers; identification of the standards and/or equipment used for the calibration; when appropriate, the as-found and as-left data with measurement uncertainties; and a statement that the calibration of the standards and/or equipment used is traceable to the National Institute of Standards and Technology (NIST) or other industry recognized and accepted national or international standard. A Test Uncertainty Ratio (TUR) of at least 4:1 is required to ensure the item meets tolerance requirements; however, if a TUR of at least 4:1 is not achievable, guardbanding shall be performed. TUR and guardbanding information, as applicable, shall be provided with the calibration report. The certification shall contain the signature and title of an authorized SUBCONTRACTOR representative. SUBCONTRACTOR shall maintain records that provide traceability of calibrations for a minimum of one year from the date of completion of this subcontract. Such records shall be available for review by CONTRACTOR upon request.

QC-12A CERTIFICATION OF CALIBRATION FOR SUBCONTRACTOR M&TE (Sept 2014)

For any SUBCONTRACTOR measuring and test equipment (M&TE) that provides measurement on the acceptability of CONTRACTOR items/processes and is by design required to be calibrated, SUBCONTRACTOR shall make available for CONTRACTOR'S review or provide copies, as requested, all current calibration documentation associated with SUBCONTRACTOR owned M&TE.

For SUBCONTRACTOR owned or leased M&TE used in the performance of work (or M&TE equipment owned or leased by any sub-tier SUBCONTRACTOR) that provides measurement on the acceptability of CONTRACTOR items/processes, M&TE shall be suitably marked for traceability to the calibration documentation with recalibration due dates marked on the applicable M&TE.

SUBCONTRACTOR shall maintain a user log or other documented means to identify where each calibrated M&TE device was used, including the date(s) used.

Dated **QC-12B POST-USE CERTIFICATION OF CALIBRATION FOR SUBCONTRACTOR M&TE (Sept 2014)**

Unless waived in writing by CONTRACTOR, SUBCONTRACTOR shall provide to the CONTRACTOR's Purchasing Agent, M&TE post-use calibration documentation indicating that current and proper calibration of M&TE was verified and maintained (i.e., M&TE is shown to still be in calibration after use) within fourteen (14) calendar days of completing the work. The SUBCONTRACTOR post-use calibration documentation shall contain a statement that the calibration of the standards and/or equipment used in the M&TE calibration is traceable to the National Institute of Standards and Technology (NIST) or other industry recognized and accepted national or international standard. Additionally, the SUBCONTRACTOR's post-use calibration documentation shall include the following:

- title (e.g., "Calibration Certificate"),
- name and address of the calibration laboratory (which may or may not be the original equipment manufacturer),
- identification of the standards and/or equipment used for the calibration,
- a reference to any applicable procedures used to calibrate,
- description of the item being calibrated, including any applicable model and serial numbers,
- date of calibration,
- calibration results, including as-found and as-left data,
- tolerance/uncertainty of measurement,
- any conditions of concern that may have an influence on the measurement results, and
- signature(s) of authorized persons.

SUBCONTRACTOR shall immediately notify CONTRACTOR if post-work calibration of M&TE is found to be out-of-calibration. CONTRACTOR and SUBCONTRACTOR shall jointly evaluate the validity of previous measurement, inspection, or test results, and the acceptability of items previously inspected or tested. SUBCONTRACTOR shall be responsible for additional costs associated with any additional M&TE measurements necessary as a result of out-of-calibration SUBCONTRACTOR M&TE used to provide measurement on the acceptability of CONTRACTOR items/processes.

QC-13 CERTIFIED MATERIAL TEST REPORTS (Jun 2011)

SUBCONTRACTOR shall provide to CONTRACTOR, with or prior to the first shipment, a Certified Material Test Report (CMTR) for the material(s) supplied. The CMTR shall be legible and shall specifically identify the actual chemical and/or physical properties and any test(s) performed to the applicable nationally recognized standards. The CMTR shall be signed by the manufacturer's authorized representative as defined by the manufacturer's quality assurance program or as otherwise authorized, and the CMTR shall be traceable to the shipment supplied through heat number, batch number, manufacturer's lot numbers, or other method.

