

BROOKHAVEN NATIONAL LABORATORY SUPPLIER QUALITY ASSURANCE REQUIREMENTS (BNL-QA-101)

PO/Contract No.: 427051

1.0 PURPOSE & SCOPE

- 1.1 This document establishes quality assurance requirements to which Suppliers to Brookhaven Science Associates (BSA) shall conform when specified in the procurement documentation.
- 1.2 This document contains two main sections. Section 3.0 covers the general requirements that are applicable to all Suppliers. Section 4.0 contains special quality requirements that are applicable only when specifically invoked in the procurement documentation.

2.0 DEFINITIONS

- 2.1 The term Procurement documentation means the purchase order (PO), contract, subcontract, Request for Proposal (RFP), Request for Quotation (RFQ) or other written agreement with the Supplier (seller) in which the requirements of BSA are incorporated.
- 2.2 The term Buyer means BSA operating Brookhaven National Laboratory, acting by and through its Procurement & Property Management Division (PPM) issuing the PO/contract.
- 2.3 The term Supplier (seller) means the legal entity, which is the contracting party, with the Buyer with respect to the procurement documentation.
- 2.4 The term article or item means a product and/or a service.

3.0 GENERAL REQUIREMENTS

Unless otherwise specified in the procurement documentation, the following General Requirements apply:

3.1 Supplier's Quality System and Quality Requirements

The Supplier shall have and maintain an effective quality system that will, as a minimum, comply with all of the requirements as designated by the following:

- ☐ **3.1.1** A quality system certified/registered to the ISO 9001 standard: (latest revision as of the date of issuing the procurement documentation).
- ☐ **3.1.2** A quality system that meets the requirements of the ISO 9001 standard: "Quality Management Systems – Requirements" (latest revision as of the date of issuing the procurement documentation).
- ☐ **3.1.3** Conformance to Supplier's/Manufacturer's quality program or system.
- ☒ **3.1.4** Other: Refer to procurement documentation, (e.g. PO, Statement of Work [SOW], specifications, drawings) for quality requirements.

NOTE: Clauses 3.2 through 3.22 apply to all POs and will be included collectively in other procurement documentation when required/specified.

3.2 Assessment by Buyer

The Supplier's quality system is subject to assessments by the Buyer's Representative(s) for conformance with the requirements of the PO. Supplier or Distributor shall allow BSA representatives, BSA customers, and regulatory agencies right of entry into the Supplier's facilities to determine and verify product, processes, records, personnel, material, procedures, and systems.

3.3 Change Approval

No change(s) shall be made to any Buyer requirements, (e.g. part number, model number, etc.) without the prior written approval of the Buyer.

3.4 Responsibility for Subcontractors

It is the responsibility of the Supplier to impose applicable requirements from this document upon their subcontractors. Additionally, the Buyer reserves the right to disapprove, in writing, any subcontractor.

3.5 Responsibility for Conformance

The Supplier is responsible to provide items that conform to the requirements of the PO regardless of any assessments, surveillances, inspections and/or tests by the Buyer or its representatives at either the Supplier's or Buyer's facility. The Buyer reserves the right to request failure analysis and corrective action for non-conforming articles or items submitted or supplied to the Buyer. The Supplier is responsible for notifying the Buyer of any recalls or alerts associated with this PO.

3.6 Protection of Material and Equipment

The Supplier shall employ procedures that assure adequate protection of material and equipment during shipment and while in storage. Such protection shall include special environmental packaging, as necessary. All items shipped (originally packaged or repackaged) to BNL or other locations cited in the PO or contract, shall comply with the requirements for preservation, packaging and marking as stated in the latest revision of ASTM Standard D 3951 Standard Practice for Commercial Packaging.

3.7 Measuring and Test Equipment (M&TE) Calibration

The Supplier shall calibrate any M&TE used in the fulfillment of the PO requirements against certified standards that are traceable to the National Institute of Standards and Technology (NIST), or some other recognized national or international standard, or physical constant. The Supplier shall notify the Buyer of any condition found during the calibration, servicing or repair of measuring and test equipment that can affect the end item requirements.

