



Quality Assurance Deliverable Requirements for Subcontractors

Institutional Quality & Performance Assurance Division

EXHIBIT “H” PART 1

SUBCONTRACTOR must comply with the clauses in this Exhibit that have been incorporated in this subcontract.

QD-01, NQA-1 CERTIFICATE OF CONFORMANCE (Nuclear Safety)

SUBCONTRACTOR must provide with or prior to delivery, a Certificate of Conformance for this subcontract in accordance with their approved certification system. The Certificate must:

- a) reference CONTRACTOR’s procurement/requisition/purchase order number.
- b) identify the material(s), item(s) and/or service(s) being certified traceable to the material(s), item(s), and/or service(s) delivered;
- c) identify the specific requirements of the procurement that are certified to have been met by listing the specific materials or equipment and the requirements met or not met, or by providing a copy of the purchase order and any approved deviations with the certificate including any nonconformance reports identifying requirements not met;
- d) identify any approved changes and/or deviations from the contract and describe or reference any requirements that have not been met;
- e) be signed by a person defined as having responsibility to sign in SUBCONTRACTOR’s approved certification system.

QD-02, INSPECTION AND TEST REPORTS

SUBCONTRACTOR must provide with or prior to delivery, inspection and/or test reports for the items and attributes thereof described or referenced below. These inspection and/or test reports must demonstrate compliance to the specific subcontract requirements and acceptance criteria described or referenced below.

Items and attributes:

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QD-03, ENGINEERING DRAWINGS, CALCULATIONS, AND ANALYSES

SUBCONTRACTOR must provide with or prior to delivery, engineering drawings, calculations, and/or analyses as specified below. Any drawings must detail the design of the items/systems and be traceable to any item(s) provided. For items, this requirement may be satisfied by inclusion of drawings, calculations, and/or analyses in a technical operations/maintenance manual. Drawings, calculations, and/or analyses may be for use in design activities only and/or for fabrication/construction to occur at a later date. Drawings, calculations, and/or analyses must be submitted as required by the subcontract.

Drawing, calculation, and/or analysis requirements:



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QD-04, CERTIFICATE OF CALIBRATION FOR SUBCONTRACTOR OWNED MEASURING AND TEST EQUIPMENT (M&TE)

SUBCONTRACTOR must provide with or prior to delivery of items or services, records demonstrating the calibration status of any M&TE used to perform required inspections or tests as specified in the procurement documents. These records must include, at a minimum, the following:

- a. title;
- b. the name and address of the laboratory;
- c. the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;
- d. unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
- e. the name and contact information of the customer;
- f. identification of the method used;
- g. a description, unambiguous identification, and, when necessary, the condition of the item;
- h. the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;
- i. the date(s) of performance of the laboratory activity;
- j. the date of issue of the report;
- k. reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;
- l. a statement to the effect that the results relate only to the items tested, calibrated or sampled;
- m. the results with, where appropriate, the units of measurement;
- n. additions to, deviations, or exclusions from the method;
- o. identification of the person(s) authorizing the report;
- p. clear identification when results are from external providers;
- q. the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g., percent);
NOTE According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.
- r. the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;
- s. a statement identifying how the measurements are metrologically traceable;
- t. the results before and after any adjustment or repair, if available;
- u. where relevant, a statement of conformity with requirements or specifications;
- v. where appropriate, opinions and interpretations.

QD-05, CERTIFIED MATERIAL TEST REPORTS

SUBCONTRACTOR must provide with or prior to delivery, Certified Material Test Reports (CMTRs) for the materials specified or referenced below. CMTRs must report physical and/or chemical properties of the material(s) as described below and be in accordance with any referenced national or international material standards (e.g., ASTM, ANSI) for the material type. CMTRs must be the results of test performed by the material manufacturer or by a material verification process, if such a process is allowed by the standard governing the material type and must specify the test method and the source of the acceptance criteria. Each CMTR must be authenticated by an authorized representative of the testing entity, be traceable to the materials delivered via heat, lot, or other identification, and must meet any content requirements of the applicable national or international standards invoked for the material type.



