

# BOEING QMS 001 Checklist

Boeing Representative/Auditor:

Survey Date:

Company Name:

Boeing Supplier Code #:

Active work? yes ☐ no ☐

## (001) Basic Processor Quality System for D1-4426

Issue: November 2018

Change summary: Added Note 1 to section 8.7.6.

### 1. Scope

This audit criteria is to be used to verify compliance with Boeing Quality System requirements in conjunction with another Special Process commodity audit. Upon satisfactory completion of both this audit and the commodity audit approval to Boeing QMS 001 will be granted.

No sections can be excluded from this checklist; all questions must be answered.

The scope of this checklist does not include quality system requirements for design and development. If the facility is responsible for design, AS/EN/JISQ 9100 or AS/EN 9110 accreditation may be required.

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## 2. GENERAL INSTRUCTIONS

### 2.1 Auditor Instructions

In completing this assessment, auditors are instructed to respond with a YES or NO to address compliance with each statement of requirement. For any negative responses, the auditor must clearly indicate if the NO reflects noncompliance with respect to existence, adequacy, and/or compliance, where existence relates to the lack of evidence of a documented procedure or policy, adequacy relates to the lack of completeness of the procedure or policy, and compliance relates to the lack of evidence of effective implementation.

“NOTES” are included from the AS/EN/JISQ 9100 Standard.

“Audit Notes” are guidance on the use of the not-applicable (NA) response.

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All negative responses require a non-conformance (NCR) or explanation. All NA responses must be explained.

For any NCR that requires special attention or is of concern, a note shall be placed in the Auditor notes field.

The audit report should not include any customer proprietary information.

At the conclusion of the audit, a copy of the audit findings shall be provided to the organization.

### 2.2 Instructions for the Organization

#### Prior to the Audit:

Prior to the audit, the organization should complete a self-audit using this checklist in preparation for the accreditation audit. The self-audit is to be completed with the related document name(s)/procedure number(s) along with paragraph reference marked next to the checklist question where applicable. For those nonconformances identified through the self-audit and when containment is not implemented prior to the audit, an NCR shall be written.

All NO and NA answers must be explained and nonconformances marked accordingly.

Nonconformances of a technical nature found during the actual audit may require a follow-up audit.

#### During the Audit:

The organization should provide for an in-briefing/opening meeting. Key members of the organization's staff should attend so the audit purpose, methods, and assessment processes can be discussed.

The audit will be conducted in English, unless otherwise approved by the Auditor.

Working space/equipment for the Auditor are to be provided as required. This could include desk or table, chair, copier, printer, scanner, and internet access, as necessary.

A final out-briefing will be conducted at the completion of the audit. Each nonconformance will be reviewed and the organization will be given the opportunity to discuss.

#### Following the Audit:

The organization has 30 calendar days from the date of nonconformance notification to submit corrective action for each NCR. The responsibility for meeting this due date rests on the organization. Failure to comply with specified dates will result in significant delays in the organization's approval.

The response must address the root cause of the nonconformance from a systems management approach and the actions taken or to be taken to preclude reoccurrence in accordance with the defined requirements.

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### 3. ORGANIZATION INFORMATION

#### General Information

Identify the Nature of the Business \_\_\_\_\_

Indicate the Type of Work Performed \_\_\_\_\_ Captive House or Accepts Outside Work

Total Number of Employees \_\_\_\_\_

Number of QA Personnel \_\_\_\_\_

Facility Size (square footage) \_\_\_\_\_

Number of Operating Shifts \_\_\_\_\_

#### Audit Contacts

Identify the Primary Contact(s) for the Audit, including Consultants

NAME	TITLE

#### Approvals (Quality System, Other)

Certifying Agency	Approval Criteria	Certificate Issue Date	Certificate Expiration Date

#### Verification

Did the Supplier complete their self-audit at least 30 days prior to the audit - utilizing the version of the checklist(s) applicable to the audit?

For each question in the checklist, has the supplier identified where the means of compliance or evidence\* of compliance may be found?

(\* = procedure, checklist, physical location of evidence, etc.)

Have corrective actions from the previous audit been verified and found to be effective?

Audit Note: NA would apply for initial audits and where the previous audit had zero (0) NCRs.

