ASME QPS-1-2021

Quality Program for Suppliers: A Quality Program Standard for General Industry

Gap Analysis – Audit check list

Material Suppliers

March 23, 2021

	2-1 Quality Program			
	In the space provided below, detail the objective evidence (documentation reviewed, records reviewed, and personnel interviewed) to ensure conformance with QMS requirements. Detail any discrepancies / nonconformances identified.			
	Requirement:		**Objective Evidence/Comments:**	**Finding #:**
	2-1.1 General			
		Has the organization established, documented, implemented and maintains a Quality Program for all products and services provided in accordance with ASME QPS-1?		
		Does a Quality System Program exist?		
		Is this program documented?		

		Is the program planned, implemented and maintained?		
	2-1.2 Quality Manual or equivalent Quality Document			
		Is the manual in a controlled/uncontrolled condition?		
		Is the program supported by procedures?		
		Are technical aspects considered?		
		Are special controls / equipment being considered?		
		Are quality-check methods described?		
		2-1.3 Delegation of Duty		
		Is there a procedure for delegation of roles and responsibilities for the activities?		
		2-1.4 Authorized Personnel		
		Is there a documented procedure for defining Authorization at each significant level or function?		
		Is there a documented procedure that demonstrates that all employees are aware of their impact on product quality and the importance of their activity in achieving and maintaining and improving quality including risks related to non-compliance with customer requirements?		
		Is there a documented procedure for identifying training needs, including awareness to achieve the competence of personnel involved in activities that affect compliance with product or process requirements?		

2-2 ORGANIZATION

			Requirement:	Objective Evidence/Comments:	Finding #:
		2-2.1 General			
			Has been identified the person of the organization's Management Representative and roles / responsibilities.?		
			Has the authority, responsibility, delegation and escalation of technical / quality personnel been defined regarding all activities that affect the quality of the product?		
		2-2.2 Credentialed Personnel			
			Is there a documented procedure for identifying the necessary credentials of the personnel involved in the activities described in the technical job file?		
			Is employee credential/certification maintained where the quality outcome of process cannot be verified and it strongly dependent upon operator competence?		
			Are suitable records of maintained?		
		2-2.3 Competency Requirements –Quality Manager			
			Have the requirements of competence, experience in the function for the role of **quality manager** been defined as prescribed by the quality program?		
			Did the quality manager participate in the ASME QSP-1 standard course obtaining the credential?		
		2-2.4 Competency Requirements –Technical Manager			
			Have the requirements of competence, experience knowledge in the function for the role of technical manager been defined as prescribed by the quality program?		
		2-2.5 Assessment of Resources By Executive Management			
			Has the organization established, implemented and maintained a documented procedure to identify the methods of monitoring, measuring, analyzing and evaluating resources necessary to guarantee the performance and effectiveness of the quality system?		
			Has the periodicity for the analysis of the results obtained from monitoring and measurement of the adopted quality system been defined?		
			all the resources arising from the planned management review were systematically analyzed and implemented?		
			Have the **training and education needs** of the personnel been analyzed during the periodic management review in relation to the results of the monitoring of production processes?		

		2-3 DOCUMENT CONTROL			
		Requirement:		**Objective Evidence/Comments:**	**Finding #:**
		2-3.1 General			
			Is there a documented procedure that defines the preparation, approval and issuance and modification of **quality documents or that affect product quality**?		
			how are documents of external origin verified to ensure that relevant versions are used and maintained?		
			How obsolete documents are identified and removed to ensure against unintended use?		
			How does the organization ensure integration of external documents into the product realization process or any other affected process?		
		2-3.2 Competency Matrix			
			Have the requirements of competence, experience knowledge been defined as prescribed by the quality program?		
		2-3.3 Access to Controlled Documents			
			How is the documented information required by the quality program checked to ensure availability for use where and when it is needed?		
			how is the documented information required by the quality program adequately protected?		
			Has the organization prepared the following activities on documented information? - distribution, access, recovery, use - conservation and readability - management of change - availability		

			2-4 TECHNICAL JOB FILE REQUIREMENTS		
			Requirement:	**Objective Evidence/Comments:**	**Finding #:**
		2-4.1 General			
			Is the scope of work clearly defined?		
		2-4.2 Preparation, Review and Approval of Technical Job Files			
			Have the following points been considered in the definition of the technical job? - Melting practice? - heat analysis? - mechanical properties? - Certification of material specification? - Testing, examination, repair required by the material specification. Included certifications - Dimensional requirements? - Handling, storage methods?		
			How is the technical job file checked to **ensure availability** for use where and when it is needed?		
			In the technical job file are defined the **processes in which credential personnel is required**?		
			Is the technical job file reviewed by **competent personnel** who have access to the latest applicable documentation?		
			Are responsibilities for the technical job file preparation, review and approval identified based on competency?		

