Risk Assessment - QA

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Intent/Outcome/Purpose

To identify, assess, and document risks to quality and technical performance of contracts that require Government Contract Quality Assurance (GCQA) surveillance.

Process

This instruction contains managers' internal control provisions that are subject to evaluation and testing as required by DCMA-FBP Manager's Internal Control Program Instruction.

NOTE: This instruction may not apply to Safety of Flight (SOF), Navy Special Emphasis Programs (NSEP), and mandated surveillance requirements identified in National Aeronautics and Space Administration (NASA) delegation. These processes are controlled by their respective instructions; SOF, NSEP, and NASA instructions. In a Host Nation environment, risk assessments shall be performed and documented in accordance with the International Agreements / International Memorandum Of Understanding / Host Nation Contract Management Services instruction.

1. Quality Assurance (QA) Personnel Develop Risk Profile - Risk Assessment results in the development, modification, or validation of a Risk Profile. **QA personnel shall develop and document the Risk Profile portion of the** Risk Profile and Plan**.** The Risk Profile provides the minimum documentation of the applicability of specific risk factors and documents the relationship between risk factors and planned GCQA surveillance activities. The profile provides easily retrievable objective evidence to rationalize decreasing or increasing the GCQA surveillance efforts. For subcontractors with Letters of Delegation (LOD) to only verify or witness specific tasks, a risk profile is not required. For Quality Assurance Letters of Instruction (QALI) or LODs containing a mixture of specific mandatory surveillance requirements and more general identification of risks or surveillance activity, the mandatory aspects do not need to be risk assessed. **If QALI requirements are believed to be excessive or vague, QA personnel shall inform the customer and recommend alternative surveillance strategies, supported by performance data and/or analysis. If the CMO determines a customer QALI should be rejected, the CMO shall obtain approval for the rejection from the applicable Operational Directorate (Operations, International or Special Programs).**

1.1. The risk profile may be used on a facility-wide basis (covering all supplier contracts), a program, product/ product line, or when appropriate on a contract by contract basis. Examples of situations under which contract by contract risk profiles may be appropriate include:

- Suppliers that normally go months between contracts
- A supplier that is awarded a single contract markedly different from its other workload

1.2. A risk profile has six areas to be addressed during the risk assessment process. The Risk Profile and Plan Tool includes all six areas, as follows:

- Facility Process List
- Risk Impact (Risk Statement Generator)
- Risk Statement(s) (Risk Profile and Plan)
- Performance Factors Assessment
- Risk Causes (Risk Profile and Plan)
- Risk Likelihood Assessment (Risk Profile and Plan)

2. QA Personnel Develop/Update the Facility Process List - This is a list (or flowchart) of supplier processes, including special processes the supplier uses to design, produce, and deliver the contracted supplies and/or services. **The facility process list shall be a part of the risk profile.** The Facility Process List may be developed using an end-to-end review of the flow of product and data through the supplier's facility. The preferred method for this end-to-end review is to begin at packaging and shipping processes and then working backwards through all of the processes to the initial contract planning process. For suppliers operating under a formal Quality Management System (QMS), the process list may identify the QMS as a whole, break out individual clauses, or any combination as needed.

3. QA Personnel Identify Risk - **QA personnel shall review all available risk information to identify potential risks and develop/update a risk profile.** The results of contract review provide QA personnel a sound basis to identify potential risks from both an impact and likelihood perspective when assessed in conjunction with other risk information. Other sources of risk information include but are not limited to:

- Customer Feedback, including QALIs & Product Quality Deficiency Reports (PQDRs)
- Pre-Award Survey results
- Critical Characteristics
- Critical Processes

- Contract or purchase order
- Memorandum of Agreement (MOA), QALI or LOD
- Drawings
- Specifications
- Quality data and performance history

3.1. QA Personnel Perform Risk Impact Assessment **-** Risk impact is the consequence of an uncertain event or condition occurring. **QA personnel shall perform a risk impact assessment.** The assessment consists of reviewing identified risk impact indicators on the **Risk Statement Generator** and making a determination of the applicability of each indicator to the contract, supplier, or product/service. **QA personnel shall use the Risk Statement Generator to develop risk statements and shall document those statements and their associated risk impact rating (High, Moderate, or Low) on the Risk Profile and Plan.** Risk statements answer the question, "What do we want to make sure doesn't happen?" The **Risk Statement Generator** contains the minimum indicators associated with conditions or circumstances that would typically indicate a higher impact or consequence should the risk statement occur.