QC-14 UN TEST SUMMARY REPORT (May 2008)

SUBCONTRACTOR shall provide to CONTRACTOR, with or prior to the first shipment, a UN Test Summary Report for the material(s) supplied. The UN Test Summary report, at a minimum must contain the following information:

1. Name and address of test facility;
2. Name and address of applicant (where appropriate);
3. A unique test report identification number;
4. Date of the test report;
5. Manufacturer of the packaging;
6. Description of the packaging design type (e.g. dimensions, materials, closures, thickness, etc.), including methods of manufacture (e.g. blow molding) and which may include drawing(s) and/or photograph(s);

7. Maximum capacity;
8. Characteristics of test contents, e.g. viscosity and relative density for liquids and particle size for solids;
9. Test descriptions and results; and
10. Signed with the name and title of signatory.

QC-16 SHELF LIFE CERTIFICATIONS/STORAGE REQUIREMENTS (Jun 2011)

SUBCONTRACTOR shall have an effective storage and age control system for items whose acceptability is limited by its age or manner of storage. Items provided with a designed shelf life must be marked or have their packaging marked with cure/manufacturing dates or expiration dates. At the time of receipt, the material shall not have less than 85% (allowing for rounding to whole months) of its shelf life remaining without prior written approval from CONTRACTOR. In lieu of product or container marking, SUBCONTRACTOR may include shelf life information on a certification document provided with the ordered material delivered to CONTRACTOR. Any applicable special storage and handling instructions shall be provided.

QC-17 MANUALS / INSTRUCTIONS (Jun 2011)

SUBCONTRACTOR shall submit manuals/instructions or other documents that identify the items provided and include as applicable, drawings/sketches, part/model numbers (including recommended spare and replacement parts and data required for ordering), storage guidelines, safety precautions, installation/test instructions, and operating and maintenance instructions. The manual/instructions shall be written in clear, concise language readily understandable by a technician or craftsman, and shall conform to the industry standards that prevail for the preparation of such documents.

QC-17A CATALOG DATA (Jun 2011)

SUBCONTRACTOR shall submit their most up to date technical catalog data applicable to the item(s) being procured, including any applicable technical bulletins regarding installation, operations, or maintenance.

QC-18 CERTIFICATE OF PROOF TEST (Sept 2014)

SUBCONTRACTOR shall provide to CONTRACTOR with or prior to each shipment, a Certificate of Proof Test that is traceable by serial number or other means to the item being shipped. A proof test is a nondestructive test performed by the manufacturer or applicable testing agency to verify construction and workmanship of hoisting, lifting, and rigging devices either specific to the exact item(s), or to the same batch or lot number, or to the original prototype design. If specified in the procurement documents, individual proof tests will be performed on the actual items being purchased. The manufacturer's or applicable testing agency's authorized representative shall sign the certificate.

QC-19 FIRST ARTICLE INSPECTION/REVIEW (Jun 2011)

When requested by CONTRACTOR, SUBCONTRACTOR shall demonstrate to CONTRACTOR'S satisfaction, before the start of fabrication of any production lot of items, that the first article conforms to the requirements of this subcontract. SUBCONTRACTOR shall obtain CONTRACTOR'S written approval/authorization of the first article before proceeding with the production of the remaining items. The manufacturer shall identify this article as the "first article".

QC-21 SOURCE INSPECTION PRIOR TO SHIPMENT (Jun 2011)

In addition to other reviews or inspections by CONTRACTOR of supplies and services provided by SUBCONTRACTOR, CONTRACTOR shall have the right to inspect the fabrications and/or other supplies covered by this subcontract at its source during the duration of the subcontract, prior to shipment to CONTRACTOR. These CONTRACTOR source inspections may be in conjunction with SUBCONTRACTOR'S conduct of final inspection and test. CONTRACTOR reserves the right to

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designate selected manufacturing, inspection, and/or test operations as "witness points" or "hold points" within subcontract documents. To facilitate this potential source inspection, CONTRACTOR shall notify SUBCONTRACTOR of its readiness to begin source inspection activities at least five (5) working days before the date on which they are anticipated to begin.

