

QUALITY ASSURANCE PROCUREMENT REQUIREMENTS Argonne Award No.

1.0 SCOPE

- 1.1 This document, when invoked by purchase order or contract, establishes the quality assurance requirements to which suppliers to Argonne National Laboratory shall conform during the work performance required.
- 1.2 This document contains three main sections. Section 3.0 covers the general requirements that are applicable to all suppliers. Section 4.0 contains special quality assurance requirements that are applicable when invoked by the purchase order/contract. Section 5.0 relates to computer software; additional requirements, if any, will be stated in Section 6.0

2.0 DEFINITIONS

- 2.1 "Purchase Order" means the purchase order, contract, Blanket Agreement, subcontract or other written agreement with the supplier in which the requirements of this document are incorporated by reference.
- 2.2 "Buyer"/"Laboratory" means Argonne National Laboratory, acting by and through its Procurement Department issuing the purchase order.
- 2.3 "Supplier" means the legal entity which is the contracting party with the buyer in respect to the purchase order.
- 2.4 "PAAA" means (Price Anderson and Amendments Act) compliance with the requirements of 10 CFR 820 and all specified requirements of these procurement documents.

3.0 GENERAL REQUIREMENTS

Unless otherwise specified in the purchase order or statement of work, the following General Requirements apply:

3.1 SUPPLIER'S QUALITY ASSURANCE PROGRAM/INSPECTION SYSTEM

- 3.1.1 Quality Assurance Program (e.g. DOE 5700.6C, MIL-Q-9858A, ASME NQA-1.)
- 3.1.2 Calibration System (e.g. DOE 414.1A)
- 3.1.3 Dimensional Inspection/Sampling Plan (e.g. 414.1A)

3.2 AUDIT BY ARGONNE

3.3 CONFORMANCE TO REQUIREMENTS

All items or services furnished to the Laboratory shall conform with the requirements of the purchase order. No change(s) shall be made without prior written approval of the Laboratory.

3.4 RESPONSIBILITY FOR CONFORMANCE

Audits, surveillance, inspection and/or tests made by the Laboratory or its representative(s) at supplier's or buyer's facility shall not relieve the supplier of the responsibility to furnish items or services which conform to the requirements of the purchase order/contract.

3.5 PROTECTION OF MATERIAL AND EQUIPMENT

The supplier shall ensure adequate protection of material and equipment during shipment/storage, and shall included special environmental packaging, as necessary.

3.6 PRICE ANDERSON AND AMENDMENTS ACT (PAAA)

The goods or services being provided by the supplier will be subject to the requirements of 10 CFR 820.

4.0 SPECIAL REQUIREMENTS

The following special requirements are applicable when invoked by purchase order, or as indicated (check marked):

- 4.1 QA MANUAL: The supplier shall submit to the Laboratory for review and approval, a copy of the organization's quality assurance manual or other appropriate documents which describe their quality assurance program.
- 4.2 QA PLAN: The supplier shall submit to the Laboratory for review and approval, a quality assurance plan describing those procedures and activities used to assure the quality required for the purchase order.
- 4.3 CONFIGURATION CONTROL SYSTEM: To assure that all end items (including spares) are of the proper configuration, and all approved changes are incorporated at specified effectivity points, records shall be maintained verifying the configuration of each item.
- 4.4 MANUFACTURING/INSPECTION/TEST PLAN: At least ten (10) working days prior to fabrication, the supplier shall prepare and submit for the Laboratory's review and written approval a manufacturing/inspection/test plan which satisfies the following:
 - 4.4.1 Identification of critical manufacturing operations including inspection and test checkpoints.
 - 4.4.2 Identification of parts and/or subassemblies showing integrated flow into end item(s).
 - 4.4.3 Revisions or deviations from the approved plan shall be submitted to the Laboratory for review and approval prior to implementation.
- 4.5 PROCESS SHEETS, TRAVELERS, ECT.: A system defining the sequence of manufacturing/inspection/test activities shall be incorporated to assure completion and proper sequencing of required operations (operations, types of inspection, and tests shall be identified).
- 4.6 "WITNESS" POINTS: The Laboratory reserves the right to designate manufacturing, inspection, and/or test operations as "witness" points. The supplier shall provide the Laboratory with 72 hours notice (or other time frames stipulated by Argonne) before reaching such points during the manufacturing and test cycle.
- 4.7 TEST AND INSPECTION PROCEDURES: These procedures are required to meet purchase order/contract requirements. They shall be prepared by the supplier and submitted to the Laboratory for review and approval thirty (30) days prior to use.
- 4.8 QUALIFICATION OF SPECIAL PROCESS PERSONNEL, PROCEDURES, FACILITIES AND EQUIPMENT: Prior to use, personnel, procedures, facilities and equipment used for performance of special processes shall be qualified. Records of qualification shall be available to the Laboratory upon request.
 - 4.8.1 QUALIFICATION AND CERTIFICATION OF PERSONNEL FOR SPECIAL PROCESSES: Supplier's personnel responsible for performing or verifying processes requiring special skills shall be qualified and certified. Qualifications for these processes shall be by formal test to assure the proficiency of each individual. Personnel satisfactorily passing the required tests shall have objective evidence of certification