3.1.1. Identified risks should include the risk of nonconforming raw materials and processes that impact material properties. See additional raw material guidance.

3.1.2. Identify risks associated with special processes. Question #10 on the **Risk Statement Generator**is where special processes fit in the risk impact assessment. A typical risk statement may be "Supplier fails to control process requirements resulting in nonconforming product being accepted by the Government.**"** (See Information Memorandum 10-294 (Archived) in the Additional Tools and Guidance section for further information)

3.1.3**.** Identify risks associated with suspect counterfeit parts. Question #11 on the Risk Statement Generator is where counterfeit parts may be considered during the risk impact assessment. (Reference: Q-Tips 11-011 and 12-001). A typical risk statement may be "Supplier fails to prevent counterfeit parts from being presented to the Government for acceptance."

3.1.4. Risk statements can be expressed in general terms such as "Supplier fails to deliver conforming items," or in specific terms such as "Supplier fails to control Critical Safety Item (CSI) critical characteristics / processes."

3.1.5. **If none of the 15 questions in the Risk Statement Generator apply, QA personnel shall use "Supplier fails to deliver conforming items" as the risk statement and identify the risk as "Low" for impact.**

3.1.6. On program acquisitions, customer coordination may provide program specific risk statements. For example, a risk statement addressing a specific milestone or event.

3.1.7. The risk impact assessment should not be repeated for each contract unless new requirements would require an additional risk statement on the Risk Statement Generator.

4. QA Personnel Identify Risk Causes – Risk causes are the potential reasons why a risk statement will occur. The cause is expressed in terms of a manufacturing, inspection or test process, product characteristic, QMS clause, or other contractual requirement that if not controlled might allow the risk to occur. Risk causes require GCQA surveillance appropriate to the likelihood of occurrence. **QA personnel shall identify and document risk causes in the Risk Causes Column of the Risk Profile and Plan**.

4.1. QA Personnel Complete the Appropriate Performance Factors Assessment **-** The performance factors are designed to determine the risk causes. There are two Performance Factors Assessment forms, one for all suppliers, which also contain the requirements of the Standard Inspection checklist, and one with additional factors for suppliers with higher-level quality requirements. These forms contain the minimum risk factors to be addressed during this assessment. The assessment consists of a review of identified risk performance factors, making a determination of the applicability to the supplier, and identifying processes with performance problems that may be considered risk causes. **QA personnel shall complete the appropriate** Performance Factors Assessment, **using the results of data analysis (Data Collection and Analysis) as a key component for this assessment.**

4.1.1. The factors are in the form of questions associated with the supplier's experience and performance history that would typically indicate a higher likelihood of that risk statement occurring. The performance factors address the supplier's demonstrated satisfactory accomplishment and control associated with the Quality Management System, Inspection practices, and manufacturing capabilities. In some cases the applicability of the factor is unknown and may be recorded as such.

4.1.2. The Supplier Risk System (SRS) provides a number of data elements that are referred to in the "Negative Factor" section of the Performance Factors (PQDRs, Corrective Action Requests (CARs), Negative Preaward Survey Results (PAS) results, Delinquent schedules). These occurrences are then calculated to create the Supplier's Risk Indicators. **SRS shall be reviewed for the Supplier's current risk indicators.**

4.1.3. **QA personnel shall review risk performance factors that indicate a negative condition against each applicable risk statement to determine risk causes**. **Once identified, risk factors that represent negative conditions shall be explained and documented on the Performance Factor Assessment to assist in risk cause identification.**

4.1.4. The performance factors identified on the Performance Factors Assessment may be revised to align with Agency priorities.