QC-22 CONTRACTOR'S RIGHT OF ACCESS TO SUBCONTRACTOR'S FACILITY (Visit) (Jun 2011)

CONTRACTOR reserves the right to send its representatives to visit SUBCONTRACTOR'S facilities, on a non-resident basis, for surveillance and survey/audit purposes, to assure/verify SUBCONTRACTOR'S conformance to the technical requirements of this subcontract, including test and inspection requirements, and all applicable quality assurance requirements. Such personnel shall be allowed full access to: (1) witness all operations/tests involved in the performance of this subcontract; and (2) survey/audit all records pertaining to the subcontract. Reasonable advance notice (minimum 24 hours), in writing, will be provided to SUBCONTRACTOR prior to any such visits. SUBCONTRACTOR shall flow down this requirement for CONTRACTOR'S right of access to all lower-tier subcontractors and suppliers.

QC-23 CONTRACTOR'S RIGHT OF ACCESS TO SUBCONTRACTOR'S FACILITY (Resident) (May 2008)

CONTRACTOR, at its discretion, may assign and station resident representatives at SUBCONTRACTOR'S facility to provide program coordination. These representatives will assist in expediting actions between CONTRACTOR and SUBCONTRACTOR, maintain program surveillance, and evaluate program progress. The resident representatives shall have access to all areas and all information directly related to the scope of their responsibilities hereunder. SUBCONTRACTOR agrees to provide appropriate office space, office supplies, secretarial services, and communication facilities for such representatives at no additional cost to CONTRACTOR.

QC-24 DESIGN REVIEW PRIOR TO PRODUCTION (Sept 2011)

Unless waived in writing by CONTRACTOR, before release of the design documents, SUBCONTRACTOR shall provide for one or more design reviews by CONTRACTOR and shall obtain written approval/authorization from CONTRACTOR to finalize design and/or begin production/fabrication/construction. To facilitate the design review, SUBCONTRACTOR shall notify CONTRACTOR of its readiness for a design review conference at least five (5) working days before the date on which the conference is scheduled. The notification shall include the proposed conference agenda and one reproducible copy of each document that constitutes the design or helps to demonstrate that the design meets CONTRACTOR'S requirements.

QC-25 NONCONFORMANCE REPORTING (Mar 2016)

SUBCONTRACTOR shall evaluate and notify CONTRACTOR of each nonconformance against items and services that do not meet procurement document requirements within three (3) working days of discovery. This includes, but is not limited to, nonconformance with documentation requirements and technical or material requirements, including situations where an item may be restored so as to function unimpaired, but it does not meet the original subcontract/design requirement. Notice of a nonconformance shall consist of a written description of the nonconformance and when available, an assessment of the cause and the proposed disposition/corrective action, including technical justifications for any proposed Use-As-Is or Repair dispositions. In cases where the SUBCONTRACTOR proposes a Use-As-Is or Repair disposition, the disposition of the nonconformance will be approved by CONTRACTOR with corresponding disposition implementation verified. Such Use-As-Is or Repair nonconformance documentation will be supplied by SUBCONTRACTOR to CONTRACTOR and *all* records of nonconformance shall be maintained by the SUBCONTRACTOR. SUBCONTRACTOR shall allow for the return of any materials determined by CONTRACTOR to be nonconforming as a result of CONTRACTOR'S receipt inspection.

Dated **QC-26 CORRECTIVE ACTION REPORTS (Jun 2011)**

SUBCONTRACTOR shall provide a written acknowledgement within five (5) working days of receipt of a request for corrective action from CONTRACTOR. SUBCONTRACTOR shall respond in writing within 30 days, with actual corrective actions taken or planned. Prior to implementation, such actions will be evaluated and approved by CONTRACTOR to ensure corrective actions have been/will be effectively implemented.