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Materials:

QD-06, SHELF-LIFE CERTIFICATION / STORAGE REQUIREMENTS

The items described or referenced below with limited shelf life, expirations dates, or similar must be delivered with accompanying documentation or labeling which defines the lifecycle for those items and their expiration date. The documentation must also specify storage requirements for the specific item(s) provided.

Items:

QD-07, CERTIFICATE OF PROOF LOAD TEST

The items or assemblies described or referenced below must be accompanied by test reports and records of performance which demonstrate successful Proof Load Testing of the items delivered in accordance with the specified standards for the item type.

Items or assemblies:

QD-08, SERIALIZATION AND MARKING

Items must be marked with unique identification as described or referenced below.

Serialization/markings requirements:

QD-09, HOLD POINTS

Mandatory hold points (as defined below) are associated with this subcontract beyond which work may not proceed unless written authorization is received from CONTRACTOR in accordance with subcontract requirements. SUBCONTRACTOR must notify CONTRACTOR a minimum of seven (7) days for work performed off the LANL site and a minimum of two (2) days for work performed on the LANL site in advance of performing the following activities so that CONTRACTOR may witness the activities.

Hold points:

QD-10, AUDIT REPORT



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SUBCONTRACTOR must provide to CONTRACTOR copies of the following:

- a. Audit plan(s),
- b. Audit Report(s), and
- c. any additional records as specified in the subcontract.

QD-11, NON-NUCLEAR CERTIFICATE OF COMPLIANCE/CONFORMANCE

SUBCONTRACTOR must provide with or prior to delivery, a certificate, regardless of document title/name, signed by an authorized representative of the item(s) manufacturer stating that item(s) provided under this subcontract have been manufactured in accordance with the applicable codes, standards, or other requirements specified below. The certificate must be traceable to the item(s) provided such as through lot, purchase order, or other similar identifier. If applicable, the certificate must identify any approved changes, waivers, or deviations, and any specific procurement requirement that were not met.

QD-12, CERTIFICATE OF CALIBRATION

SUBCONTRACTOR must provide with or prior to delivery, for each instrument/system specified below, a certificate of calibration stating the calibration instrument/system has been calibrated, the calibration results, and, if required by procurement documentation, the SUBCONTRACTOR was ISO/IEC 17025 accredited through a Signatory to the ILAC Mutual Recognition Arrangement (e.g., A2LA, NVLAP, ANAB, PJLA, Dakks, etc.). The certification must contain, at a minimum, the following:

- a) title;
- b) the name and address of the laboratory;
- c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;
- d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
- e) the name and contact information of the customer;
- f) identification of the method used;
- g) a description, unambiguous identification, and, when necessary, the condition of the item;
- h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;
- i) the date(s) of performance of the laboratory activity;
- j) the date of issue of the report;
- k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;
- l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;
- m) the results with, where appropriate, the units of measurement;
- n) additions to, deviations, or exclusions from the method;
- o) identification of the person(s) authorizing the report;
- p) clear identification when results are from external providers;
- q) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g., percent);



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NOTE According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.

- r) the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;
- s) a statement identifying how the measurements are metrologically traceable;
- t) the results before and after any adjustment or repair, if available;
- u) where relevant, a statement of conformity with requirements or specifications;
- v) where appropriate, opinions and interpretations.

Instruments/systems:

QD-13, NONCONFORMANCE REPORTS

SUBCONTRACTOR must notify CONTRACTOR's representative, as identified for this subcontract, in writing of each nonconformance to subcontract requirements identified for items and/or services affecting items to be provided under this subcontract. Excluded from reporting are nonconformances corrected prior to offering item(s) for CONTRACTOR acceptance by continuing or repeating the original manufacturing process, or by performing a LANL approved rework process. Nonconformances that must be reported include but are not limited to, nonconformances with documentation requirements and technical or material requirements, including situations where an item may be restored so as to function unimpaired but will not meet the original subcontract/design requirement.