Records of qualification shall be available to the Laboratory upon request. Only those personnel who have been qualified shall be used in performance of these processes.

The effectivity period for all certifications shall be specified. Individuals shall be recertified at the end of these periods through retesting.

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- 4.8.2 SPECIAL PROCESS PROCEDURES: Thirty (30) days prior to use, copies of written detailed procedures or specifications describing each special process shall be submitted to the Laboratory for review and written approval. Revisions or changes to the Laboratory's approved special process procedures or specifications shall be submitted for written approval prior to reimplementation.
- 4.8.3 SPECIAL PROCESS CERTIFICATION: Each shipment shall be accompanied by a certification for the special processes covered by specifications/contract. Special processes include: Heat Treating, Welding/Brazing, Nondestructive Tests (incl. Helium Leak, Hydro or Pneumatic Pressure Tests), Surface Prep/Treatment etc. The certification shall list the applicable specifications including letters and numbers to which the processes conform, the name of the agency performing them (if other than the supplier), the date, and authorized signature of the responsible representative. When parts are serialized, serial numbers shall appear on the certification.
- 4.9 WELDING PROCEDURES AND SPECIMENS:
 - 4.9.1 The supplier shall prepare detailed procedures for each type of weld and weld joint to be used in accordance with ASME Boiler and Pressure Code Section IX or AWS D1.1. These procedures are subject to approval by the Laboratory. Qualification tests shall be performed and documented by the supplier prior to fabrication.
 - 4.9.2 The supplier shall prepare samples of typical weld joints using the same material required for the finished part. These samples are to be submitted to the Laboratory for written approval prior to the start of welding operations. In the event of disapproval, the supplier will receive a written explanation of inadequacies.
- 4.10 NONDESTRUCTIVE TEST REPORTS: Nondestructive tests (NDT) shall be conducted in compliance with the applicable provisions of the contract and/or applicable specifications. Personnel and equipment utilized in performance of such tests shall be evaluated and certified in accordance with ASNT-TC-1A. The supplier shall furnish with or prior to each shipment reports and observed results. These reports shall be specified in the contract or specifications and be identifiable to the respective item or material. Reports shall contain the signature and title of the individual performing the tests. If parts are serialized, numbers shall appear on the reports. Reports are subject to review and acceptance by the Laboratory.

NDT required by purchase order/contract:

- 4.10.1 Penetrant
- 4.10.2 Magnetic Particle
- 4.10.3 Eddy Current
- 4.10.4 Ultrasonics
- 4.10.5 Leak or Pressure
- 4.10.6 Radiography

- 4.10.6.1 RADIOGRAPHIC REQUIREMENTS: Items requiring radiographic inspection shall be radiographed and processed in accordance with design specifications, standards and contract requirements. Findings shall be reported on an appropriate form, including the name of the interpreter and signature. The radiographic film and a copy of the report shall accompany each shipment. An adequate method of identifying and cross referencing each exposure, report, and item shall be provided. When parts are serialized, serial number shall appear on the report and film. Personnel interpreting film shall have been subjected to examination and certification. Responsibility for certification shall rest with the supplier, whether the supplier does the work or subcontracts to a specialized laboratory.
- 4.10.7 Other _____
- 4.11 CHEMICAL OR PHYSICAL TEST REPORTS: Reports shall be submitted to the Laboratory with or prior to each shipment; each report shall contain: actual test results or analysis obtained from the originating source of the material; and the signature of an authorized contract representative of the supplier or contract representative of the agency performing test. The supplier shall be responsible for the validity of content. Reports shall be subject to review and acceptance by the Laboratory.
 - 4.11.1 Chemical
 - 4.11.2 _____
- 4.12 Functional Test Report: Each shipment shall be accompanied by the reports of actual test results identifiable to the acceptance criteria designated in the procurement package and listed in one or more of the following documents:
 - Purchase Order/Subcontract
 - Statement of Work
 - Schedule One
 - Specifications
 - Procedures
 - Drawings

