

Quality-Significant Procurement Guideline - 2.9.G (08/05/04)

Note: This is an Interim Guideline awaiting DOE/NNSA approval.

[Last Update: \(08/05/30/04\) RShibata:kma - 2.9.G.0](#)

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This guideline was extensively revised to address administrative changes throughout the document.

Definitions

10 CFR 830 Subpart A. The prevailing federal regulation regarding quality processes in a nuclear environment. The two criteria that pertain to procurement processes are:

- Criterion 7 - Performance/Procurement
 - procure items and services that meet established requirements and perform as specified;
 - evaluate and select prospective suppliers on the basis of specified criteria; and
 - establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.
- Criterion 8 – Performance/Inspection and Acceptance Testing

- inspect and test specified items, services; and
- process using established acceptance and performance criteria.

Dedication. Process whereby an item is evaluated by the Requester to determine if pre-established critical characteristics are met and the item(s) can be accepted for a specific Quality-Significant (Q-Sig) application.

Inspection Plan. An internal document that will be used by the Requester to inspect/test upon receipt of the item or during/at completion of the service. Generally, it will not be included in the contract or sent to the Contractor. The Sandia Contracting Representative (SCR) will incorporate appropriate clauses in Section I of the contract in accordance with the Terms and Conditions (Ts&Cs) and Q-Sig clauses.

Price-Anderson Amendments Act. Congress enacted the Price-Anderson Amendments Act in 1957 as an amendment to the Atomic Energy Act of 1954 to encourage the development of the nuclear industry and to ensure prompt and equitable compensation in the event of a nuclear accident. Subsequently, the Price-Anderson Amendments Act (PAAA) of 1988 made three significant changes:

- greatly increased the amount of indemnification;
- made indemnification mandatory in all DOE/NNSA contracts; and
- established a system of civil penalties for DOE/NNSA indemnified Contractors, subcontractors, and suppliers.

Procurement Quality Assurance Representative (PQAR). A person who has the responsibility for managing the Q-Sig infrastructure within Procurement. This individual is the subject matter expert for issues and requests for assistance regarding Q-Sig procurements.

Quality Assurance Representative. A person who is a member of the Quality Assurance Working Group (QAWG) having been selected by the Division Vice President to represent the Division on matters affecting quality and to participate in the implementation of the Corporate Quality Assurance Program.

Quality-Significant (Q-Sig). Relating to the procurement of goods and services where quality aspects are of greater importance due to their potential to harm people, property, and the environment.

Goods and services are Q-Sig if their use will:

- cause a significant adverse impact to program/project cost, schedule, or performance if it fails;
- significantly impact the safe operation of any Sandia facility or activity;
- involve the use, handling, or storage of radioactive material or radiation-generating devices, or involve exposure to ionizing radiation;
- relate to the design, analysis, manufacture, or assembly of hardware, equipment, or software for present or future use with radioactive material; or
- be used in any safety-significant or safety-critical system, component, or application whose failure could adversely affect people, property, or the environment.

Exceptions:

- Q-Sig procurements for staff augmentation personnel may be exempt from Q-Sig procedures as determined appropriate by the Requester. Requester should assess the risk involved in the contracted position and determine whether their internal procedures adequately manage that risk. Specifics of the job to be considered when evaluating risk include: the critical nature of the work, level of supervision, degree of decision-making discretion, inherent hazards, training, education and experience requirements, etc.
- Q-Sig procurements may not apply to activities involving only incidental use (nonscheduled, nonroutine usage, occasional use) and generation of radioactive material or radiation such as check and calibration sources; use of radiation sources in research and experimental and analytical laboratory activities, electron microscopes; and x-ray machines.
- This corporate process requirement does not apply to internal transfers of items when Logistic/Reapplication is not involved. If an item is obtained from Reapplication, it shall not be used in a Q-Sig application. For an internal transfer of critical/hazardous items, the Sandian taking possession should follow the requirements of CPR400.1.1, ES&H Manual, understand how it had previously been used and obtain any necessary pedigree documentation to ensure the transferred item will meet the needs of the Receiving organization.

Quality-Significant Database. Electronic on-line database of Q-Sig information pertaining to evaluated suppliers and dedicated purchases at URL address: https://www-irm.sandia.gov/cgi-bin/sqa/sqa.cgi?submit_button=SQADatabaseQuery.

Supplier Quality Evaluation. Any documentation or supplier quality assessment that gives assurance that the supplier has the capability of producing or manufacturing the goods or providing the service and that the goods/services to be procured will function as intended. Once performed, an evaluation is performed; an evaluation is effective for up to 36 months depending on the Requester's confidence.

Background - 2.9.G.1

This guidance is the mechanism by which the Procurement Center will comply with CPR001.3.2, "Corporate Quality Assurance Program" and DOE/NNSA quality assurance requirements. Compliance with this guidance satisfies the contractual requirement for compliance with DOE O 414.1A and the legal requirement for compliance with 10 CFR 830.120.