			2-5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS		
			Requirement:	**Objective Evidence/Comments:**	**Finding #:**
		2-5.1 General			
			is there documented information that describes the activities/processes that have a qualitative impact on the product? As (where applicable): - Procedures - Work instructions - Technical / functional drawing - Acceptance criteria - Sampling methods - Quality plans		
		2-5.2 Preparation, Review and Approving for Use			
			Are responsibilities for the preparation, review and approval of these documented information identified based on competency?		

		2-6 PROCUREMENT DOCUMENT CONTROL			
		Requirement:		**Objective Evidence/Comments:**	**Finding #:**
		2-6.1 General			
			Has the organization established, implemented and maintained a procedure for managing orders to approved suppliers?		
			Does the organization **communicates through documented information** to suppliers the requirements for: - processes and products to be supplied - criteria for the approval of methods, processes and equipment - releases of products and services - competence and credential of personnel - control and monitoring of supplier performance - verification or validation activities to be carried out at the supplier		
		2-6.2 Preparation, Review and Approval for Release of Purchase Orders			
			Does the organization communicate through documented information to external suppliers the criteria for the **acceptance of products** and services?		
			Is the purchase documentation checked before issuing by competent personnel to confirm compliance with the requirements of the technical job file requirements?		
			Are responsibilities for the preparation, review and approval of these documented information identified based on competency?		

2-7 CONTROL OF PROCURED PRODUCTS

		Requirement:	Objective Evidence/Comments:	Finding #:
		2-7.1 General		
		Has the organization restricted the procurement of products or processes following categories: approved suppliers, suppliers indicated by the customer, customer as a supplier?		
		Are the purchase from unapproved suppliers prevented by a properly control?		
		2-7.2 Procurement of Product from an Approved Supplier		
		Has the organization implemented a procedure for; - select the types and extent of controls. - acceptance criteria - identification of materials - handling of products - storage of products		
		2-7.3 Procurement of Product from a Supplier Specified by The Customer		
		if the customer requires a **specific supplier** for the supply of products or processes, does the organization use the same methods identified in point 2-7.2, whichever is the applicable?		
		2-7.4 Customer Supplied Product		
		in case the customer supplies products or processes, does the organization use the same methods identified in point 2-7.2?		
		2-7.5 Approved Supplier Evaluation		
		Has the organization determined a procedure for **evaluation, selection, performance monitoring and re-evaluation of suppliers**, based on the ability to provide processes or products and services in accordance with the requirements? and based on one of the **following tasks**:		
		presence of an ASME certificate in accordance with the requirements		
		verification and acceptance of objective evidence of the quality of the products and services provided, by competent and authorized personnel for the evaluation		
		Does audit results carried out on supplier management system by appointed, competent and certified personnel?		
		Analysis of previous performances carried out by competent and authorized personnel as: -inspections at the supplier -surveillance at the supplier -quality of the products supplied -time to delivery		
		2-7.6 Source Documentation Package		
		Is there evidence that all material certifications, process certifications and certifications of compliance are supplied with the materials are traceable? (i.e batch number, heat codes..)		