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4.	CONTEXT OF THE ORGANIZATION			
4.1	Understanding the Organization and its Context			
4.1.1	Has the organization determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system?	Yes	No	
4.1.2	<p>Does the organization monitor and review information about these external and internal issues?</p> <p><i>NOTE 1: Issues can include positive and negative factors or conditions for consideration.</i></p> <p><i>NOTE 2: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional, or local.</i></p> <p><i>NOTE 3: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge, and performance of the organization.</i></p>	Yes	No	
4.2	Understanding the Needs and Expectations of Interested Parties			
4.2.1	<p>Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, has the organization determined:</p> <p>the interested parties that are relevant to the quality management system;</p> <p>the requirements of these interested parties that are relevant to the quality management system?</p>	Yes	No	
4.2.2	Does the organization monitor and review information about these interested parties and their relevant requirements?	Yes	No	
4.3	Determining the Scope of the Quality Management System			
4.3.1	Has the organization determined the boundaries and applicability of the quality management system to establish its scope?	Yes	No	
4.3.2	<p>When determining this scope, has the organization considered:</p> <p>the external and internal issues referred to in 4.1.1;</p> <p>the requirements of relevant interested parties referred to in 4.2.1;</p> <p>the products and services of the organization?</p>	Yes	No	
4.3.3	Did the organization apply all the requirements of this checklist, within the determined scope of its quality management system?	Yes	No	

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4.3.4	Is the scope of the organization's quality management system available and is it maintained as documented information?	Yes	No	
4.3.5	Does the scope state the types of products and services covered, and provide justification for any requirement of this checklist that the organization determines is not applicable to the scope of its quality management system?  <i>Audit Note: Conformity to this checklist can only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.</i>	Yes	No	
4.4	Quality Management System and its Processes			
4.4.1	Does the organization establish, implement, maintain, and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this checklist?	Yes	No	
4.4.2	Does the organization's quality management system address customer and applicable statutory and regulatory requirements?	Yes	No	
4.4.3	Has the organization:  determined the processes needed for the quality management system and their application throughout the organization;  determined the inputs required and outputs expected from these processes;  determined the sequence and interaction of these processes;  determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;  determined the resources needed for these processes and ensure their availability;  assigned the responsibilities and authorities for these processes;  addressed the risks and opportunities as determined in accordance with the requirements of 6.1;  evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results;  improved the processes and the quality management system?	Yes	No	
4.4.4	To the extent necessary, does the organization:  maintain documented information to support the operation of its processes;  retain documented information to have confidence that the processes are being carried out as planned?	Yes	No	

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4.4.5	<p>Has the organization established and maintained documented information that includes the scope of the quality management system and assignment of the responsibilities and authorities?</p> <p><i>NOTE: The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual.</i></p>	Yes	No	
	Notes:			
5.	LEADERSHIP			
5.1	Leadership and Commitment			
5.2	Customer Focus			
5.2.1	<p>Does top management demonstrate leadership and commitment with respect to customer focus by ensuring that:</p> <p>customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;</p> <p>product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved?</p>	Yes	No	

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5.3	Policy			
5.3.1	Establishing the Quality Policy			
	Has top management established, implemented, and maintained a quality policy that:  is appropriate to the purpose and context of the organization and supports its strategic direction;  provides a framework for setting quality objectives;  includes a commitment to satisfy applicable requirements;  includes a commitment to continual improvement of the quality management system?	Yes	No	
5.3.2	Communicating the Quality Policy			
	Is the quality policy available and maintained as documented information; communicated, understood, and applied within the organization, and available to relevant interested parties, as appropriate?	Yes	No	
5.4	Organizational Roles, Responsibilities, and Authorities			
5.4.1	Has top management ensured that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization?	Yes	No	
5.4.2	Has top management assigned the responsibility and authority for:  ensuring that the quality management system conforms to the requirements of this checklist;  ensuring that the processes are delivering their intended outputs;  reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;  ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?	Yes	No	
5.4.3	Has top management appointed a specific member of the organization's management, identified as the management representative, who shall have the responsibility and authority for oversight of the above requirements?	Yes	No	
5.4.4	Does the management representative have the organizational freedom and unrestricted access to top management to resolve quality management issues?  <i>NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</i>	Yes	No	