SUBCONTRACTOR must document and evaluate each reportable nonconformance using Form 2276, *Subcontractor Nonconformance Report* and submit Form 2276 to CONTRACTOR within four (4) business days of discovery. Documentation and evaluation of the nonconformance must consist of the completed subcontractor section of Form 2276, which includes a written description of the nonconformance (with sketches and pictures highlighting the nonconforming condition if necessary to clearly describe the condition), and an assessment of the cause and the proposed disposition/corrective action including technical justification. CONTRACTOR must approve the disposition of the nonconformance with corresponding disposition implementation verified as described in the disposition via Form 2276.

Completed nonconformance documentation must be supplied by SUBCONTRACTOR to CONTRACTOR with or prior to delivery or acceptance of the items by CONTRACTOR and all records of nonconformance must be maintained by the SUBCONTRACTOR in accordance with subcontract requirements. SUBCONTRACTOR must not intentionally perform work that will result in a nonconforming condition without express written approval by CONTRACTOR.

SUBCONTRACTOR must flow this requirement down to any of their sub-tier suppliers who will provide quality affecting items for this subcontract.

QD-14, PROJECT SPECIFIC QUALITY ASSURANCE/QUALITY CONTROL (QA/QC) PLAN

Prior to performing quality affecting work under this subcontract, SUBCONTRACTOR must develop a work or project-specific Quality Assurance/Control Plan and submit to CONTRACTOR for review and approval. The plan and any quality affecting revisions to the plan must be reviewed and approved by CONTRACTOR prior to SUBCONTRACTOR performing work under this subcontract. The plan must describe the specific work control documents that will be used to control the work activities to be performed and must identify which activities will be controlled by which documents.



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The plan must identify any required training or certification requirements for personnel to be able to perform specific work tasks under this subcontract and identify the method of ensuring personnel have met those requirements prior to performing the task(s). The plan must identify any procedures, test plans, test methods, or other processes to be used to verify quality of work performed in accordance with the subcontract documents. All work performed under this subcontract must be performed in accordance with the approved Quality Assurance/Control Plan.

Specific requirements and content for the Quality Assurance/Control Plan are specified and/or referenced below:

QD-15, SPARE AND REPLACEMENT PART IDENTIFICATION

SUBCONTRACTOR must provide with or prior to delivery, a list of recommended spare or replacement parts for the items and/or assemblies specified below, and the necessary information to be able to order those parts, such as part numbers, manufacturer identification numbers, or product lines.

Items and/or assemblies:

QD-16, AS-BUILT DRAWINGS

SUBCONTRACTOR must provide with or prior to delivery, drawing(s) detailing the as-built condition of any items, assemblies, and/or components provided to CONTRACTOR under this subcontract. As-built drawings must be generated using the approved final drawing(s) for the subcontract, including any changes made during subcontract performance (usually required to be authorized using Form 2178, *Subcontractor Deviation Disposition Request* or Form 2276, *Subcontractor Nonconformance Report*), by adding as-built condition information to the drawing(s). As-built drawings must be authenticated by SUBCONTRACTOR personnel who are responsible for verifying the as-built conditions. The as-built condition includes identifying as applicable: final dimensions, material identification, weld maps including filler material used, serial numbers, and test results.

QD-17, SUBCONTRACTOR PERSONNEL QUALIFICATIONS / CERTIFICATIONS

SUBCONTRACTOR must provide with or prior to delivery of products/services records showing that personnel who have or will perform the specific tasks and/or types of work specified below have the necessary qualifications and/or certifications to perform the work as determined by SUBCONTRACTOR's Quality Assurance Program or as specified in this subcontract. These may include but are not limited to non-destructive examination certifications, welder certifications, inspection personnel certifications, lead auditor qualifications/certifications, etc.