3.8 Suspect Counterfeit Parts

- The Supplier shall verify the procurement source and associated certifying paperwork.
- Appropriate incoming inspection test methods shall be used to detect potential counterfeit parts and materials.

- The Supplier shall flow this requirement down to all sub-tier suppliers to prevent the inadvertent use of counterfeit parts and materials.
- Distributors shall not modify, rework or repair material shipped on this order.

* For more information refer to the following Department of Energy website: <https://www.energy.gov/ehss/corporate-reporting-analysis/databases/suspectcounterfeit-and-defective-items>

3.9 Electrostatic Discharge Control

Items that are susceptible/sensitive to electrostatic discharge (ESDS) shall be handled and packaged to protect them from damage. Items and/or packages shall be labeled to indicate the susceptibility to electrostatic discharge.

3.10 Electrical or Fire Protection Equipment, Material, and Systems

All electrical or fire protection equipment, material, and systems delivered to BNL shall be certified, listed, or labeled by a Nationally Recognized Testing Laboratory (NRTL). The CE mark is NOT a recognized NRTL certification mark. (For a listing of OSHA-recognized NRTLs, refer to <http://www.osha.gov/>)

For electrical or fire protection equipment, material, and systems which no NRTL accepts, certifies, lists, labels, or otherwise determined to be safe, the Supplier shall determine the equipment to be safe for its intended use. The determination must be made on the basis of test data. The determination and test data documents shall be made available to BSA prior to or upon delivery for review and acceptance by the applicable BSA Authority Having Jurisdiction (AHJ).

In accordance with 29 CFR 1910.147(c)(2)(iii) whenever new machines or equipment are provided with energy isolating devices, those devices shall be designed to accept a lockout device.

3.11 Hoisting & Rigging Equipment

All hoisting & rigging equipment used at BNL shall meet the requirements of the latest applicable OSHA Regulations and ASME B30 Series standards for design, construction, markings, and proof load testing.

When proof load testing is required by the standards, a certificate shall be provided upon delivery documenting the proof test.

3.12 Deleted

3.13 Powered Machine Shop Equipment

All powered machine shop equipment (e.g., lathe) delivered to BNL shall meet the requirements of the latest applicable OSHA 1910 Regulations (e.g., part subpart O). Equipment purchased must include an integrated NFPA 79 compliant emergency stop and an anti-restart device.

3.14 Vehicle-Mounted Elevating and Rotating Aerial Devices

All vehicle-mounted and rotating aerial devices equipment used at BNL shall meet the requirements of ANSI A92.2.

3.15 Self-propelled Elevating Work Platform Equipment

All self-propelled elevating work platform equipment (e.g., scissor lift) used at BNL shall meet the requirements of ANSI A92.6.

3.16 Manually Propelled Elevating Aerial Platform Equipment

All manually propelled elevating aerial platform equipment used at BNL shall meet the requirements of ANSI 92.3.

3.17 Boom Supported Elevating Work Platform Equipment

All boom supported elevating work platform equipment used at BNL shall meet the requirements of ANSI 92.5.

3.18 Powered Industrial Trucks and Attachments

Powered industrial trucks (e.g. forklifts, hi-lows) shall meet the requirements of the ANSI/ITSDF B56 series for design, construction, markings, and test loading. Industrial truck attachments shall be approved by the truck manufacturer and supplied with an attachment data plate indicating the new truck capacities.

3.19 Used Industrial Equipment

For used industrial equipment (e.g. scissor lifts, fork lifts, etc.), a Certificate of Conformance as defined in clause 4.16, must be provided as objective evidence and must additionally state that all maintenance and manufacturing alerts have been screened and all required repairs and improvements have been completed. The Supplier shall provide records of the last year of maintenance.