		2-7.7 Supplier Performance Management			
			Has the organization included in his audit program schedule, audit process and audit product at the supplier?		
			Has the organization determined, based on the risks, the performance of the supplier, the certifications obtained, and the organizational level, **the criteria on the need, the type and frequency of audits?**		
			Is the system, process or product audit carried out at the supplier's premises performed by **authorized personnel** of the organization?		
			Are the reports of these audits kept and maintained by the organization?		
			Are the personnel performing **quality management system audits** at the supplier premises (second type) identified in the competence matrix?		
			Has the organization determined, based on the risks, the performance of the supplier, the certifications obtained, and the organizational level, the criteria on the need, type and frequency of audits?		
			Are the personnel performing an process inspection/ surveillance activity at the supplier premises identified in the competency matrix?		
			Are the personnel performing **product** inspection/ test activity at the supplier premises identified in the competency matrix?		
		2-7.8 Receiving Inspection			
			Have **the responsibilities for the control** of incoming material been defined in procedures and instructions?		
			Is inspected material **adequately identified** as to acceptance or rejection and traceable to receiving inspection report?		
			Does the organization have a documented procedure to ensure that the processes, products and services purchased **comply with the current legal requirements** applicable in the country of receipt, in the country of dispatch and in the country of destination identified by the customer?		
			Does the **organization keep documented information** of these activities and all necessary actions resulting from the assessments?		

2-8 CONTROL AND IDENTIFICATION OF PRODUCTS

		Requirement:		Objective Evidence/Comments:	Finding #:
			Has the organization planned, documented and implemented **control plans** to verify compliance with the requirements, for each subsystem, component and / or production material and all externally sourced products and services throughout the production processes?		
			Are appropriate **work instructions** available where needed that accurately describe all work methods including inspections and tests to be done during production?		
			Are parts correctly identified throughout the entire processing route, including storage?		
			Is there a technique defined to check for unidentified material, containers, loose parts etc in the facility?		
			Is a **batch traveller (or route card) utilized** and does it clearly define all processing and inspection steps for each product lot as it progresses through manufacturing and test?		
			Does this card reflect the **sequence of manufacture**?		
			Are there procedures and practices to prevent contamination or degradation of parts from dust, oil, hazardous substances or other environmental contaminants?		
			Is **traceability** of critical and significant characteristics assured?		
			Are record retention periods in accordance with client, standard and regulatory requirements implemented and followed?		
			Are raw material and parts identified to allow traceability to the subcontractor's process?		
			does the organization determine and implement the identification of **non-conform** or suspect products?		
			Is the process for identification and handling of reworked material documented and followed?		

2-9 CONTROL OF PROCESSES

		Requirement:		Objective Evidence/Comments:	Finding #:
		2-9.1 General			
			Have the processes that influence the quality of the product been **defined** and have the **competent personnel** involved in these processes been identified?		
			Are written improvement plans are implemented to **reduce sources of variation**?		
		2-9.2 Identifying and Controlling a Special Process			
			Has the organization **identified** the special processes?		
			Are the personnel carrying out special processes **formally trained** and in possession of credentials?		
			Is there a documented, up-to-date training/certification plan for these personnel?		
			Is the responsibility for executing / verifying these plans defined?		
			the skills of the personnel performing special processes comply with all the requirements of the competence matrix?		
		2-9.3 Planned Maintenance			
			Does the organization determine and implement a **documented maintenance system**?		
			Are the process **equipment** to make a product that meets the requirements **identified**?		
			Is the preventive maintenance schedule is followed since product cannot be made with tools that are **outside of maintenance period**?		
			Are **periodic maintenance activities** established, implemented and documented?		
			Are the **resources required** for periodic maintenance established?		
			Are the **personnel involved** in periodic maintenance and repairs competent and identified and have the necessary skills?		
			if the periodic maintenance and repair **service is outsourced**, has the supplier been approved in accordance with what is specified in par 2-7.5?		
			Is the **documentation relating to periodic maintenance** and repairs kept and the responsibilities and storage period defined?		