QC-27 SUSPECT/COUNTERFEIT ITEMS (S/CI) (Sept 2014)

- (a) A suspect item is one in which there is an indication by visual inspection, testing, or other information that it may not conform to established Government or industry-accepted specifications or national consensus standards. A counterfeit item is a suspect item that is a copy or substitute, without legal right or authority to do so, or one whose material, performance, or characteristics are knowingly misrepresented by the vendor, supplier, distributor, or manufacturer.
- (b) SUBCONTRACTOR warrants that all items, including their subassemblies, components, and parts, tendered to CONTRACTOR shall be genuine (i.e., not counterfeit), new and unused, and conform to the requirements of this subcontract, without substitution unless otherwise provided for within this subcontract or approved in writing by CONTRACTOR prior to delivery.
 - (1) SUBCONTRACTOR shall ensure (as applicable) that malicious software (and hardware) is prevented from entering into their supply chain for items/services to be provided to CONTRACTOR.
- (c) SUBCONTRACTOR further warrants that all components, parts, materials, and supplies incorporated into CONTRACTOR'S facilities or equipment by SUBCONTRACTOR, during performance of work at LANL, shall be genuine, new and unused, and original-equipment-manufacturer items, without substitution unless otherwise provided for within this subcontract or approved by CONTRACTOR in writing as suitable for the intended purpose prior to use.
 - (1) If SUBCONTRACTOR discovers any S/CI items or S/CI conditions of concern for items in use or in the process of being installed at LANL, SUBCONTRACTOR shall temporarily segregate/control the items and immediately notify CONTRACTOR. CONTRACTOR will make subsequent notifications in accordance with CONTRACTOR'S S/CI procedures and provide SUBCONTRACTOR direction as to S/CI disposition.
- (d) As part of the foregoing warranties, SUBCONTRACTOR also certifies that all labels and/or trademarks or logos affixed, or designed to be affixed; to items supplied or delivered to CONTRACTOR, and to certifications, affirmations, information, or documentation related to the authenticity and quality of items supplied or delivered to CONTRACTOR under this subcontract, are genuine.
- (e) Falsification of information or documentation may constitute criminal conduct; accordingly, SUBCONTRACTOR grants CONTRACTOR the right to temporarily segregate items, and related paperwork, that are suspected to be S/CI, pending a determination by National Nuclear Security Administration (NNSA) or Department of Energy (DOE) officials whether the segregated items should be impounded as evidence.
 - (1) In the event NNSA/DOE directs CONTRACTOR to impound the segregated items, no liability shall be asserted or enforceable against CONTRACTOR, NNSA, or DOE because of the impoundment, all such liability being expressly waived by SUBCONTRACTOR or any person claiming any right or interest under this subcontract in the impounded items.
 - (2) CONTRACTOR shall incur no liability for failure to return impounded items to SUBCONTRACTOR and does not assume any liability for loss or damage to the items

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impounded or temporarily segregated pursuant to this clause regardless of the circumstances under which said loss or damage may have occurred, and whether the impounded or temporarily segregated items are in CONTRACTOR'S possession or under its control.

- (f) Nothing in this clause shall limit CONTRACTOR'S right to reject S/CI, and related paperwork, as nonconforming, to deny payment for such items, to return such items to SUBCONTRACTOR once NNSA/DOE has released the items, or to assert other remedies provided under this subcontract or by law.

QC-28 SERIALIZATION AND MARKING (Mar 2016)

The manufacturer shall serialize parts, components, assemblies, and subassemblies as required by drawings, specifications, and this subcontract. The manufacturer's serial number control system shall ensure that the same serial number is not used more than once. Associated quality documents (e.g. test/inspection reports, certification documents) shall refer to any applicable serial numbers/lot numbers of the items; serial numbers/lot numbers are required to be directly marked on items or, if not feasible, the item shall be indirectly identified (e.g. tagged) with serial number/lot number.

QC-29 HANDLING, RECEIVING, STORAGE, SHIPPING, AND PACKAGING (Mar 2016)

SUBCONTRACTOR shall control the handling, receiving, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. Such activities shall include as applicable, the appropriate controls for items categorized as Level A, B, C, or D per ASME NQA-1 2008/2009a, Part II, Subpart 2.2. This includes items being provided by SUBCONTRACTOR to CONTRACTOR as well as any items being provided by CONTRACTOR to SUBCONTRACTOR. Handling, storage, and shipping of items shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity. Items shall be packaged according to size, manufacturer, dimensional and manufacturer lot or heat number. Packages shall be closed and labeled in a manner that identifies the item, dimensions and weight (where applicable), SUBCONTRACTOR'S and/or manufacturer's name, and CONTRACTOR'S subcontract number. Non-conforming packages may be returned to SUBCONTRACTOR at SUBCONTRACTOR'S expense.

