QUALITY ASSURANCE REQUIREMENTS
FOR
CAPITAL PROJECT CONSTRUCTION, DECOMMISSIONING, DEMOLITION, AND FABRICATION

1.1 SUMMARY

Related Documents:
1. Master Agreements, Subcontracts, Statements of Work, Specifications, and other explicitly identified or referenced documents apply.

2. The Subcontractors are responsible for ensuring that all documents submitted to LBNL as part of the initial and/or modified subcontract includes all requirements and information discussed in this Master Agreement/Subcontract.

1.2 REFERENCES

A. General:
1. This document and referenced requirements and/or industry standards form part of the QA specifications and requirements to the extent stated. Where differences exist among various codes, regulations and standards, the one affording the greatest protection shall apply.

2. Unless otherwise noted, the referenced edition is the current one at the time of this subcontract is issued.

B. Quality Assurance Requirements:

1. The Subcontractor shall be responsible for full compliance (inclusive of its lower-tier subcontractors) with all applicable Quality Assurance regulations, requirements and/or standards, including but not limited to:

   a. 10 CFR 820, Procedural Rules for DOE Nuclear Activities.
   b. 10 CFR 830, Nuclear Safety Management
   c. DOE O 414.1D, Quality Assurance
   d. LBNL/PUB-3111, Quality Assurance Program Description (QAPD) (https://commons.lbl.gov/display/oiawebfiles/Quality+Assurance)

2. The Subcontractor will flow-down all QA regulations, requirements, standards and/or expectations to its lower-tier subcontractors.

C. Price-Anderson Amendment Act (PAAA) Enforceable Rules

The following Codes of Federal Regulation (CFRs) are applicable to subcontracts that include radiological work including but not limited to: radiological material/equipment use, calibration, analysis, handling, packing, storage or waste accumulation/management activities, with the exception of incidental use and generation of radioactive materials and radiation.

- 10 CFR 708, DOE Contractor Employee Protection Program
- 10 CFR 820, Procedural Rules for Nuclear Safety Management
- 10 CFR 830, Nuclear Safety Management

The Subcontractor shall be responsible to ensure that all work performed under the Subcontract (inclusive of lower-tier subcontractors) is performed in accordance with the Department of Energy's (DOE) Contractor Employee Protection Program (10 CFR 708) and “Nuclear Safety Management” rules codified in 10 CFR 820 and 10 CFR 830. The Subcontractor is subject to all applicable procedures for
investigating violations, enforcing compliance with requirements, and assessing civil penalties or fee reductions for violations under the DOE’s “Nuclear Safety Management” rule.

The Subcontractor shall report all issues, incidents and events including those contributed to by their lower-tier subcontractors to the LBNL Project Manager. Issues, incidents and events are evaluated by LBNL to determine if noncompliances with specific CFRs exist. Subcontractor and lower-tier subcontractor noncompliances may be enforced by the DOE, which could result in an Enforcement Action including, an Enforcement Letter, civil monetary penalty, and/or a Notice of Violation.

The Subcontractor shall cooperate with LBNL in all fact-finding activities, inquiries, and/or investigations, including ensuring subcontractor and lower-tier subcontractor personnel are available for interviews and providing unfettered access to LBNL fact finding, inquiry and investigation personnel to documents and records that are deemed pertinent. The Subcontractor shall participate in fact-finding activities, inquiries, and/or investigations, as requested by LBNL, at no additional expense to LBNL. LBNL issues management and occurrence reporting processes will be followed to address fact-finding activities to include near misses.

Costs associate with action taken by the Subcontractor and lower-tier subcontractor(s) upon receipt of a Notice of Intent to Investigate are unallowable and not reimbursable.

1.3 SUBCONTRACTOR ONSITE QUALITY ASSURANCE PROFESSIONAL

A. The Subcontractor shall provide a person(s) who will perform dedicated QA supervision, management and oversight to ensure the implementation of quality assurance requirements through the duration of the work. The Subcontractor will determine if the QA professional is a dedicated QA individual or an individual who will serve multiple functional roles, including QA. The QA professional will be a part of the Subcontractor Project Team, and will have the authority and independence from cost and schedule considerations; and authority and responsibility to monitor and enforce the all of the quality, technical and safety requirements of this Master Agreement/Subcontract; and implement the Subcontractors QAPjP. The QA professional(s) shall not be indirectly or directly involved with or responsible for the work that they are overseeing.