3.20 Global Harmonized System Compliance

The supplier of chemicals shall deliver the chemical in full compliance with the Department of Labor, Occupational Safety & Health Administration (OSHA)'s Globally Harmonized System (GHS) Hazard Communication Standard (29CFR1910.1200), available at:

<https://www.osha.gov/dsg/hazcom/HCSFinalRegTxt.html>

All hazardous chemicals delivered to BNL shall be accompanied by an GHS Safety Data Sheets (SDS) with the format and content specified in 29CFR1910.1200. For information on the GHS SDS see OSHA Brief- Hazard Communication Standard: Safety Data Sheets Publication 3514 available at:

<https://www.osha.gov/Publications/OSHA3514.pdf>

All hazardous chemicals delivered to BNL after 12/01/2015 shall have a label with the elements specified in 29CFR1910.1200 [product identifier; pictograms; signal words; hazard statement(s); precautionary statement(s); and manufacturer, importer, or distributor's name, address, and telephone number]. For information on the GHS label, see OSHA Brief- Hazard Communication Standard: Labels and Pictograms Publication 3636 available at: <https://www.osha.gov/Publications/OSHA3636.pdf>

3.21 Age/Shelf Life and Storage Control

The Supplier shall have an effective storage and age control system for items where acceptability is limited by the age or manner of storage of the item. The system must include a method of identifying the expiration date on the containers in which material is delivered to the Buyer. Special handling conditions shall be recorded on certifications and shipping documents covering the material delivered to the Buyer. At the time of receipt, the material shall not have less than three-quarters of its shelf life remaining, without prior written approval from the Buyer for each shipment.

3.22 Product Recalls/Product Bulletins/Safety Alerts

Any and all product recall alerts, product bulletins, or safety alerts should be communicated by email directly to ProductRecallAlert@BNL.gov. Provide the Purchase Order Number(s) and names of purchasers with notification to assist BNL in locating and identifying the subject material.

4.0 SPECIAL REQUIREMENTS

The following Special Requirements are applicable only when specified in the procurement documentation or as indicated by check mark hereon. These Requirements can be modified as required.

INSTRUCTIONS: Since sub-clauses (e.g., 4.4.1) are tied to the main clause (e.g., 4.4), the requirements of the main clause will apply by default whenever any sub-clause is selected (regardless of whether the main clause was selected/checked).

☐ **4.1 Quality Assurance Program or Manual**

The Supplier shall submit a copy of their Quality Assurance Program or Manual with their proposal for review and evaluation.

☐ **4.2 Configuration Control System**

The Supplier shall establish and maintain a system to assure that all end items (including spares) are of the proper configuration, and that all approved configuration changes are incorporated at the specified effectivity points. Records shall be maintained to verify the configuration of each item.

☐ **4.3 Process Sheets, Travelers, etc.**

The Supplier 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. Flow sheets, or equivalent, shall be provided for sign-off by designated inspection personnel at specified inspection and test points, including, as required, re-inspection and re-test points, to assure completion as well as proper sequencing of required operations.

☐ **4.4 Manufacturing/Inspection/Test Plan**

Sixty (60) calendar days prior to performance of work, the Supplier shall submit for the Buyer's approval a Manufacturing/Inspection/Test Plan for the item(s) to be produced. Once approved, changes/revisions must be approved by the Buyer prior to implementation. The Plan shall satisfy one or more of the following as selected:

☐ **4.4.1** Identification of parts and subassemblies showing integrated flow into end item(s).

☐ **4.4.2** Identification of critical manufacturing operations, as well as inspection and test checkpoints.

☐ **4.4.3** The Plan may be a single document, or may make use of existing "travelers," or other suitable planning and control documents.

☐ **4.5 "Witness" Points**

The Buyer reserves the right to designate selected manufacturing, inspection, and/or test operations as "witness" points. The Supplier shall provide the Buyer with five (5) working days notice in advance of reaching such witness points during the manufacturing and test cycle of each item.

☐ **4.6 Test and Inspection Procedures**

Test and inspection procedures required to demonstrate satisfactory completion of requirements shall be prepared by the Supplier and submitted to the Buyer for approval sixty (60) calendar days prior to use of such procedures. Once approved, changes/revisions must be approved in writing by the Buyer prior to implementation.

☐ **4.7 Special Processes**

Processes (e.g., welding, brazing, bonding, plating, chemical machining, chemical coating, chemical cleaning, precision cleaning, heat treating, or waste processing) that either cannot be verified non-destructively or require a unique (special) non-destructive test / inspection (e.g., radiographic inspection, ultrasonic testing, pressure

leak testing) shall be performed in accordance with detailed written procedures. These procedures shall specifically describe the exact manner in which the processes are to be performed. Additionally, the following requirements apply as selected:

☐ **4.7.1** Copies of special process procedures shall be made available on request for review by the Buyer's representative.