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	Notes:			
6.	PLANNING			
6.1	Actions to Address Risks and Opportunities			
6.1.1	When planning for the quality management system, does the organization consider the issues referred to in 4.1.1 and the requirements referred to in 4.2.1 and determine the risks and opportunities that need to be addressed?	Yes	No	
6.1.2	Does the organization plan actions to address these risks and opportunities?	Yes	No	
6.2	Quality Objectives and Planning to Achieve Them			
6.2.1	Has the organization established quality objectives at relevant functions, levels, and processes needed for the quality management system?	Yes	No	
6.2.2	Are the quality objectives: consistent with the quality policy, measurable; taking into account applicable requirements; relevant to conformity of products and services and to enhancement of customer satisfaction; monitored, communicated and updated as appropriate:	Yes	No	
6.2.3	Does the organization maintain documented information on the quality objectives?	Yes	No	
6.3	Planning of Changes			
6.3.1	When the organization determines the need for changes to the quality management system, are the changes carried out in a planned manner (see 4.4)?  <i>NOTE: The organization may consider:</i> <i>a. the purpose of the changes and their potential consequences;</i> <i>b. the integrity of the quality management system;</i> <i>c. the availability of resources;</i> <i>d. the allocation or reallocation of responsibilities and authorities.</i>	Yes	No	

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	Notes:			
7.	SUPPORT			
	Resources			
7.1	Has the organization determined and provided the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system?	Yes	No	
	People			
7.2	Has the organization determined and provided the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes?	Yes	No	
	Infrastructure			
7.3	Has the organization determined, provided, and maintained the infrastructure necessary for the operation of its processes and to achieve conformity of products and services?  <i>NOTE: Infrastructure can include: buildings and associated utilities; equipment, including hardware and software; transportation resources; information and communication technology.</i>	Yes	No	
	Environment for the Operation of Processes			
7.4	Has the organization determined, provided, and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services?			
7.5	Monitoring and Measuring Resources			
7.5.1	The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. Does the organization ensure that the resources provided: are suitable for the specific type of monitoring and measurement activities being undertaken; are maintained to ensure their continuing suitability for their purpose?	Yes	No	
7.5.2	Does the organization retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources?	Yes	No	

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7.6	Measurement Traceability			
7.6.1	When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, is the measuring equipment: calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, is the basis used for calibration or verification retained as documented information; identified in order to determine their status; safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results?	Yes	No	
7.6.2	Has the organization established, implemented, and maintained a process for the recall of monitoring and measuring equipment requiring calibration or verification?	Yes	No	
7.6.2.1	Does the organization maintain a register of the monitoring and measuring equipment?	Yes	No	
7.6.3	Does the register include the equipment type, unique identification, and the calibration or verification method, frequency, and acceptance criteria?  <i>NOTE: Monitoring and measuring equipment can include, but are not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity</i>	Yes	No	
7.6.4	Is calibration or verification of monitoring and measuring equipment carried out under suitable environmental conditions (see 7.4)?	Yes	No	
7.6.5	Does the organization determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and take appropriate action as necessary?	Yes	No	
7.7	Competence			
7.7.1	Does the organization: determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system; ensure that these persons are competent on the basis of appropriate education, training, or experience; where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; retain appropriate documented information as evidence of competence?  <i>NOTE: Consideration should be given for the periodic review of the necessary competence.</i> <i>NOTE: Applicable actions can include, for example, the provision of training to the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.</i>	Yes	No	

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7.8	Awareness			
7.8.1	Does the organization ensure that persons doing work under the organization's control are aware of: the quality policy; relevant quality objectives; their contribution to the effectiveness of the quality management system, including the benefits of improved performance; the implications of not conforming with the quality management system requirements; relevant quality management system documented information and changes; their contribution to product or service conformity; their contribution to product safety; the importance of ethical behavior?	Yes	No	
7.9	Documented Information			
	General			
7.9.1	Does the organization's quality management system include: documented information required by this checklist: documented information determined by the organization as being necessary for the effectiveness of the quality management system?  <i>NOTE: The extent of documented information for a quality management system can differ from one organization to another due to:</i> - the size of organization and its type of activities, processes, products, and services; - the complexity of processes and their interactions; - the competence of persons	Yes	No	
	Creating and Updating			
7.9.2	When creating and updating documented information, does the organization ensure appropriate: identification and description (for example: a title, date, author, or reference number); format (for example: language, software version, graphics) and media (for example: paper, electronic); review and approval for suitability and adequacy?	Yes	No	
7.9.3	Control of Documented Information			
7.9.3.1	Is documented information required by the quality management system and by this checklist controlled to ensure: it is available and suitable for use, where and when it is needed; it is adequately protected (for example: from loss of confidentiality, improper use, or loss of integrity)?	Yes	No	