QC-31 REPORTING OF DEFECTS AND NONCOMPLIANCE PURSUANT TO 10 CFR 21 (Sept 2011)

SUBCONTRACTOR shall comply with the requirements of Title 10 Part 21 of the Code of Federal Regulations, when applicable. An individual, manufacturer, or a supplier of a commercial grade item is not subject to the regulations of 10 CFR 21. As defined in subpart 21.3:

- (1) When applied to nuclear power plants licensed pursuant to 10 CFR part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).
- (2) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70,71 or 72, commercial grade item means an item that is:
 - (i) Not subject to design or specification requirements that are unique to those facilities or activities;
 - (ii) Used in applications other than those facilities or activities; and
 - (iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).


Dated **QC-32 LANL APPROVAL (IN SUPPORT OF ONSITE WORK REQUIREMENTS) OF INTERNATIONAL BUILDING CODE (IBC) FIELD AND LABORATORY TESTING AGENCIES AND SPECIAL INSPECTION AGENCIES (Jun 2011)**

SUBCONTRACTOR and all lower tier subcontractors who perform field and/or laboratory testing or special inspections of work shall be approved by the LANL Building Official (LBO) or LBO assigned Chief Inspector, prior to starting work.

QC-33 REQUIREMENTS FOR SUBCONTRACTOR PURCHASE OF NUCLEAR GRADE HEPA FILTERS GOVERNED BY ASME AG-1, SECTION FC & FK TO BE USED ON-SITE AT LANL (Sept 2011)

SUBCONTRACTOR shall ensure that any High Efficiency Particulate Air (HEPA) Filters installed on-site for filtration of radiological constituents are designed and constructed to the requirements of ASME AG-1, Section FC or Section FK, as applicable and acceptance tested by the DOE Filter Test Facility (FTF) (Air Techniques International Testing Laboratories, Suite 104, 1708 Whitehead Rd., Baltimore, MD 21207, phone 410-277-8981, fax 410-277-3448, email ATITL@atitest.com) in accordance with the applicable sections of ASME AG-1, Article FC-5000 or Article FK-5000 and DOE-STD-3025, prior to use.

QC-34 DOCUMENTS AND RECORDS (May 2012)

Any documents and records required to be submitted by SUBCONTRACTOR to CONTRACTOR are identified in this subcontract, including any dates/times for submittal. SUBCONTRACTOR shall retain records resulting from subcontract performance for  years from final payment, unless otherwise specified by applicable law. Disposition of Subcontractor maintained records after the specified retention times are at the discretion of the SUBCONTRACTOR.

QC-34A DOCUMENTS AND RECORDS: ENVIRONMENTAL WORK (May 2012)

For environmental work, SUBCONTRACTOR shall maintain the Administrative Record as defined in applicable regulations and shall provide a copy of the Administrative Record to CONTRACTOR upon completion of work.

QC-35 CERTIFICATE OF ANALYSIS (for Weapons Program Chemicals) (Sept 2011)

SUBCONTRACTOR shall provide to CONTRACTOR, with or prior to shipment, a Certificate of Analysis (C of A) Report for the material(s) supplied and any associated Material Safety Data Sheet (MSDS). The C of A shall contain the following information:

1. Name of chemical/product
2. Item number of chemical/product
3. Name and address of facility making the product
4. Lot number of material that C of A refers to
5. Quantity of material certified
6. Analyzed concentration/purity
7. Analytical accuracy
8. Date material produced unless each item is individually labeled with the date that the material was produced (only applicable for items which are identified by the manufacturer as having an expiration date)
9. Specification parameters product tested against (as applicable)
10. Actual results of inspection/test where standardization of measuring equipment was performed using NIST-traceable reference material
11. Name of person certifying lot (Quality Manager's Name)