These reports shall contain the date, results or data and signature of the responsible representative and name of the organization performing the tests and shall be subject to review and acceptance by the Laboratory.
- 4.13 PART IDENTIFICATION
 - a. Each drawing or specification for parts, components, subassemblies, or end items shall specify the location and methods of applying the appropriate identification which included the following.
 - Drawing Number, including revisions
 - Part Number
 - Part Number, revision letter
 - Serial Number (when applicable)
 - b. Each part, component or subassembly shall bear the appropriate identification in accordance with drawings and specifications .
- 4.13.1 MANUFACTURING LOT OR BATCH NUMBER IDENTIFICATION: All parts and materials, plus applicable documents, shall be identified by a manufacturing lot batch number stamped on the smallest unit packaged by the supplier.

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- 4.13.2 SERIAL NUMBERS: The supplier shall assign a separate and distinct serial number to each end item. Where impractical due to size or shape, the serial number shall be marked on identifying tags or the smallest unit package. No two items having the same part number are to be identified with the same serial number. Records of serial numbers for each part number shall be maintained by the supplier.
- 4.13.3 IDENTIFICATION OF AGE CONTROL ITEMS: Material identification shall be supplied for each item, package or container having limited shelf life. The cure date, date of manufacture, shelf life, storage temperature, humidity, and special handling conditions in addition to required identification, such as name, part number, type size, quantity, etc., shall be provided.
- 4.13.4 MATERIAL TRACEABILITY: All items shall be traceable to the raw materials. Methods of identifying materials, parts and components shall be submitted to the Laboratory for approval prior to use.
- 4.13.5 ASSEMBLY AND PARTS LIST: An assembly parts list designating the part number, serial or lot control number for each part incorporated, including an Laboratory furnished components or subassemblies shall be furnished by the supplier.
- 4.14 MATERIAL CERTIFICATION: Shall be submitted with or prior to each shipment, indicating purchase order or contract number and identification of the specification to which the material conforms. Certifications shall include the signature and title of the authorized representative for the agency who verified the compliance. The supplier shall be responsible for certification validity.
- 4.15 CERTIFICATE OF CONFORMANCE: With each shipment of items or services covered by the purchase order, a certificate of conformance shall be submitted. Objective evidence shall be retained by the supplier, including records of inspections/tests, preservation/packaging, and preparation for shipment. These records shall be made available to the Laboratory for review, if requested. The certificate shall be signed by an officer of the company, and shall constitute representation by the supplier that:
- 4.15.1 Materials used are those which have been specified by the Laboratory, and the items or services delivered were produced from materials for which the supplier has reports of chemical or physical analysis, or other equivalent evidence of conformance.
- 4.15.2 Processes used in the fabrication were in compliance with applicable specifications required by the purchase order, and/or other Laboratory approved procedures. No significant process changes were made during manufacturing or since issued of the Laboratory's purchase order/contract without written approval.
- 4.15.3 Items or services as delivered comply with specifications or other purchase order requirements.
- 4.15.4 Items in this contract have been produced from material supplies by the Laboratory on Argonne Shipper No.
- 4.16 FIRST ARTICLE ACCEPTANCE: Laboratory acceptance of first article(s) is required prior to the production run. The first article(s) shall be identified, including the purchase order number, part number and name. The supplier is required to:
- 4.16.1 Submit the first article(s) for inspection or test by the Laboratory.
- 4.16.2 Submit a record of results of supplier's first article(s) inspection or test, including the actual dimensions or value of each specified characteristic.
- 4.16.3 After the Laboratory's acceptance all remaining units required by the purchase order shall be produced using the same design, materials, processes and tooling utilized to manufacture the approved first article(s). Any changes shall have written prior approval from the Laboratory.
- 4.17 SOURCE INSPECTION OF SURVEILLANCE: Items or services to be delivered under this purchase order require inspection, tests or surveillance by the Laboratory's representative at the supplier's facility. A minimum of 72 hours notice (or other time frames stipulated by Argonne) shall be given by the supplier for scheduling of source inspection or surveillance.
- 4.18 NONCONFORMANCE REPORT: Any nonconformance to drawings, specifications or other contract requirements shall be recorded as found and submitted to the Laboratory for disposition. Further processing, delivery, installation, or use of nonconforming items shall be controlled pending an approved disposition by the Laboratory. Copies of the Argonne approval document shall accompany each affected shipment or in the case of a service, a copy shall be included in a final buy-off release. Nonconformances shall be reported on Form ANL-311, "Supplier Disposition Request" (SDR).
- 4.19 END ITEM DOCUMENTATION PACKAGE: Each item supplied shall have objective evidence that it complies with purchase order requirements. Documentation shall be complete, legible, indexed, and traceable to the item supplied, and contain the following, as applicable.
- 4.19.1 Reports for required inspections, examinations and tests, properly validated by the supplier's authorized personnel.
- 4.19.2 Record of the as-built configuration for each delivered item (including drawing number and revisions, parts list or other means of positive identification).
- 4.19.3 "Supplier Disposition Requests" properly dispositioned with Laboratory approval (Ref. 4.18).
- 4.19.4 Material test reports with actual physical and/or chemical properties (Ref. 4.11).
- 4.19.5 A certificate of Conformance (Ref. 4.15).
- 4.20 SHIPMENT: The supplier shall be responsible for providing the documentation package as required in 4.19 for review by the Laboratory. Three (3) copies shall be shipped to the Laboratory with or prior to shipment.
- 4.20.1 SHIPMENT DESTINATION OTHER THAN THE LABORATORY: If items are shipped to a destination other than the Laboratory, copies of the required quality assurance data shall accompany the shipment. In addition, one copy shall be mailed to the Laboratory on the day of shipment.
- 4.21 RESUBMITTAL OF ITEMS: Items which have been returned to the supplier by the Laboratory for rework, repair or replacement shall be resubmitted accompanied by a copy of the report of non-conformance (NCR) (Form ANL-267). A notation shall be made on the packing list identifying the resubmittal and the NCR number.
- 4.22 SUPPLIER CONTROLLED PRODUCTS: Copies of applicable specifications, drawings, installation, operation and maintenance instructions or catalogues shall accompany the initial shipment of material. No changes shall be made in subsequent shipments unless approved by the Laboratory.
- 4.23 CHANGES PROPOSED BY THE SUPPLIER: Prior to a supplier's change in the Laboratory's approved design, workmanship standards, or manufacturing processes, the supplier shall obtain the Laboratory's written approval (Supplier Disposition Request, Ref. 4.18). Changes shall be identified in shipping documents.