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7.9.3.2	For the control of documented information, does the organization address the following activities, as applicable: distribution, access, retrieval, and use; storage and preservation, including preservation of legibility; control of changes (for example: version control); retention and disposition; prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose?	Yes	No	
7.9.3.3	When documented information is managed electronically, are data protection processes defined (for example: protection from loss, unauthorized changes, unintended alteration, corruption, physical damage)?  <i>Audit Note: NA would apply if there is no electronic information.</i>	Yes	No	NA
7.9.3.4	Is documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system identified as appropriate, and controlled?	Yes	No	
7.9.3.5	Is documented information retained as evidence of conformity protected from unintended alterations?	Yes	No	
	Notes:			
8.	OPERATION			
8.1	Operational Planning and Control			
8.1.1	Does the organization plan, implement, and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in clause 6, by: determining the requirements for the products and services; establishing criteria for and implementing control of the processes and the acceptance of products and services;  <i>NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:</i> - process control; • selection and verification of key characteristics; • process capability measurements; • statistical process control;	Yes	No	

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	<ul style="list-style-type: none"> <li>• <i>design of experiments;</i></li> <li>- <i>verification;</i></li> <li>- <i>failure mode, effects, and criticality analysis.</i></li> </ul> <p>planning, implementing, and controlling processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer;</p> <p>determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;</p> <p>determining, maintaining, and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products and services to their requirements;</p> <p>determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;</p> <p>engaging representatives of affected organization functions for operational planning and control;</p> <p>determining the products and services to be obtained from external providers;</p> <p>establishing the controls needed to prevent the delivery of nonconforming products and services to the customer?</p>			
8.1.2	<p>Is the output of this planning suitable for the organization's operations?</p> <p><i>NOTE: As an output of this planning, documented information specifying the processes of the quality management system and the resources to be applied to a specific product, service, project, or contract can be referred to as a quality plan.</i></p>	Yes	No	
8.1.3	Does the organization control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary?	Yes	No	
8.1.4	<p>Does the organization ensure that outsourced processes are controlled (see 8.4)?</p> <p><i>Audit Note: NA applies when no processes are outsourced.</i></p>	Yes	No	NA
8.1.5	Has the organization established, implemented, and maintained a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements?	Yes	No	NA
8.1.6	<p>Does the process ensure that work transfer impacts and risks are managed?</p> <p><i>NOTE: For the control of work transfer from the organization to an external provider, or from an external provider to another external provider, see 8.4. For the control of work transfer from one organization facility to another, or from an external provider to the organization, see 8.5.</i></p>	Yes	No	
8.2	Configuration Management			
8.2.1	Has the organization planned, implemented, and controlled the process for configuration management as appropriate to the organization and its products	Yes	No	

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	and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle?			
8.2.2	Does this process: control product identity and traceability to requirements, including the implementation of identified changes; ensure that the documented information (for example: requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services?	Yes	No	
8.3	<a href="#">Requirements for Products and Services</a>			
8.3.1	Customer Communication			
8.3.1.1	Does communication with customers include: providing information relating to products and services; handling enquiries, contracts, or orders, including changes; obtaining customer feedback relating to products and services, including customer complaints; handling or controlling customer property; establishing specific requirements for contingency actions, when relevant?	Yes	No	
8.3.2	Determining the Requirements for Products and Services			
8.3.2.1	When determining the requirements for the products and services to be offered to customers, does the organization ensure that: the requirements for the products and services are defined, including: any applicable statutory and regulatory requirements and those considered necessary by the organization; the organization can meet the claims for the products and services it offers; special requirements of the products and services are determined; operational risks (for example: new technology, ability and capacity to provide, short delivery time frame) have been identified?	Yes	No	
8.3.3	Review of the Requirements for Products and Services			
8.3.3.1	Does the organization ensure that it has the ability to meet the requirements for products and services to be offered to customers?	Yes	No	
8.3.3.2	Does the organization conduct a review before committing to supply products and services to the customer, including:	Yes	No	
8.3.3.3	Is this review coordinated with applicable functions of the organization?	Yes	No	
8.3.3.4	If upon review the organization determines that some customer requirements cannot be met or can only partially be met, does the organization negotiate a mutually acceptable requirement with the customer?	Yes	No	
8.3.3.5	Does the organization ensure that contract or order requirements differing from those previously defined are resolved?	Yes	No	
8.3.3.6	Are the customer requirements confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements?	Yes	No	
8.3.3.7	Does the organization retain documented information, as applicable, on the results of the review and on any new requirements for the products and services?	Yes	No	