☐ **4.7.2** At least sixty (60) calendar days prior to use on items deliverable to the Buyer, the Supplier shall submit to the Buyer copies of all applicable process procedures for review and approval. Revisions or changes to Buyer-approved special process procedures must be submitted to the Buyer for review and approval prior to implementation.

☐ **4.7.3 Qualification of Procedures, Facilities, Equipment and Personnel**

The Supplier shall, prior to use, qualify the procedures / specifications, facilities, equipment and personnel that will be used for the performance of special processes. Only those personnel who have been qualified to perform a specific special process shall be used to perform that process. Records of such qualification shall be available to the Buyer's representative upon request.

4.8 Qualification of Procedures, Facilities, Equipment

Superseded by Sub-clause 4.7.3

4.9 Qualification of Special Process Personnel

Superseded by Sub-clause 4.7.3

☐ **4.10 End-Item Documentation Package**

The Supplier shall provide a documentation package for each shipment of the item(s) supplied, which consists of objective evidence of compliance with PO requirements. This documentation package shall be complete, legible, indexed, and traceable to the item supplied. Additionally, the following requirements apply as selected:

☐ **4.10.1** Copies of reports of all required or necessary inspections, examinations and tests, properly validated by the Supplier's authorized personnel.

☐ **4.10.2** A listing of the as-built configuration of each delivered item; this may be defined by the use of drawing numbers and revisions, unique parts lists or other such means of positive identification.

☐ **4.10.3** Copies of nonconformance reports dispositioned as "rework / repair" or "use-as-is", and all BSA approved deviation/waivers.

☐ **4.10.4** Copies of material test certificates for specified materials, showing physical and chemical properties.

4.10.5 – Superseded by Clause 4.16

☐ **4.11 Release for Shipment**

The documentation package required in Clause 4.10 shall be approved by the Buyer's representative prior to release of the item for shipment.

☐ **4.12 Shipment of Documentation Package to Buyer**

Three (3) copies of the documentation package required in Clause 4.10 shall be shipped to the Buyer with or prior to each shipment of the purchased items.

4.13 Failure Reporting, Analysis and Corrective Action

The Supplier shall maintain a failure reporting, analysis and corrective action system that shall, as a minimum, evaluate, analyze and correct failures occurring during qualification, first article and end-item acceptance testing and inspection. The results of all failure evaluations and analyses shall be documented and available for review by the Buyer.

4.14 Source Inspection/Surveillance

Items to be delivered require inspection, tests or surveillance by the Buyer's representative at the Supplier's facility. Five (5) working days advance notice, for acceptance inspections and tests, shall be provided by the Supplier to the Buyer to permit scheduling of source inspection.

4.15 Chemical and Physical Test Report

One copy of the actual chemical and physical test report(s) for each heat, batch or lot shall accompany each shipment. Test reports shall list the actual parameters tested, the acceptable limits for each parameter, and shall contain the actual readings taken during test.

4.16 Certificate of Conformance (C of C)

With each shipment, per the procurement documentation, the Supplier shall submit a Certificate of Conformance (C of C). In case of drop shipment, a copy of the certificate shall be submitted to the Buyer at the time of shipment. The certificate shall include the title of and be signed by an authorized representative of the company, and shall constitute a representation by the Supplier that:

- A. Materials used are those which have been specified by the Buyer, and that the items delivered were produced from materials for which the Supplier has on file, reports of chemical or physical analysis, or any other equivalent evidence of conformance of such items to applicable specifications;
- B. Processes used in the fabrication of items delivered were in compliance with applicable specifications included as part of the PO/contract, or Buyer-approved procedures or specifications;
- C. The items as delivered comply with all applicable drawings, specifications, deviations/waivers and other requirements of the procurement documentation; and-
- D. When specified, cleaning and cleanliness requirements have been completely satisfied. The C of C shall reference the Supplier's applicable cleaning procedures.

