Subpart 46.1 - General

Parent topic: Part 46 - Quality Assurance

46.101 Definitions.

As used in this part-

Acceptance means the act of an authorized representative of the Government by which the Government, for itself or as agent of another, assumes ownership of existing identified *supplies* tendered or approves specific services rendered as partial or complete performance of the contract.

Conditional acceptance means *acceptance* of *supplies* or services that do not conform to *contract quality requirements*, or are otherwise incomplete, that the contractor is required to correct or otherwise complete by a specified date.

Contract quality requirements means the technical requirements in the contract relating to the quality of the product or service and those *contract clauses* prescribing *inspection*, and other quality controls incumbent on the contractor, to assure that the product or service conforms to the contractual requirements.

"Counterfeit item" means an unlawful or unauthorized reproduction, substitution, or alteration that has been knowingly mismarked, misidentified, or otherwise misrepresented to be an authentic, unmodified item from the original manufacturer, or a source with the express written authority of the original manufacturer or current *design activity*, including an authorized aftermarket manufacturer. Unlawful or unauthorized substitution includes used items represented as new, or the false identification of grade, serial number, lot number, date code, or performance characteristics.

Critical item means an item, the failure of which is likely to result in hazardous or unsafe conditions for individuals using, maintaining, or depending upon the item; or is likely to prevent performance of a vital agency mission.

Critical nonconformance means a nonconformance that is likely to result in hazardous or unsafe conditions for individuals using, maintaining, or depending upon the *supplies* or services; or is likely to prevent performance of a vital agency mission.

Design activity means an organization, Government or contractor, that has responsibility for the design and configuration of an item, including the preparation or maintenance of design documents. *Design activity* could be the original organization, or an organization to which design responsibility has been transferred.

Government contract quality assurance means the various functions, including *inspection*, performed by the Government to determine whether a contractor has fulfilled the contract obligations pertaining to quality and quantity.

Major nonconformance means a nonconformance, other than critical, that is likely to result in failure of the *supplies* or services, or to materially reduce the usability of the *supplies* or services for their intended purpose.

Minor nonconformance means a nonconformance that is not likely to materially reduce the usability of the *supplies* or services for their intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the *supplies* or services.

Off-the-shelf item means an item produced and placed in stock by a contractor, or stocked by a distributor, before receiving orders or contracts for its sale. The item *may* be commercial or produced to military or Federal specifications or description.

Patent defect means any defect which exists at the time of acceptance and is not a latent defect.

Subcontractor (see 44.101).

Suspect counterfeit item means an item for which credible evidence (including but not limited to, visual *inspection* or *testing*) provides reasonable doubt that the item is authentic.

Testing means that element of *inspection* that determines the properties or elements, including functional operation of *supplies* or their *components*, by the application of established scientific principles and procedures.

46.102 Policy.

Agencies shall ensure that-

(a) Contracts include *inspection* and other quality requirements, including *warranty* clauses when appropriate, that are determined necessary to protect the Government's interest;

(b) *Supplies* or services (including *commercial services*) tendered by contractors meet contract requirements;

(c) *Government contract quality assurance* is conducted before *acceptance* (except as otherwise provided in this part), by or under the direction of Government personnel;

(d) No contract precludes the Government from performing *inspection*;

(e) Nonconforming *supplies* or services are rejected, except as otherwise provided in <u>46.407</u>;

(f) Contracts for *commercial products* rely on a contractor's existing quality assurance system as a substitute for compliance with Government *inspection* and *testing* before tender for *acceptance* unless customary market practices for the *commercial product* being acquired permit in-process *inspection* (<u>41 U.S.C. 3307</u>). Any in-process *inspection* by the Government *shall* be conducted in a manner consistent with commercial practice; and

(g) The quality assurance and *acceptance* services of other agencies are used when this will be effective, economical, or otherwise in the Government's interest (see 42.002 and subpart 42.2.

46.103 Contracting office responsibilities.

Contracting offices are responsible for-

(a) Receiving from the activity responsible for technical requirements any specifications for *inspection, testing,* and other *contract quality requirements* essential to ensure the integrity of the *supplies* or services (the activity responsible for technical requirements is responsible for prescribing *contract quality requirements,* such as *inspection* and *testing* requirements or, for service contracts, a quality assurance surveillance plan);

(b) Including in *solicitations* and contracts the appropriate requirements for the contractor's control of quality for the *supplies* or services to be acquired;

(c) Issuing any necessary instructions to the cognizant *contract administration office* and acting on recommendations submitted by that office (see 42.301 and 46.104(f));

(d) When contract administration is retained (see $\underline{42.201}$), verifying that the contractor fulfills the *contract quality requirements*; and

(e) Ensuring that nonconformances are identified, and establishing the significance of a nonconformance when considering the acceptability of *supplies* or services which do not meet contract requirements.

46.104 Contract administration office responsibilities.

When a contract is assigned for administration to the *contract administration office* cognizant of the contractor's plant, that office, unless specified otherwise, *shall*-

(a) Develop and apply efficient procedures for performing *Government contract quality assurance* actions under the contract in accordance with the written direction of the *contracting office*;

(b) Perform all actions necessary to verify whether the *supplies* or services conform to *contract quality requirements;*

(c) Maintain, as part of the performance records of the contract, suitable records reflecting-

(1) The nature of *Government contract quality assurance* actions, including, when appropriate, the number of observations made and the number and type of defects; and

(2) Decisions regarding the acceptability of the *products*, the processes, and the requirements, as well as action to correct defects.

(d) Implement any specific written instructions from the *contracting office;*

(e) Report to the *contracting office* any defects observed in design or technical requirements, including *contract quality requirements*; and

(f) Recommend any changes necessary to the contract, specifications, instructions, or other requirements that will provide more effective operations or eliminate unnecessary costs (see 46.103(c)).

46.105 Contractor responsibilities.

(a) The contractor is responsible for carrying out its obligations under the contract by-

(1) Controlling the quality of *supplies* or services;

(2) Tendering to the Government for *acceptance* only those *supplies* or services that conform to contract requirements;

(3) Ensuring that vendors or suppliers of raw materials, parts, *components*, subassemblies, etc., have an acceptable quality control system; and

(4) Maintaining substantiating evidence, when required by the contract, that the *supplies* or services conform to *contract quality requirements*, and furnishing such information to the Government as required.

(b) The contractor *may* be required to provide and maintain an *inspection* system or program for the control of quality that is acceptable to the Government (see 46.202).

(c) The control of quality by the contractor may relate to, but is not limited to-

(1) Manufacturing processes, to ensure that the product is produced to, and meets, the contract's technical requirements;

(2) Drawings, specifications, and engineering changes, to ensure that manufacturing methods and operations meet the contract's technical requirements;

(3) *Testing* and examination, to ensure that practices and equipment provide the means for optimum evaluation of the characteristics subject to *inspection*;

(4) Reliability and maintainability assessment (life, endurance, and continued readiness);

(5) Fabrication and delivery of *products*, to ensure that only conforming *products* are tendered to the Government;

(6) Technical documentation, including drawings, specifications, handbooks, manuals, and other technical publications;

(7) Preservation, packaging, packing, and marking; and

(8) Procedures and processes for services to ensure that services meet contract performance requirements.

(d) The contractor is responsible for performing all *inspections* and test required by the contract except those specifically reserved for performance by the Government (see 46.201(c)).