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8.3.4	Changes to Requirements for Products and Services			
	Does the organization ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed?	Yes	No	
8.4	Control of Externally Provided Processes, Products, and Services			
8.4.1	General			
8.4.1.1	Does the organization ensure that externally provided processes, products, and services conform to requirements?	Yes	No	
8.4.1.2	Has the organization demonstrated responsibility for the conformity of all externally provided processes, products, and services, including from sources defined by the customer?	Yes	No	
8.4.1.3	Has the organization ensured, when required, that customer-designated or approved external providers, including process sources (for example: special processes), are used?	Yes	No	
8.4.1.4	Does the organization identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers (for example: direct and sub-tier external providers, sources identified by the customer)?	Yes	No	
8.4.1.5	Does the organization require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met?	Yes	No	
8.4.1.6	Has the organization determined the controls to be applied to externally provided processes, products, and services when: products and services from external providers are intended for incorporation into the organization's own products and services; products and services are provided directly to the customer(s) by external providers on behalf of the organization; a process, or part of a process, is provided by an external provider as a result of a decision by the organization?	Yes	No	
8.4.1.7	Has the organization determined and applied criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements?	Yes	No	
8.4.1.8	Does the organization retain documented information of these activities and any necessary actions arising from the evaluations?  <i>NOTE: During external provider evaluation and selection, the organization can use quality data from objective and reliable external sources, as evaluated by the organization (for example: information from accredited quality management system or process certification bodies, external provider approvals from government authorities or customers). Use of such data would be only one element of an organization's external provider control process and the organization remains responsible for verifying that externally provided processes, products, and services meet specified requirements.</i>	Yes	No	



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8.4.1.9	Does the organization: define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status; maintain a register of its external providers that includes approval status (for example: approved, conditional, disapproved) and the scope of the approval (for example: product type, process family); periodically review external provider performance including process, product and service conformity, and on-time delivery performance; define the necessary actions to take when dealing with external providers that do not meet requirements; define the requirements for controlling documented information created by and/or retained by external providers?	Yes	No	
8.4.2	Type and Extent of Control			
8.4.2.1	Does the organization ensure that externally provided processes, products, and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers?	Yes	No	
8.4.2.2	Does the organization: ensure that externally provided processes remain within the control of its quality management system; define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output; determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements?  <i>Note: When defining the controls, take into consideration:</i> - the potential impact of the externally provided processes, products, and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements; - the effectiveness of the controls applied by the external provider; - the results of the periodic review of external provider performance (see 8.4.1.9)	Yes	No	
8.4.2.3	Are verification activities of externally provided processes, products, and services performed according to the risks identified by the organization?	Yes	No	
8.4.2.4	Do these verification activities include inspection or periodic testing, as applicable, when there's high risk of nonconformities including counterfeit parts?  <i>NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve the organization of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.</i>  <i>NOTE 2: Verification activities can include:</i> - review of objective evidence of the conformity of the processes, products and services from the external provider (for example: accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter); - inspection and audit at the external provider's premises;	Yes	No	

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	<ul style="list-style-type: none"> <li>- review of the required documentation;</li> <li>- review of production part approval process data;</li> <li>- inspection of products or verification of services upon receipt;</li> <li>- review of delegations of product verification to the external provider.</li> </ul>			
8.4.2.5	<p>When externally provided product is released for production use pending completion of all required verification activities, is it identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements?</p> <p><i>Audit Note: NA applies when product is never released prior to completion of all requirements.</i></p>	Yes	No	NA
8.4.2.6	<p>When the organization delegates verification activities to the external provider, have the scope and requirements for delegation been defined and a register of delegations maintained?</p> <p><i>Audit Note: NA applies when the organization does not delegate.</i></p>	Yes	No	NA
8.4.2.7	<p>Does the organization periodically monitor the external provider's delegated verification activities?</p> <p><i>Audit Note: NA applies when the organization does not delegate.</i></p>	Yes	No	NA
8.4.3	Information for External Providers			
8.4.3.1	Does the organization ensure the adequacy of requirements prior to their communication to the external provider?	Yes	No	
8.4.3.2	<p>Does the organization communicate to external providers its requirements for:</p> <ul style="list-style-type: none"> <li>the processes, products, and services to be provided including the identification of relevant technical data (for example: specifications, drawings, process requirements, work instructions);</li> <li>the approval of: <ul style="list-style-type: none"> <li>- products and services;</li> <li>- methods, processes, and equipment;</li> <li>- the release of products and services;</li> </ul> </li> <li>competence, including any required qualification of persons;</li> <li>the external providers' interactions with the organization;</li> <li>control and monitoring of the external providers' performance to be applied by the organization;</li> <li>verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises;</li> <li>special requirements, critical items, or key characteristics;</li> <li>test, inspection, and verification (including production process verification);</li> <li>the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;</li> </ul> <p><i>Audit Note: NA applies for the above sub-questions where there are no organizational requirements.</i></p>	Yes	No	NA NA NA NA NA NA NA NA
8.4.3.3	Does the organization communicate to external providers the need to: <ul style="list-style-type: none"> <li>implement a quality management system;</li> <li>use customer-designated or approved external providers, including process sources (for example: special processes);</li> </ul>	Yes	No	