4.17 Report with Each Shipment

Superseded by Clause 4.10

4.18 First Article Acceptance

Buyer acceptance of first article(s) is required prior to the production run. The first article(s) shall be identified as such, including the PO number/contract, part number, and part name. The Supplier is required to:

- ☐ **4.18.1** Submit the first article(s) to the Buyer's representative for test/inspection to be conducted at the Supplier's facility by the Buyer's representative.
- ☐ **4.18.2** Submit the first article(s) to the Buyer for test / inspection by the Buyer at the Buyer's facility.
- ☐ **4.18.3** Submit the first article(s) to the Buyer together with documents showing data representing results of the Supplier's first article(s) test/inspection, including the actual dimension or value for each specified characteristic.

- ☐ **4.18.4** After Buyer acceptance of first article(s), all of the remaining units required by the PO/contract shall be produced by the Supplier and the Supplier's suppliers using the same design, materials, processes, methods and tooling that were used to manufacture the approved first article(s). Any changes must have prior written approval from the Buyer.

4.19 Notification of Change to Design, Methods, or Processes

The Supplier shall immediately notify the Buyer of any significant changes (those that may affect form, fit, function, reliability, safety, or interchangeability) in product design, fabrication methods, materials, or processing from those used by the Supplier at time of Supplier's quotation or offer to the Buyer, which resulted in the PO.

4.20 Age/Shelf Life and Storage Control

Superseded by Clause 3.21

4.21 Serial Numbers

The Supplier shall assign/mark a separate and distinct serial number to each end-item in accordance with the procurement documentation. A record of the serial number, for each part number, shall be maintained by the Supplier.

4.22 Lot or Batch Numbers

For items furnished in accordance with the procurement documentation, the manufacturing lot or batch number shall be indicated on the packing list, certifications and other applicable documents. Where impractical to mark individual parts due to size or shape, the lot or batch number shall be marked on identifying tags or the smallest unit package.

4.23 Material Traceability

Materials used must be identified by material type, applicable specification and revision number, and be traceable to their lot and/or heat number(s). Traceability records shall be available for review by the Buyer's representative.

4.24 Shipment Destination Other than BNL

The material ordered is to be shipped to other than the Buyer's facilities. Copies of the data required in accordance with the procurement documentation shall accompany the shipment; in addition, one copy of such data shall be mailed to the Buyer on the same day that shipment is made.

4.25 Heat Treat Bars

Superseded by Clause 4.7

4.26 Burn-in

Burn-in shall be performed on each completed item, per the procurement specification or Supplier's Burn-In process approved by the Buyer. Records of burn-in testing, repairs and test results shall be maintained and shall be available to the Buyer's representative upon request.

4.27 Welding Procedures

Superseded by Clause 4.7

4.28 Weld/Braze Inspection Report

A report(s) shall be submitted that indicates the complete inspection of welds or brazes from the initial fit-up stage through final inspection. Inspection reports shall be accompanied by all radiographic films, filler metal reports etc. The reports shall contain the signature or stamp, and title of an authorized Supplier representative.

4.29 Radiographic Quality Requirements

Items requiring radiographic inspection shall be radiographed and processed in accordance with the Supplier's special process

procedures that satisfy design specifications, standards or other procurement documentation requirements. Personnel reading and interpreting film shall have been examined and certified. Responsibility for this certification shall rest with the Supplier, whether the Supplier does the work or subcontracts to a specialized laboratory. A report of the findings shall include the name of the reader and the signature and title of a responsible representative. The radiographic film and a reproducible copy of the report shall accompany each shipment. An adequate method of identifying and cross-referencing each film exposure, report, and item shall be provided. When parts are serialized, serial numbers shall appear on the report and the film.

☐ **4.30 Nondestructive Test Reports**

All nondestructive testing shall be conducted in compliance with the Supplier's special process procedures that satisfy the applicable provisions of the design specifications, or other procurement documentation requirements. Personnel and equipment utilized in performance of such tests shall be qualified for the type of test performed. The Supplier shall furnish with, or prior to, each shipment reports of such nondestructive examination of material or items furnished. These reports shall be identifiable to the respective item or material including the specific section, joints or views of the item furnished. These reports shall contain the signature and title of an authorized Supplier representative. When items are serialized, the serial numbers shall appear on the reports.