12. Signature of person certifying the lot and date of certification

QC-35A CERTIFICATE OF ANALYSIS (for Institutional Chemicals) (Sept 2011)

SUBCONTRACTOR shall provide to CONTRACTOR, with or prior to shipment, a Certificate of Analysis (C of A) for the material(s) supplied and any associated Material Safety Data Sheet (MSDS). The C of A shall include:

1. Name of chemical/product
2. Purchase Order # and/or Lot # traceable to purchase document and/or chemical container
3. Name and address of facility manufacturing/supplying product
4. Quantity of certified material
5. Analyzed concentration/purity
6. Analytical accuracy
7. Date of manufacture and/or date of shelf life expiration (only applicable for items which are identified by the manufacturer as having an expiration date)
8. Signature and date of SUBCONTRACTOR'S certifying authority

QC-36 SOFTWARE QUALITY ASSURANCE (SQA) (Sept 2014)

SUBCONTRACTOR shall take all necessary precautions to ensure that malicious software is prevented from entering into their supply chain for items/services to be provided to CONTRACTOR.

SUBCONTRACTOR shall maintain records for all computer software which will identify and state the software engineering activities used to manage the software life cycle activities (based upon a consensus SQA standard; e.g. ASME NQA-1, ISO/IEC/IEEE 12207 or equivalent Contractor specific standard) required for the purchased software items/products or services, and these records shall be made available for CONTRACTOR'S review upon request. The software life cycle activities will be identified, testable, and controlled, including: requirements, design, user implementation, acceptance testing, verification, validation, problem reporting, corrective action, software configuration management, and in-use testing processes used for the software item/products or services to be purchased.

The Subcontractor shall include or otherwise make available for review at Contractor's request, the following activities and associated documentation that are marked with an X, as appropriate and graded for the software being used or developed:

1. Software Project Management Plan and/or Software Quality Assurance Plan to include but not be limited to:
 - a) Roles & responsibilities for the project team, including software design verification.
 - b) Interface controls including responsibilities for design interfaces, related procedures, and any necessary interface controls between Subcontractor and Contractor.
 - c) Identification of documents (including baseline documents) needing to be controlled and/or maintained as records
2. Software Risk Management Plan (to include; identification of potential risks, analysis and prioritizing of risks, impact and mitigation of risks)
3. Software Configuration Management documentation
 - a) Include establishment of a software baseline no later than the completion of the software validation process

- b) Changes subsequent to establishment of the software baseline are traceable to software requirements, approved, documented, and added to the baseline so that the baseline defines the most recently approved software configuration
- 4. Applicable Subcontractor sub-tier supplier evaluation documentation and sub-tier software procurement documentation providing evidence of incorporation and verification of applicable procurement quality requirements
 - a) Commercial Grade Dedication plan, as applicable
- 5. Software Requirements which are identified, testable, controlled, and documented
 - a) Requirements document or specification
 - b) Requirements traceability matrix
- 6. Software Design Documentation
 - a) Model or algorithm
 - b) Design description/components
 - c) Programmer's reference manual
- 7. Software hazard analysis documentation
 - a) Hazard analysis including identification and analysis of hazards with potential to defeat a safety function
 - b) Mitigation (or elimination) strategies for identified hazards (at the software system and component level as applicable)
- 8. Verification and Validation (V&V)
 - a) V&V document (e.g. test plan/test cases) that describes methods used in developing and validating the software (including acceptance criteria) and controls and documents V&V activities
 - b) V&V report (e.g. results) that demonstrates requirements are met
 - c) User Instructions
- 9. Problem Reporting and Corrective Action (communicate as necessary with LANL)
 - a) Supplier notification of defects, new releases, or other operational impacts to software users
 - b) Subcontractor/Supplier provide mechanism for software users to report defects and request operational assistance
- 10. Training and Qualification
 - a) Subcontractor personnel Training and Qualification records associated with the design and development of software
 - b) Subcontractor provided training to Contractor personnel in the use and evaluation of purchased software

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