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	<p>notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;  prevent the use of counterfeit parts (see 8.1.1);  notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval;  flow down to external providers applicable requirements including customer requirements;  provide test specimens for inspection/verification, investigation, or auditing;  retain documented information, including retention periods and disposition requirements?  the right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain?</p>			
8.5	Production and Service Provision			
8.5.1	Control of Production and Service Provision			
8.5.1.1	Does the organization implement production and service provision under controlled conditions?	Yes	No	
8.5.1.2	<p>Do the controlled conditions include, as applicable:  the availability of documented information that defines the characteristics of the products to be produced, the services to be provided, or the activities to be performed and the results to be achieved;  the availability and use of suitable monitoring and measuring resources;  the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;  ensuring that documented information for monitoring and measurement activity for product acceptance includes:  - criteria for acceptance and rejection;  - where in the sequence verification operations are to be performed;  - measurement results to be retained (at a minimum an indication of acceptance or rejection);  - any specific monitoring and measurement equipment required and instructions associated with their use;</p> <p><i>NOTE: Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts lists, materials, and process specifications.</i></p> <p><i>NOTE: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (for example: manufacturing plans, travelers, routers, work orders, process cards), and verification documents.</i></p>	Yes	No	
8.5.1.3	Do the controlled conditions include, as applicable: ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability);	Yes	No	NA

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	<p>the use of suitable infrastructure and environment for the operation of processes;</p> <p><i>NOTE: Suitable infrastructure can include product specific tools (for example: jigs, fixtures, molds) and software programs.</i></p> <p>the appointment of competent persons, including any required qualification; the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;</p> <p><i>NOTE: These processes can be referred to as special processes (see 8.5.3)</i></p> <p><i>Audit Note: NA may apply for some of the sub-questions, but not all.</i></p>			
8.5.1.4	<p>Do the controlled conditions include, as applicable:</p> <p>the establishment of criteria for workmanship (for example: written standards, representative samples, illustrations);</p> <p>the accountability for all products during production (for example: parts quantities, split orders, nonconforming product);</p> <p>the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;</p> <p>the determination of methods to measure variable data (for example: tooling on-machine probing, inspection equipment);</p> <p>the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages; the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;</p> <p>the provision for the prevention, detection, and removal of foreign objects;</p> <p>the control and monitoring of utilities and supplies (for example: water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.3);</p> <p>the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements?</p>	Yes	No	<p>NA</p> <p>NA</p> <p>NA</p> <p>NA</p> <p>NA</p>
8.5.2	Control of Equipment, Tools, and Software Programs			
8.5.2.1	Are equipment, tools, and software programs used to automate, control, monitor, or measure production processes validated prior to final release for production and maintained?	Yes	No	
8.5.2.2	Are storage requirements defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks?	Yes	No	
8.5.3	Validation and Control of Special Processes			
8.5.3.1	For processes where the resulting output cannot be verified by subsequent monitoring or measurement, does the organization establish arrangements for these processes including:	Yes	No	
	definition of criteria for the review and approval of the processes;			

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	<p>determination of conditions to maintain the approval;  approval of facilities and equipment;  qualification of persons;  use of specific methods and procedures for implementation and monitoring the processes;  requirements for documented information to be retained?</p> <p><i>Audit Note: NA applies when special process requirements do not have a requirement for specific approvals.</i>  <i>Audit Note: NA applies when the special process(es) does not have industry or customer requirements.</i></p>			NA NA
8.5.4	Production Process Verification, Including Control of Changes			
8.5.4.1	<p>Has the organization implemented production process verification activities to ensure the production process is able to produce products that meet requirements, including when changed?</p> <p><i>NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans</i></p>	Yes	No	
8.5.4.2	<p>Does the organization use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements?</p> <p><i>NOTE: This activity can be referred to as First Article Inspection (FAI).</i>  <i>Audit Note: NA applies when not required by the customer.</i></p>	Yes	No	NA
8.5.4.3	<p>Is this activity repeated when changes occur that invalidate the original results?</p> <p><i>NOTE: Production or service provision changes can include engineering changes or the changes affecting processes, production equipment, tools, or software programs.</i></p> <p><i>Audit Note: NA applies when not required by the customer.</i></p>	Yes	No	NA
8.5.4.4	Are persons authorized to approve production or service provision changes identified?	Yes	No	
8.5.4.5	Does the organization retain documented information on the results of production process verification?	Yes	No	
8.5.5	Identification and Traceability			
8.5.5.1	Does the organization use suitable means to identify outputs when it is necessary to ensure the conformity of products and services?	Yes	No	
8.5.5.2	Does the organization maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration?	Yes	No	
8.5.5.3	Does the organization identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision?	Yes	No	
8.5.5.4	When acceptance authority media are used (for example: stamps, electronic signatures, passwords), does the organization establish controls for the media?	Yes	No	NA