2-10 INSPECTIONS AND TESTS

			Requirement:	Objective Evidence/Comments:	Finding #:
		2-10.1 General			
			Have **control and inspection plans (or equivalent documents)** been established, implemented, documented, and maintained to ensure compliance with present standard and technical job file requirements?		
			Control plans or inspection instructions, compliant with update technical job file requirements?		
			Is all required inspection and test equipment **available and adequate** for the relevant standard of technical job file requirements?		
			Are all required inspection, test equipment and fixtures **within the calibration system**?		
			In the case of verification of products manufactured in batches, lots, heats have sampling methods been implemented, documented and maintained for the control of conformity?		
		2-10.2 Inspections			
			Has the organization planned and implemented inspections during each job phase to verify **compliance with requirements**, where applicable?		
			Has the organization defined, implemented, and documented through the technical personnel in charge the type, methods and extent of inspections and defined the related characteristics to be inspected?		
			Are the responsibilities and authorities of the personnel who carry out, document and evaluate the results of the inspections defined?		
		2-10.3 Tests			
			Has the organization planned and implemented tests during each job phase to verify compliance with requirements, where applicable?		
			Has the organization defined, implemented, and documented through the technical personnel in charge the type, methods and extent of tests and defined the related characteristics to be tested?		
			Are the responsibilities and authorities of the personnel who carry out, document and evaluate the results of the tests defined?		
		2-10.4 Testing Laboratory			
			Does the organization for test carried out externally, use laboratories on the **list of approved suppliers**?		

			Is it verified for ISO 17025 accredited laboratories that **the accreditation scope** is in accordance with the tests specification to be performed, not expired, withdrawn or suspended?		
			For non-accredited laboratories, the quality manager carried **out periodic audits** to confirm the supplier's ability to comply with the criteria of ISO 17025?		
			Has the **customer's approv**al been requested in the case of using a non-accredited laboratory?		
		2-10.5 Inspection and Test Status Indicators			
			Has the organization ensured that all records that provide evidence that the work has passed/ not pass specific acceptance criteria for inspections and /or tests, are maintained, identified on the product or traceable?		
			Has the organization established and implemented documented information to ensure immediate identification and removal from use of any equipment, product, tooling and machinery found to be non-compliant? As: -Has failed in operation in any parameter -Shows evidence of physical damage -Is suspect for any reason -Has not been calibrated in acc with the established time scale -ect		
			Have methods been defined and implemented to identify the status of inspections and tests on the product, by using markings, authorized stamps, tags, labels, routing cards, inspection records, physical location, barcode, quick response (QR), frequency identification (RFID) or other suitable means which indicate the conformance or nonconformance of work performed?		
133		2-10.6 Competency Requirements – Inspection and Test Personnel, Production and Quality Personnel			
			Has the organization defined the responsibility and authority of the personnel assigned to controls during all stages of production, the final release of the product and inspections /tests?		
			Have the responsibilities and authorities been defined on the matrix of competences?		
			Has the organization identified and established procedures for assessing personnel to inspection and test activities (including instrumentation and equipment) based on their skills, experience and knowledge?		
			Has the organization identified on the competence matrix the personnel assigned to the inspection and test activities in possession of the credentials, considering the type of credentials and the organization that issued the credentials?		
			Has the organization identified and established procedures for the maintenance and proficiency of personnel credentials?		
			Have the personnel with credentials assigned to non-destructive testing activity been listed in the matrix of competence?		

2-11 CONTROL OF MEASURING AND TESTING EQUIPMENT

		Requirement:		Objective Evidence/Comments:	Finding #:
		2-11.1 General			
			Are measuring devices, gauges routinely calibrated and controlled per documented procedures?		
			Have the control periodicity and **acceptability criteria been identified** in the instrument management system?		
			Is the documentation relating to **periodic calibration** kept and the responsibilities and storage period defined?		
			Are appropriate controls in place to verify the suitability and accuracy of **computer software** prior to initial use in checking product quality or control of processes?		
			Is there a formal method use to qualify **new o rebuilt** quality devices or test equipment prior to use?		
		2-11.2 Calibration of Measuring and Testing Equipment			
			Are gauges and calibrated against standards traceable to a recognized regulatory body or agency?		
			Has the person responsible for internal calibrations been appointed based on competence, knowledge and experience (at least ISO 17025)?		
			Has the personnel who internally calibrates the instrumentation that affects the quality of the product or process been identified and has the necessary competence and training?		
		2-11.3 Calibration Laboratory			
			Does the organization for calibration carried out externally, use laboratories on the list of approved suppliers?		
			is it verified for ISO 17025 accredited laboratories that the accreditation scope is in accordance with the calibrations to be performed, not expired, withdrawn or suspended?		
			For non-accredited laboratories, the quality manager carried out periodic audits to confirm the supplier's ability to comply with the criteria of ISO 17025?		
			Has the **customer's approv**al been requested in the case of using a non-accredited laboratory?		
		2-11.4 Calibration Status Indicators			
			Is each item of inspection, test, measuring equipment and fixtures correctly and uniquely identified (including next calibration date) within the calibration system?		
			Has his status been **identified**?		
			Is these information present on the instrumentation?		
			Is all measuring and test equipment in **good working order**?		
		2-11.5 Discrepancies in Measuring and Testing Equipment			
			Is assessment made to check the validity of previous measurements done on products where **out-of-calibration measuring devices** were used? -the previous measurement results obtained with this device are verified and stored -the customer is notified in case of shipment of the products		