The Subcontractor will submit, along with other key project personnel, the resume and evidence of relevant professional certifications (e.g., American Society for Quality (ASQ) Certified Manager of Quality/Organizational Excellence, Certified Inspector, Certified Engineer, Certified Quality Auditor, Certified Calibration Technician, Certified Master Black Belt, Certified Commissioning Professional (CCP), etc.) of the person(s) who will perform the QA/QC function for the project, and will ensure that the person(s) is/are available for interview upon request by LBNL. The QA professional(s) will be technically proficient in quality assurance principles, quality requirements specific to this project and implementation thereof.

B. If the QA professional(s) is/are determined by LBNL and/or the Subcontractor to be unqualified to manage, oversee and/or perform certain QA/QC functions, including but not limited to the assessment, inspection, performance management, and monitoring requirements, the Subcontractor shall engage the services of a qualified QA professional(s) to perform the specialized duties.

C. The Subcontractor shall remove and replace its QA professional(s), at the request of the LBNL Project Manager, if the project is unsuccessful in enforcing the contractual requirements of the Master Agreement/Subcontract and maintaining hazard free worksites.

1.4 SUBCONTRACTOR QUALITY PROGRAM

A. After acceptance of the Master Agreement/Subcontract, the Subcontractor shall prepare a documented QA Project Plan (QAPjP) that effectively describes how quality assurance and quality control will be
The Subcontractor shall have a structured approach to QA/QC that, at a minimum, includes provisions for the following functional areas applicable to the work to be performed:

1. Organizational structure, including the independence of the assurance function from the line, and cost and schedule considerations;
2. Management processes, including work planning, scheduling and resourcing;
3. Training and qualification;
4. Quality and continuous improvement;
5. Document and records management and control;
6. Administrative and engineering controls;
7. Nonconforming items;
8. Measurement and testing equipment control and calibration;
9. Design (processes, software, hardware, systems, structures and components);
10. Procurement, including the process and criteria by which they evaluate and select a subcontractor; and the validation process that is used to ensure the lower-tier subcontractor is meeting requirements and performing as intended;
11. Inspection and testing, including receipt inspection;

B. The Subcontractor shall maintain applicable third-party accreditation(s) of all or part of their QMS or QA Program for the requested item(s)/service(s) that were in place at the time the Master Agreement/Subcontract was executed. Examples of third-party accreditations include, but are not limited to: ISO, International Electrotechnical Commission (IEC), National Voluntary Laboratory Accreditation Program (NVLAP), DOE Laboratory Accreditation Program (DOELAP), Automotive Servive Excellence (ASE), Accredited Quality Contractor (AQC), National Environmental Balancing Bureau (NEBB) Firm Accreditation, Testing, Adjusting and Balancing Bureau (TABB) Certified Commissioning Contractor (CCC).

C. The LBNL Technical or Project Manager, LBNL Construction Manager, LBNL QA Program Manager and LBNL Environmental, Safety and Health (ESH) representatives have responsibility and authority to stop work if unsafe or noncompliant conditions exist. This applies to all LBNL employees, affiliates, and contractors are responsible for stopping work activities considered to be an imminent danger. The Stop Work policy applies to all activities conducted at Berkeley Lab and to all off-site facilities operated by Laboratory personnel (https://commons.lbl.gov/display/rpm2/Stop+Work+Policy). The Subcontractor shall not be entitled to an extension of time or additional fee or damages by reason of or in connection with any unsafe conditions work stoppage.