Specific tasks and/or types of work requiring personnel qualification and/or certification:



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QD-18, CERTIFICATE OF ANALYSIS

SUBCONTRACTOR must provide with or prior to delivery to CONTRACTOR, a Certificate of Analysis (C of A) and any associated Safety Data Sheets (SDS) for the material(s) referenced below. The C of A must include:

- a) Name of chemical/product
- b) Purchase Order # and/or Lot # traceable to purchase document and/or chemical container
- c) Name and address of facility manufacturing/supplying product
- d) Quantity of certified material
- e) Analyzed concentration/purity
- f) Analytical accuracy
- g) 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)
- h) Signature and date of the certifying authority

Materials:

QD-19, MANUALS / INSTRUCTIONS

SUBCONTRACTOR must submit with or prior to delivery manuals, instructions, or other documents that identify the items and/or software specified below and include as applicable safety precautions, installation/test instructions, and operating and maintenance instructions. The manual/instructions must be provided in English, written in clear, concise language readily understandable by a technician, craftsman, or programmer, and must conform to applicable industry standards for the preparation of such documents.

Items and/or software:

QD-20, COMMERCIAL GRADE DEDICATION PLAN AND RESULTS

SUBCONTRACTOR must develop and submit to CONTRACTOR with or prior to delivery, unless alternate timeline indicated below, a Commercial Grade Dedication (CGD) Plan specific to the work or project prescribed to be dedicated by this subcontract. The CGD Plan must describe at a minimum the critical characteristics of the item(s) and/or service(s) to be dedicated, the method(s) of dedication for each critical characteristic, the acceptance criteria where applicable, and the document(s) to be generated demonstrating verification of the critical characteristics. The CGD Plan must identify any procedures, test plans, test methods, or other processes to be used to perform the identified dedication method(s). When critical characteristics or design criteria are not provided, the CGD Plan must also include documented identification of critical characteristics based on defined safety functions for the item(s) and/or service(s) to be dedicated. All dedication activities performed under this subcontract must be performed in accordance with the CGD Plan(s). The CGD Plan and revisions to the CGD Plan must be reviewed and approved by CONTRACTOR prior to SUBCONTRACTOR performing or continuing work under this subcontract. A CGD record package



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must be submitted to CONTRACTOR with, or prior to, provision of the item(s)/services(s) being dedicated by SUBCONTRACTOR. The record package documents must be traceable to the item(s)/service(s) dedicated and must include the following based on the method(s) used for dedication:

- a. dedication plans or procedures including the essential elements of the dedication process
- b. commercial grade item or service procurement documents (unless CONTRACTOR procured them)
- c. critical characteristics identification and acceptance criteria
- d. test reports or results, inspection reports, analysis reports (if method 1 is used)
- e. commercial grade survey reports (if method 2 is used)
- f. source verification reports (if method 3 is used)
- g. historical performance information (if method 4 is used)
- h. dedication report containing sufficient data to accept the item or service

When this box is checked, SUBCONTRACTOR must submit Commercial Grade Dedication (CGD) Plans for CONTRACTOR review and receive CONTRACTOR approval to proceed prior to commencing dedication activities.

QD-21, TECHNICAL EVALUATION

SUBCONTRACTOR must submit either at contract completion or prior to performance of dedication activities, technical evaluation documentation as specified in the subcontract documents that meets the applicable requirements of NQA-1 2008;2009a, Part II, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services* sections 400 and 500. Documentation must include the following:

- a. technical evaluations
- b. critical characteristics identification and acceptance criteria

QD-22, ITEM/COMPONENT TRACEABILITY DOCUMENTATION

SUBCONTRACTOR must submit with or prior to delivery authenticated documentation demonstrating the traceability of items, components, and/or materials used in products provided for this subcontract to the lot/batch/heat or other identifier for the item, component, and/or material. This traceability must establish the link between the unique item, component, and/or material used, its lot/batch/heat or other identifier, and its installation/incorporation and/or use as applicable in product(s) supplied under this subcontract. Lot/batch/heat or other identifiers used must be traceable to any supporting documentation of the item, component, and/or material such as test reports.

QD-23, SUSPECT/COUNTERFEIT ITEM REPORTS

SUBCONTRACTOR must notify CONTRACTOR's representative by email to scic@lanl.gov within five (5) business days of identification of any potential or actual Suspect/Counterfeit Items (S/CI) among products they have or will deliver to CONTRACTOR. Notifications must include a description of the item(s), what requirements the item(s) are required to meet, and how the item(s) do not, or are suspected of not, meeting those requirements.