Roles and Responsibilities - 2.9.G.2

Roles and responsibilities regarding Q-Sig.

Requester's Role - 2.9.G.2.a

The Requester is responsible for determining Q-Sig applicability. If the procurement is coded Q-Sig, appropriate actions shall be taken by involved persons to comply with the Q-Sig Handbook.

If the procurement is not coded Q-Sig and the assigned SCR agrees with the decision, the action will be placed without regard to Q-Sig procedures.

If the procurement is not coded Q-Sig and the SCR does not agree with the decision, the SCR and the Requester will jointly review and discuss the procurement specification and Statement of Work (SOW) until an agreement is reached (management decision may be required). Should the involved managers not agree on Q-Sig applicability, it will be reviewed and a determination may be required by the Vice President, Business Management/CFO.

Sandia Contracting Representative's Role - 2.9.G.2.b

The SCR must fulfill an integral role in the process. The SCR is responsible for:

- identifying purchase requirements that may require a Q-Sig procurement,
- reviewing Requester documentation to verify that an Inspection Plan has been written,
- working with the Requester to ensure Supplier Evaluation/Dedication is performed, and
- communicating any deficiencies to the Contractor and negotiating a resolution (after receipt and inspection, if applicable).

The SCR must be knowledgeable about the Quality-Significant Procurement Handbook in order to assist the Requester in the process either through direct support of the customer or directing them to the proper subject matter expert or Q-Sig job aid.

Quality-Significant Determination Issues - 2.9.G.3

Q-Sig Applicability - 2.9.G.3.a

SCR should review the SOW to determine Q-Sig applicability. The SCR must review the particulars of the requirement and gain a complete understanding of the Requester's requirements before proceeding. Situations that may occur are presented below.

Situation	Action
• PR is submitted to Procurement and is coded Q-Sig.	SCR proceeds with the acquisition and follows Q-Sig procedures.

<ul style="list-style-type: none"> PR is not coded Q-Sig and appears to involve Q-Sig issues (e.g., SOW indicates that there may be a safety issue--item might present hazardous concerns to individuals or environment). 	<ul style="list-style-type: none"> SCR contacts the Requester to verify whether Q-Sig applicability was considered. Note: If the SCR needs further assistance regarding the Q-Sig Program, they should contact the Procurement Quality Assurance Representative (PQAR). SCR forwards the issue to the Procurement Department Manager who will work with the Requester and their line manager.
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Note: The SCR shall address Q-Sig applicability either in the Procurement Action Summary (PAS) or Procurement Action Documentation (PAD).

Oracle Category Coding - 2.9.G.3.b

Oracle category codes to be used for all Q-Sig requisitions are as follows: Quality-Significant and Mfg.

Processing a Quality-Significant Procurement - 2.9.G.4

The following steps are used in processing a Q-Sig procurement.

Step	Who	Action
1	Requester	<ul style="list-style-type: none"> Determines the method of quality control. Selects one of the following: <ul style="list-style-type: none"> Dedication (most often used), or Supplier Quality Evaluation. Annotates the “Note to Buyer” field with either “Dedication” or Supplier Quality Evaluation.” Ensures that the findings are input into the Q-Sig database if performing a Supplier Quality Evaluation
2	SCR	<ul style="list-style-type: none"> Confirms the item/service description is adequate to enable the Contractor to deliver the intended item/service. Contacts the Requester if more information is required. Checks “Note to Buyer” field to ensure that the Requester has included a

		<p>reference to their Inspection Plan. If no reference is included, contacts the Requester to get their assurance that an Inspection Plan will be created prior to delivery.</p> <ul style="list-style-type: none"> • Includes relevant information/determinations regarding Q-Sig applicability in the PAS/PAD. • Contacts the Radiation Generating Device and Radioactive Source Registrar for approval if nuclear and radioactive material is involved and provides the following information: <ul style="list-style-type: none"> ○ isotope, ○ quantity of material, and ○ Requester name and organization. <p>Note: The Radiation Generating Device and Radioactive Source Registrar will approve or disapprove the purchase and coordinate with other Sandia organizations as required.</p>
3	Requester	<ul style="list-style-type: none"> • Upon receipt, inspects/tests in accordance with the applicable Inspection Plan. Note: For goods/services that fail inspection, the Requester must use the “Return of Deviating/Warranted Material Report” form SF-6891-S. The SCR should resolve noncompliance with the Requester and Contractor. • Completes a Contractor Performance Evaluation form, SF 6432-CPE for Q-Sig order.

Applicable Clauses - 2.9.G.5

- SC 106-REV – Revision to Section II Clauses Due to Price-Anderson Amendments Act
- SC 107-PAA - Price-Anderson Amendments Act (PAAA)
- SC 108-QAP – Quality Assurance Program
- SC 109-QSP – Quality-Significant Purchase

Send feedback on ideas and information on this page to the Process Expert, Randy Shibata.



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