1.5 TRAINING AND QUALIFICATION

A. The Subcontractor shall ensure that personnel performing work under the Master Agreement/Subcontract are technically competent and are trained and qualified to perform assigned work. Where work performed requires specific certification or qualification to industry standards (e.g., certified welder, certified weld inspector, electrical inspector, commissioning agent, auditor, etc.), copies of certificates of training/qualification will be provided to the LBNL Project Manager. Where the Subcontractor has opted to require professional certifications of personnel performing work on this project, the professional
certifications will be provided to LBNL Project Manager. The Subcontractor shall provide continuing training to project personnel for the duration of the project, as needed.

B. QA Orientation

As part of the post award process, a meeting shall be conducted and attended by the Subcontractors’ Project Principal, Project Manager, Superintendent, Safety Officer/coordinator, QA professional(s) and representatives from lower-tier subcontractors, to discuss LBNL Quality Policies, Procedures and Requirements including LBNL’s expectations regarding QA/QC. QA/QC discussion points may be incorporated into other pre-job meetings in lieu of holding a separate meeting specifically for QA/QC considerations.

1.6 DESIGN

The Subcontractor, if performing design services, shall establish a documented design configuration management process that ensures:

- sound engineering/scientific principles and appropriate standards are used
- design inputs, such as user and technical requirements, and design bases are incorporated into design work
- the design is traceable to the design inputs
- design interfaces are identified and incorporated throughout the design process
- initial design and associated changes are documented and reviewed by all appropriate interfaces and stakeholders
- the adequacy of design output documents (i.e. drawings, engineering calculations, system design documents, etc.) are verified and/or validated by individuals qualified at the same level or higher other than those who performed the work, and that the design is verified and validated prior to implementation with approval by the Subcontractor QA professional and the LBNL Project Manager or designee.

1.7 PROCUREMENT OF ITEMS AND SERVICES

A. The Subcontractor may be subject to an audit during performance of this Master Agreement/ Subcontract to ensure that the Subcontractor is performing as intended or changes made to the Subcontractor’s QA Program and/or QA/QC procedures have/will not adversely impact performance. Audits may include a review of the Subcontractor’s QA Program and associated implementing documents and records, and may include an onsite audit or surveillance by LBNL or its representatives to conduct interviews, observe processes, etc.

B. Right of access to Subcontractor’s and lower-tier subcontractor’s facilities and records for inspection or audit by the LBNL or other designee authorized by LBNL upon issuance of the Master Agreement/ Subcontract.

C. Subcontractors are required to flow the appropriate technical, quality, and safety requirements to their lower-tier subcontractors and must assess the effectiveness of the control of technical, quality and safety requirements by lower-tier subcontractors at intervals consistent with the importance, complexity, and quantity of the product or service being provided pursuant to the lower tier Master Agreements/ Subcontracts.

D. The Subcontractor is responsible for procuring items and services that meet LBNL requirements and perform as specified. Prior to receipt of items and completion of services, the Subcontractor shall verify that the item or service being furnished complies with procurement requirements. LBNL will establish a verification method to ensure that the item or service procured meets the requirements in the procurement documentation. Verification methods include, but are not limited to:

- Source Inspection (e.g., pre-production, in-process, first article),
- Receiving Inspection,
• Pre-Installation/Factory Testing,
• Supplier Certificate(s) of Conformance, and
• Evidence of listing and/or field evaluation by National Recognized Testing Laboratory (NRTL).

1.8 SUBCONTRACTOR SUBMITTALS

Review and acceptance by the LBNL Project Manager required under the Master Agreement/Subcontract does not authorize Master Agreement/Subcontract changes nor relieve the Subcontractor of any QA responsibilities specified in the Master Agreement/Subcontract. Project submittals must be submitted to LBNL at within the agreed upon time frame with the LBNL Project Team.

1.9 INSPECTION & TESTING

A. The Subcontractor’s onsite or subcontracted QA professional(s) shall conduct, lead and/or participate in quality-affecting inspections and tests, as required per specifications, during the different phases of the project. Quality-affecting inspections may include, but are not limited to:
   • Source Inspection (e.g. pre-production, in-process, first article, etc.) at the manufacturer’s facility,
   • Acceptance Testing, and
   • Systems Testing.