			-products measured with this instrument are considered as non-conform -corrective actions are open		

		2-12 HANDLING, STORAGE, AND SHIPPING			
		Requirement:		**Objective Evidence/Comments:**	**Finding #:**
			Has the organization **established specification** for handling, storage, cleaning, packing, shipping and preservation to ensure product or equipment compliance? Are **readily accessible**?		
			Do these documentations **clearly identify the responsibility**?		
			Are these specifications **reviewed on a regular basis**?		
			Is proper equipment and methods used to prevent product damage or loss in all phases of the **material handling**?		
			Are **areas around the facility** clean and orderly and are tools and equipment properly stored and readily for use and is lighting and air quality are adequate?		
			Are the **packaging materials adequately** protected against deterioration before use?		
			Is stored product/material and equipment **periodically inspected**, and where applicable, actions are taken to prevent deterioration per documented procedures?		
			Does the organization consider the **obsolete product**, begun not in compliance with original requirements, as a non-conformity product?		

		2-13 CONTROL OF NONCONFORMITY			
		Requirement:		**Objective Evidence/Comments:**	**Finding #:**
		2-13.1 General			
			Has the organization established a documented management procedure and responsibility for non-conformity product or process results based on: - identification - Correction - Segregation, containment, return or suspension of the supply - Customer information - Obtaining the concession authorization		
		2-13.2 Nonconformity Status Indicators			
			Has the personnel authorized to carry out the actions provided for in point 2-13.1 been identified?		
		2-13.3 Dispositioning of Nonconformities			
			Has the **authorized personnel** promote, carry out, provide corrective actions?		
			Has quality personnel established and implemented **containment actions** and effective where necessary?		
			Is **product traceability maintained** to facilitate problem evaluation and corrective action?		
			Is the **use of nonconforming material** documented under a formal waiver or concession system?		
			Is there a positive recall system to **notify customers** of nonconforming product that already been shipped?		
			Have **escalation procedures** been established in case of conflict for the resolution of non-conformities?		
		2-13.4 Customer Complaints			
			Is there an effective method used to process parts which have been rejected and returned by the customer such that root cause analysis and corrective actions? (as 2-13)?		
		2-13.5 Competency Requirements - Dispositioning of Nonconformities			
			Has competent personnel to evaluate customer complaints or non-conformity, been identified?		

		2-14 CORRECTIONS AND CORRECTIVE ACTION			
		Requirement:		**Objective Evidence/Comments:**	**Finding #:**
		2-14.1 General			
			Does the organization have a documented procedure that ensures that outputs that do not comply with their requirements are identified and controlled to prevent their use or involuntary delivery?		
			Has the organization established documented actions to eliminate the causes of product or process non-conformity? As -Reviewing and classification of non-conformities -Determining cause of nonconformities -Evaluation action to prevent recurrence -Determining or implementing action needed -Recording of results -Reviewing corrective action taken for effectiveness		
			in the case of significant non-conformities that require corrective actions, have responsibilities and implementation times been established?		
			Have criteria been established for reviewing the corrective actions and evaluating their effectiveness?		