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	<i>Audit Note: NA applies when media is not used.</i>			
8.5.5.5	<p>Does the organization control the unique identification of the outputs when traceability is a requirement, and retain the documented information necessary to enable traceability?</p> <p><i>NOTE: Traceability requirements can include:</i></p> <ul style="list-style-type: none"> <li>- the identification to be maintained throughout the product life;</li> <li>- the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (for example: delivery, scrap);</li> <li>- for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;</li> <li>- for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.</li> </ul>	Yes	No	
8.5.6	Property Belonging to Customers or External Providers			
8.5.6.1	Does the organization exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization?	Yes	No	
8.5.6.2	Does the organization identify, verify, protect, and safeguard customers' or external providers' property provided for use or incorporation into the products and services?	Yes	No	
8.5.6.3	<p>When the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, does the organization report this to the customer or external provider and retain documented information on what has occurred?</p> <p><i>NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property, and personal data.</i></p>	Yes	No	
8.5.7	Preservation			
8.5.7.1	<p>Does the organization preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements?</p> <p><i>NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.</i></p>	Yes	No	
8.5.7.2	<p>Does preservation of outputs include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:</p> <p>cleaning;</p> <p>prevention, detection, and removal of foreign objects;</p> <p>special handling and storage for sensitive products;</p> <p>marking and labeling, including safety warnings and cautions;</p> <p>shelf life control and stock rotation;</p> <p>special handling and storage for hazardous materials?</p> <p><i>Audit Note: NA applies to the sub-questions when there is no requirement.</i></p>	Yes	No	NA

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8.6	Release of Products and Services			
8.6.1	Does the organization implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met?	Yes	No	
8.6.2	Does the organization ensure that the release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer?	Yes	No	
8.6.3	Does the organization retain documented information on the release of products and services?	Yes	No	
8.6.4	Does the documented information include: evidence of conformity with the acceptance criteria; traceability to the person(s) authorizing the release?	Yes	No	
8.6.5	When required to demonstrate product qualification, does the organization ensure that retained documented information provides evidence that the products and services meet the defined requirements?	Yes	No	
8.6.6	Does the organization ensure that all documented information required to accompany the products and services are present at delivery?	Yes	No	
8.7	Control of Nonconforming Outputs			
8.7.1	Does the organization ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery?  <i>NOTE: The term “nonconforming outputs” includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.</i>	Yes	No	
8.7.2	Does the organization take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services?	Yes	No	
8.7.3	Does this action also apply to nonconforming products and services detected after delivery of products, during or after the provision of services?	Yes	No	
8.7.4	Is the organization's nonconformity control process maintained as documented information including the provisions for: defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions; taking actions necessary to contain the effect of the nonconformity on other processes, products, or services; timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties; defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2)?  <i>NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.</i>	Yes	No	
8.7.5	Does the organization deal with nonconforming outputs in one or more of the following ways: - correction;	Yes	No	