☐ **4.31 Pressure or Leak Test Reports**

Test reports shall be prepared for all pressure and leak tests. Such reports shall state the requirement, the Supplier's test procedure number, and the observed result for each item, joint or connection tested. When items are serialized, the serial numbers shall appear on the report. Reports shall contain the signature/title of an authorized Supplier representative and shall accompany each shipment.

4.32 Cleaning Certification

Superseded by Clause 4.16 D

☒ **4.33 Calibration Certification**

The Supplier shall submit with each instrument/system a certification that the instrument/ system has been calibrated and is ready for use. The certification shall contain, as a minimum, the identity of the instrument/system, identification of the calibration procedure used, identification of the standards and/or equipment utilized for the calibration, and a statement that the calibration of the standards and/or equipment used is traceable to the NIST or some other recognized national or international standard, or physical constant. Unless otherwise specified, detailed support data shall remain on file for minimum of three (3) years with the Supplier and shall be available for review by the Buyer. The certification shall also contain the signature and title of an authorized Supplier representative.

- ☐ **4.33.1** The Supplier will provide "As Found" (i.e., before) and "As Left" (i.e., after) measurements with the certification.

☐ **4.34 Operating-Maintenance Manual**

Documentation containing operating procedures, maintenance instructions, spare parts lists, and handling procedures shall be submitted with the shipment of the first item.

☐ **4.35 Computer Software Configuration Management**

The Supplier shall have and maintain an effective software configuration management system. The Supplier's system shall establish requirements for placing software under configuration control, provide for the positive identification of software, and the control of all software baseline changes.

- ☐ **4.35.1** The Supplier shall submit a copy of their software configuration management procedure(s) with their proposal for review and evaluation.

4.35.2 Superseded by Sub-clause 4.35.1

☐ **4.36 Computer Software Validation**

The Supplier shall develop written procedures describing the controls applied to the design of software and the validation of the design through independent technical review. The procedures shall provide for documentation of review activities, including requirements for documenting comments and resolution of comments. Supplier software designs and review documentation shall be subject to review and approval by the Buyer.

☐ **4.37 Computer Software Verification Testing**

The Supplier shall test and verify computer software developed or modified to fulfill the requirements in the procurement documentation. The verification testing shall be accomplished by a comparison of test results with those from other verified software, or by a comparison with results from analytical solutions or Buyer-approved alternatives.

4.38 Electrostatic Discharge Control

Superseded by Clause 3.9

☐ **4.39 Records**

The Supplier shall retain objective evidence, including records, of the inspections and tests performed in the course of manufacturing, testing, inspecting, preserving, packaging, and preparation for shipment of procured items. These records shall be made available to the Buyer's representative for review upon request. These records shall be maintained for a minimum of three (3) years, unless otherwise specified in the procurement documentation, after the completion of the PO/contract.

4.40 Electrical, Fire Protection, or Scaffolding Equipment, Material, and Systems

Superseded by Clause 3.10

4.41 Hoisting & Rigging Equipment

Superseded by Clause 3.11

4.41.1 Powered Industrial Truck Attachments

Superseded by Clause 3.18

4.41.2 Custom-made Equipment

Superseded by Clause 3.11

4.41.3 Critical Lifts

Superseded by Clause 3.11

4.42 Marking of Outer Package and Hoisting & Rigging Services

Superseded by Clause 3.12

☐ **4.43 Franchised / Licensed "Distributor" Traceability**

Products that are not purchased directly from the Original Equipment Manufacturer (OEM)/Original Component Manufacturer (OCM) must be purchased only from a franchised/licensed distributor of the product being offered. The distributor shall ensure traceability of all products to the original equipment manufacturer by identifying the original manufacturer for each lot/date code on the Certificate of Conformance. The distributor shall provide a copy of the Manufacturer's certificate for the lot number being supplied, along with their franchised distributor certification. The distributor shall not use unapproved brokers (any company, person, or entity who is not an OEM/OCM) for the purchase of components and parts, unless

pre-approval has been granted by Brookhaven Science Associates (BSA).

4.44 Power Machine Shop Equipment

Superseded by Clause 3.13

4.45 Aerial Lifts Equipment

Superseded by Clause 3.14

4.46 Self-propelled Elevating Work Platform Equipment

Superseded by Clause 3.15