		2-15 MONITORING OF PROCESSES			
		Requirement:		**Objective Evidence/Comments:**	**Finding #:**
		2-15.1 General			
			Has the organization established, implemented and maintained a periodic monitoring by the process / department owners whose results are documented in the management review? Included: a) the safety culture b) the adequacy of the resources and environmental and safety conditions required to fulfill their duties and responsibilities, including those for the personnel they manage. c) performance of suppliers that are internal and external to the Certificate Holder. d) the nonconformities and corrective actions to determine the effectiveness of the corrective actions to prevent recurrences. e) the processes and the quality of work		
		2-15.2 Internal Audits			
			The organization has established, documented, implemented and maintained an **audit program** that includes the frequency, methods, responsibilities, planning requirements and reporting as a function of production processes, changes affecting the organization and the results of previous audits?		
			has the organization conducted **internal audits** at scheduled intervals to provide information on the quality management system so that? -the system complies with the requirements of the quality management system -the system complies with the requirements of QSP-1 -it is effectively implemented and maintained		
		2-15.3 Competency Requirements –Internal Auditors and Auditors			
			Are the personnel carrying out internal Audit formally trained and competent?		
			Are personnel in charge of internal audits certified as lead auditors or do they perform their duties under the direction of a certified lead auditor?		
			Does executive management guarantee and monitor compliance with the impartiality of the audit /audit process, in accordance with the policy and the responsibilities of each function?		
			Are the personnel carrying out second type Audit formally trained and competent?		
			Have the minimum competence requirements for the personnel assigned to carry out internal and second part audits been defined and respected?		
			Are audit assignments made on the basis of defined requirements and the matrix competence?		
		2-15.4 Procurement of Auditing Services			
			if the auditing service is carried out by an external supplier, does the organization use approved suppliers?		
			Does the supplier's personnel responsible for carrying out the audits meet the requirements as set out in point 2-5.3?		

		2-15.5 Executive Management Review of the Quality Program			
			Does the organization review the quality management system **at planned intervals** to ensure its continued suitability, adequacy, effectiveness and alignment with the management's strategic direction?		
			Has responsibility been established for preparing the executive management review containing at least the following information? 1) results of the monitoring activities performed by department managers 2) feedback from customer surveys or input from sales personnel 3) audit reports of suppliers 4) internal audit reports of the quality program 5) trending analysis of nonconformities and corrective actions 6) a review current resource levels		
			in the execute management review outputs, have all the previous points been addressed and described?		
			In the conclusions of the executive management review, have the following aspects been addressed and evaluated?		
			existence of a healthy company culture for quality and safety		
			existence of a knowledgeable and competent workforce		
			suitability, adequacy, and effectiveness of its quality program to correctly process a customer's agreement or product specification into realization of a conforming product		
			suitability of current resource levels or need for recruitment or additional training of existing personnel		

		2-16 CONTROL OF RECORDS			
		Requirement:		**Objective Evidence/Comments:**	**Finding #:**
		2-16.1 General			
			Has the organization defined and documented a record retention policy?		
			Does the organization have a documented process that describes the distribution, implementation of all customer standards / specifications and related reviews?		
			Does the organization identify, store, protect, retain, retrieve, and dispose of records?		
		2-16.2 Documents Retained as a Record			
			Does the organization control the documents required by **products** to ensure that the relevant versions are used and maintained?		
			Does the organization control the documents required by **the quality system** to ensure that the relevant versions are used and maintained?		
		2-16.3 Record Retention			
			Does registration control meet legal, regulatory, organizational and customer requirements?		

		2-17 CERTIFICATION STATEMENT			
		Requirement:		**Objective Evidence/Comments:**	**Finding #:**
		2-17.1 General			
			Does the **certificate of conformity** accompanying the finished product, made in accordance with the quality program certified by ASME, identify the quality *Program Supplier Certificate* number and his expiry date and the edition, revision and issue date of the organization Quality Manual or equivalent Quality Document?		
		2-17.2 Use of ASME Certificate to Identify Products			
			Does the Quality Manual or equivalent Quality Document contain **a declaration** that the certificate of conformity described in the previous point that accompanies the product confirm that all products have been made in according to all the requirements of the QPS-1 standard and the technical job file generated from original source document?		
			Does the Quality Manual or equivalent Quality Document contains a **declaration of responsibility** that the products manufactured comply with all the requirements of the QPS-1 standard implemented in its quality system certified by ASME?		
			Has the certificate of conformity been signed by the quality manager?		
			Have product conformity checks been carried out and documented before release to confirm compliance with the requirements of the technical job file and the requirements of the quality program suppler certificate?		
			Have the functions that are authorized to sign the certificate been identified in the absence of the quality manager?		
			Have the responsibilities and methodologies for communicating changes in the quality manager of the certified organization to ASME been defined?		