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	<ul style="list-style-type: none"> <li>- segregation, containment, return, or suspension of provision of products and services;</li> <li>- informing the customer;</li> <li>- obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer?</li> </ul>			
8.7.6	<p>Does the organization ensure that dispositions of use-as-is or repair for the acceptance of nonconforming products are only implemented after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization or after authorization by the customer, if the nonconformity results in a departure from the contract requirements?</p> <p>Note 1: BCA requires all organizations that provide use as is and/or repair dispositions to be authorized by BCA Supplier Engineering Liaison regardless of whether BCA contract requirements have been violated.</p> <p><i>Audit Note: NA is allowable when dispositions of use-as-is or repair are prohibited either internally or by customer.</i></p>	Yes	No	NA
8.7.7	Is product dispositioned for scrap conspicuously and permanently marked, or positively controlled, until physically rendered unusable or returned to the customer?	Yes	No	
8.7.8	Are counterfeit, or suspect counterfeit, parts controlled to prevent reentry into the supply chain?	Yes	No	
8.7.9	Does the organization ensure that conformity to the requirements are verified when nonconforming outputs are corrected?	Yes	No	
8.7.10	Does the organization retain documented information that: describes the nonconformity; describes the actions taken; describes any concessions obtained; identifies the authority deciding the action in respect of the nonconformity?	Yes	No	
	Notes:			
9.	<b>PERFORMANCE EVALUATION</b>			
9.1	<b>Monitoring, Measurement, Analysis, and Evaluation</b>			
9.1.1	Does the organization determine: what needs to be monitored and measured; the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results; when the monitoring and measuring shall be performed; when the results from monitoring and measurement shall be analyzed and evaluated?	Yes	No	
9.1.2	Does the organization evaluate the performance and the effectiveness of the quality management system?	Yes	No	



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9.1.3	Does the organization retain appropriate documented information as evidence of the results?	Yes	No	
9.2	Internal Audit			
9.2.1	<p>Does the organization conduct internal audits at planned intervals to provide information on whether the quality management system:</p> <ul style="list-style-type: none"> <li>conforms to the organization's own requirements for its quality management system and the requirements of this checklist?</li> </ul> <p><i>NOTE: The organization's own requirements should include customer and applicable statutory and regulatory quality management system requirements</i></p> <p>is effectively implemented and maintained?</p> <p><i>NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.</i></p>	Yes	No	
9.2.2	<p>Does the organization:</p> <ul style="list-style-type: none"> <li>plan, establish, implement, and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements, and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;</li> <li>define the audit criteria and scope for each audit;</li> <li>select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;</li> <li>ensure that the results of the audits are reported to relevant management;</li> <li>take appropriate correction and corrective actions without undue delay;</li> <li>retain documented information as evidence of the implementation of the audit program and the audit results?</li> </ul> <p><i>NOTE: See ISO 19011 for guidance.</i></p>	Yes	No	
9.3	Management Review			
	Does top management review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization?	Yes	No	
9.3.1	<p>Management Review Inputs</p> <p>Is the management review planned and carried out taking into consideration:</p> <ul style="list-style-type: none"> <li>the status of actions from previous management reviews;</li> <li>changes in external and internal issues that are relevant to the quality management system;</li> <li>information on the performance and effectiveness of the quality management system;</li> <li>opportunities for improvement;</li> <li>adequacy of resources;</li> <li>the continuing adequacy and suitability of the quality policy and quality objectives?</li> </ul>	Yes	No	

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9.3.2	<b>Management Review Outputs</b> Do the outputs of the management review include decisions and actions related to: opportunities for improvement; any need for changes to the quality management system; other actions?	Yes	No	
9.3.2.1	Does the organization retain documented information as evidence of the results of management reviews?  Notes:	Yes	No	
10.	<b>IMPROVEMENT</b>			
10.1	<b>General</b>			
10.1.1	Does the organization determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction?  <i>NOTE: These may include:</i> <ul style="list-style-type: none"> <li>- improving products and services to meet requirements as well as to address future needs and expectations;</li> <li>- correcting, preventing, or reducing undesired effects;</li> <li>- improving the performance and effectiveness of the quality management system.</li> </ul> <i>NOTE: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation, and reorganization.</i>	Yes	No	
10.2	<b>Nonconformity and Corrective Action</b>	Yes	No	
10.2.1	When a nonconformity occurs, including any arising from complaints, does the organization: react to the nonconformity and, as applicable, take action to control and correct it and deal with the consequences; evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by reviewing and analyzing the nonconformity; - determining the causes of the nonconformity; - determining if similar nonconformities exist, or could potentially occur; - implement any action needed;	Yes	No	

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	<ul style="list-style-type: none"> <li>- review the effectiveness of any corrective action taken;</li> <li>- make changes to the quality management system, if necessary;</li> <li>- flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;</li> <li>- take specific actions when timely and effective corrective actions are not achieved?</li> </ul>			
10.2.2	Are corrective actions appropriate to the effects of the nonconformities encountered?	Yes	No	
10.2.3	Does the organization maintain documented information that defines the nonconformity and corrective action management processes?	Yes	No	
10.2.4	Does the organization retain documented information as evidence of: the nature of the nonconformities and any subsequent actions taken; the results of any corrective action?	Yes	No	
	Notes:			