B. The Subcontractor’s onsite or subcontracted QA/QC professional(s) will perform receipt inspections of the materials and equipment to ensure that material and equipment meet LBNL requirements, to identify nonconforming items and appropriately mitigate them. Any defective tools, ladders, electrical cords, etc., must be immediately taken out of service, tagged, and promptly removed from the job site. The Subcontractor shall immediately notify the LBNL Project Team of nonconforming items, including potential suspect and/or counterfeit items.

C. The Subcontractor will document inspection results, findings and corrective, and the completed record(s) shall be kept on the job/work site and be made available to the LBNL Project Manager or LBNL QA Program Manager upon request.

D. The Subcontractor’s onsite or subcontracted QA/QC professional(s) shall cooperate with and comply with all safety directives communicated by the LBNL Project Manager or designee. The LBNL Procurement Specialist will direct the Subcontractor to make the necessary corrections commensurate with deficiencies found. The Subcontractor shall make these corrections at no additional expense to LBNL.

E. The Subcontractor will establish and implement a calibration program/process for measurement and testing equipment (M&TE), including weights, calibration sources, etc. used for inspection or testing. M&TE will be calibrated on a periodicity prescribed by the manufacturer or based on industry standards. The Subcontractor will provide calibration certifications as requested by LBNL.

F. LBNL may inspect the Subcontractor’s operation as work proceeds, at LBNL’s discretion, for compliance with requirements contained in the Master Agreement/Subcontract.

1.10 ISSUES MANAGEMENT

A. The Subcontractor shall establish a process to identify risks and issues, including noncompliances and nonconformances, determine their cause(s), and mitigate/correct them. The Subcontractor shall identify risks, and issues and their associated causes at no additional expense to LBNL. The Subcontractor shall mitigate and/or make the corrections at no additional expense to LBNL.

B. All findings, observations and best practices shall be included as lessons learned and incorporated into the Subcontractor’s QMS/QAP and/or implementing work documents.
C. The Subcontractor's violation, refusal, or failure to abate noncompliances/ nonconformances, or applicable deficiencies may be justification for Master Agreement/ Subcontract termination in accordance with the incorporated termination for default clauses.

1.11 NONCONFORMING ITEMS, AND SUSPECT/ COUNTERFEIT ITEMS & DISPOSITION

The Subcontractor shall establish a documented process by which nonconforming equipment and/or material, including suspect or counterfeit items, is identified, dispositioned and reported to the LBNL Project Manager. The Subcontractor shall mitigate and/or make corrections, including return and replace nonconforming items from the supplier, vendor or lower tier subcontractor, at no additional expense to LBNL.

1.1 ASSESSMENTS

The Subcontractor shall periodically assess the performance of work by its employees and their lower tier subcontractor employees and/or their processes to the Master Agreement/ Subcontract requirements to assure that they function effectively in successful execution of the subcontract. The assessment results will be documented and any findings or issues will be adequately tracked and managed through resolution in accordance with the Issues Management process required by Section 1.10. The Subcontractor shall make assessment results available to the LBNL Project Manager and/or LBNL QA Program Manager, as requested.

1.2 DOCUMENTS AND RECORDS MANAGEMENT

A. The Subcontractor shall ensure that documents (e.g., procedures, work instructions, inspection/ test plans, etc.) are established for and used to prescribe processes, specify requirements, and establish design, are developed, reviewed, approved, and issued prior to performing work. A change control process shall be established to ensure that the most current version of a document is available and used by personnel who need to perform work in accordance with these documents. Modification of approved procedures requires use of a formal change control process if the changes impact the quality and/or safety of the activity. The Subcontractor will ensure that personnel required to perform work to these documents will be trained on the documents and any revisions thereto.

B. All records generated by the Subcontractor and lower-tier subcontractors in support of this Master Agreement/ Subcontract are considered permanent records and may not be damaged or discarded. General correspondence, such as emails, will not be considered a record unless it serves as objective evidence of performance to requirements. The Subcontractor will ensure that these records are accessible to LBNL, upon request, throughout the duration of the Master Agreement/ Subcontract, and will provide LBNL a final hard-copy or electronic data package of project files upon completion of the Master Agreement/ Subcontract.

END OF SECTION