4.2. Identify Risk Causes From the Facility Process List - **Those supplier processes that if uncontrolled would result in the risk statement occurring shall be identified as risk causes and shall be documented on the Risk Causes column of the Risk Profile and Plan**. **In a Standard Inspection environment with the default risk statement and no negative performance factors the risk causes shall include as a minimum: the supplier's inspection and testing processes and any special processes**.

5. QA Personnel Determine the Likelihood of Occurrence - The more likely the risk cause is to occur, the more likely the risk statement is to occur. **The results of the Performance Factor Assessment, associated data analysis, and the table below shall serve as the basis for likelihood ratings. The likelihood rating shall be supported by relevant data.** Scenarios where there is no data available to show the supplier's ability to meet requirements may typically be limited to new suppliers or new processes for which there is no history. **QA personnel shall determine the likelihood ratings for each risk cause and shall document these ratings in the Risk Profile and Plan.**

Risk Cause Likelihood	How Likely is the Risk Cause to Occur?

High	It is highly likely to occur.
	Performance data shows evidence of an inability to meet the contractual requirements.
	The process is extremely difficult to perform.
Moderate	It is probable or likely to occur.
	No data available to show the supplier's ability to meet contractual requirements.
	The process is somewhat difficult to perform.
Low	It is unlikely that the risk will occur.
	Performance data shows evidence that the contractual requirements will be met.
	It is a common process and not difficult to perform.

6. QA Personnel Use Risk Assessment Results in GCQA Surveillance Planning **- QA personnel shall use the information and output of this process to complete and document a GCQA surveillance plan in accordance with the GCQA Surveillance Planning instruction.** The purpose of GCQA surveillance is to reduce the likelihood of the risk cause and to serve as the basis of confidence to accept the product or service. As GCQA surveillance is performed, the risk information should mature and the risk knowledge should increase. **The risk profile shall be kept current while there are active contracts with the supplier. As risk events or changes in performance occur, determined through data analysis, receipt of customer complaints, or CARs, impact and likelihood ratings shall be reevaluated and updated, as applicable. However, as a minimum, the risk profile shall be reevaluated and updated, as applicable, on an annual basis.**

Competencies/Certifications

Competency and Certification requirements for all QA personnel are addressed in the QA Development instruction and the Training Competency Assessment Tool (TCAT).

Training Matrix

Risk Assessment - QA Training Matrix

What TASKS are required to accomplish this process?	Methods of training						
	On-the-Job Training (OJT)	Computer Based Training (CBT)	Course (Commercial, College/ Vocational)	Contractor Sponsored Training	Guidebooks	DCMA Developed	Administrative Task (The task is wholly enabled by the contents of the instruction and requires no training intervention)
Task 1 – Develop Risk Profile						QUAL 101-201	
Task 2 - Develop facility process list						QUAL 101-201	
Task 3 - Perform Risk Impact Assessment						QUAL 101-201	
Task 4 - Identify Risk Causes						QUAL 101-201	
Task 5 - Perform Risk Likelihood Assessment						QUAL 101-201	

Task 6: Document Risk Profile and Plan	QUAL 101-201

Higher Level Regulatory Documents

- FAR 42.302(38), Contract Administration Functions
- FAR 46.202-4, Higher Level Quality Requirements
- FAR 46.402, Government Contract Quality Assurance at Source
- FAR 52.246-2 through FAR 52.246-9, Inspection Requirements
- FAR 52.246-11, Higher Level Quality Requirements

Performance Standards

- **Process Indicator/s:**
  - QA Surveillance Plans
- **Workload Indicator/s:**
  - TBD
- **Resource Indicator/s:**
  - TBD
- **Supplier Indicator/s:**
  - QA - Most Active Suppliers

PLAS

- PLAS Process code: 085B

Tools & Additional Guidance

- Risk Profile and Plan
- Risk Assessment Flowchart
- Information Memo 10-294 (Archived), Risk Assessment of Special Processes

Successful Practices

None to date

Portal/Community of Practice

Quality Assurance Sub Community (This is a sub community of the QA Portal)

Points of Contact (POC)

DCMA Instruction Point of Contact information is not available to the general public.

DCMA employees please click here for the process POC's