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- 4.24 PROPRIETARY DESIGNS AND PROCESSES: The supplier shall notify the Laboratory prior to changing proprietary processing or design of products to be shipped.
- 4.25 SPECIAL HEAT TREAT IDENTIFICATION: Heat treated items shall be legibly identified. Methods of identification shall be submitted to the Laboratory prior to application. Heat treat furnace charts shall be provided showing material lot (4.13.1), quantity, atmosphere, temperature and time.
- 4.26 MATERIAL MARKING: Materials shall be marked with specifications and heat numbers. Marking methods shall be submitted to the Laboratory for written approval prior to application.
- 4.27 ARGONNE/GOVERNMENT SUPPLIED MATERIAL: Shall be completely accounted for. Scrap or waste generated through machining/fabrication shall be dispositioned as stipulated in the purchase order/contract.
- 4.28 CLEANING CERTIFICATION: A certification stating the process and specification used shall accompany each shipment. The section numbers to which the cleaning process applies shall be listed along with the name of the agency who performed the operation (if other than the supplier), the signature of the supplier's authorized representative and the date. When parts are serialized, serial numbers shall appear on the certification. If restricted materials have been used, test results showing their removal shall be reported.
- 4.29 CERTIFICATION OF INSTRUMENTATION CALIBRATION: The certification shall contain as a minimum: the identify of the instrument(s) the calibration procedure used, the S/Ns of the standards or equipment utilized along with the date of calibration and traceability to NIST or other approved standards. Detailed support data shall remain on file with the supplier. Certification(s) shall be signed by an authorized representative.
- 4.30 BURN-IN TEST: To be performed by the supplier on electrical items or systems prior to delivery. Items shall be burned-in for a continuous 96-hour period at nominal operating power and specified maximum temperatures. At completion, each item shall be tested to determine conformance with requirements. In the event of failure during or after test, the faulty item(s) shall be repaired or replaced and be subjected to 96-hour burn-in period. Records of burn-in tests along with repairs shall be maintained by the supplier and made available to the Laboratory upon request.
- 4.31 OPERATING MANUAL(S): For off-the-shelf items, which includes additions, changes and/or modifications.

5.0 **SOFTWARE**

- 5.1 Documentation
- 5.2 Test Run Data
- 5.3 Limitations of Application
- 5.4 Limitations of Argonne Development of Purchased Programs

6.0 **OTHER REQUIREMENTS**