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AUDIT CRITERIA

AC7004 REV G Δ1

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Superseding AC7004 Rev F

Nadcap
AUDIT CRITERIA FOR
AEROSPACE QUALITY SYSTEM

TO BE USED ON AUDITS STARTING ON OR AFTER 30-DEC-2018

1. SCOPE

This audit criteria (AC) is to be used to verify compliance with Nadcap Aerospace Quality System requirements in conjunction with another Nadcap commodity audit. Upon satisfactory completion of both this audit and the commodity audit in accordance with PRI PD 1100, approval to AC7004 will be granted. PRI AC7004 accreditation is designed to support at least one Nadcap commodity accreditation.

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, 9100 or 9110 accreditation may be required.

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2. GENERAL INSTRUCTIONS

2.1 Instructions for the Auditors

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 9100 Standard.
"Audit Notes" are guidance on the use of the not-applicable (NA) response.

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 since it may be viewed by any Nadcap Subscriber.

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

2.2 Instructions for the Organization

2.2.1 Prior to the Audit

In addition to the instructions provided with the commodity checklists supporting this checklist, the organization shall 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 Nadcap audit, an NCR shall be written by the Nadcap Auditor.

All NO and NA answers must be explained and nonconformances marked accordingly. Nonconformances of a technical nature found during the actual audit will, at the Task Group's discretion, require a follow-up audit at the organization's expense.

All documentation submitted prior to the audit must be in English.

Self-Audit: In preparation for the audit, the supplier must complete a self-audit utilizing the Checklist(s) applicable at the time of the Nadcap audit. Nadcap recommends: self-audits be performed 90-120 days prior to the scheduled audit. Per OP 1114 "Task Group Operation" Nadcap requires each paragraph of the completed self-audit to identify where means of compliance or evidence* of compliance may be found. (*= procedure, checklist, physical location of evidence, etc.).

In accordance with OP 1105 Audit Process, the organization shall upload the self-audit into eAuditNet at least 30 days prior to the scheduled start of the on-site audit. The self-audit shall be uploaded into eAuditNet.

A Word version of the AC 7004 checklist can be found in Resources – Documents – Audit Criteria – Aerospace Quality System – Word Copies of Checklist

There is an Audit Handbook available for the AQS AC7004 checklist: Resources – Documents – Audit Criteria – Aerospace Quality System – Handbook and Guides

2.2.2 During the Audit

The organization should provide for an in-briefing/opening meeting with the Auditor. 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.

2.2.3 Following the Audit

Supplier feedback must be completed to allow submission of NCR responses. If there are zero (0) NCRs found during the audit, the organization has 3 business days from the date of Supplier Review email notification to complete and submit the Supplier Feedback in eAuditNet.

All responses and evidence must be in English.

The organization has 21 calendar days from the date of Supplier Review email 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 accreditation or may result in failure, per OP 1110.

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.

The AQS Task Group may, upon review, change the auditor's determination of a finding. The organization must provide a written response to each nonconformance identified by the auditor.

PRI Staff or the Task Group may, after review of the organization’s audit report, require additional information or may elect to issue additional findings.

NOTE: Final authority over the audit report, acceptability of corrective actions, and accreditation recommendation rests with the Task Group.

3. ORGANIZATION INFORMATION

3.1 General Information

Identify the Nature of the Business _____Metal Finishing

Indicate the Type of Work Performed Accepts Outside Work

Total Number of Employees ___72____

Number of QA Personnel ___1____

Facility Size (square footage) ___72,000 SQFT____

Number of Operating Shifts ___3____

3.1.1 Audit Contacts

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

NAME	TITLE
HENRY MOFFATT	QUALITY MANAGER
RODNEY CHIARELLI	VICE PRESIDENT
DAVID BERTGES	Human Resource Manager

3.2 Approvals (Quality System, Subscriber, Other)

Certifying Agency	Approval Criteria	Certificate Issue Date	Certificate Expiration Date
PRI	AC7004	06-AUG-2019	30-NOV-2022

3.3	**Verification**		
3.3.1	Did the Auditee upload a copy of their completed self-audit to eAuditNet at least 30 days prior to the audit- utilizing the version of the checklist(s) applicable to this audit? *Guidance: Nadcap recommends the self-audit be performed 90- 120 days prior to the scheduled audit. In the event of checklist revisions, Nadcap publishes the checklist(s) and sends out a notification 90 days prior to the checklist(s) becoming effective. In this case, an audit against the changes is acceptable if it supplements the existing self-audit performed prior to the release of the revised checklist(s).*	YES	
3.3.2	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.)	YES	
3.3.3	Does the self-audit include job audits as required by the TG? *Guidance: Task Group job audit requirements are defined in the checklist or the OP-1114 Appendix.* ***NA applies for AQS checklists that do not require job audits**.*		NA
3.3.4	If this is a reaccreditation audit, has the supplier informed PRI of any changes to audit contact or address of the facility? *Audit Note: NA would only apply if there were no changes made or this is an initial audit.*		NA
3.3.5	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.*	YES	

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? QM 4.1 Context of the Organization	YES
4.1.2	Does the organization monitor and review information about these external and internal issues? QM 4.1 Context of the Organization *NOTE 1: Issues can include positive and negative factors or conditions for consideration.* *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.* *NOTE 3: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge, and performance of the organization.*	YES
4.2	**Understanding the Needs and Expectations of Interested Parties**	
4.2.1	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:	
4.2.1.1	the interested parties that are relevant to the quality management system? QM 4.2 Understanding the Organization and its context	YES
4.2.1.2	the requirements of these interested parties that are relevant to the quality management system? QM 4.2 Understanding the Organization and its Context	YES
4.2.2	Does the organization monitor and review information about these interested parties and their relevant requirements? QM 4.2 Understand the Organization and its Context	YES
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? QM 4.3 Determining the Scope of the Quality Management System	YES
4.3.2	When determining this scope, has the organization considered:	
4.3.2.1	the external and internal issues referred to in 4.1.1? QM 4.3 Determining the Scope of the Quality Management System	YES
4.3.2.2	the requirements of relevant interested parties referred to in 4.2.1.2? QM 4.3 Determining the Scope of the Quality Management System	YES
4.3.2.3	the products and services of the organization? QM 4.3 Determining the Scope of the Quality Management System	YES

4.3.3	Did the organization apply all the requirements of this checklist, within the determined scope of its quality management system? QM 4.3 Determining the Scope of the Quality Management System	YES

4.3.4	Is the scope of the organization's quality management system available and is it maintained as documented information? QM 4.3 Determining the Scope of the Quality Management System	YES
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? QM 4.3 Determining the Scope of the Quality Management System *Audit Note: Conformity to this checklist may 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.*	YES
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? QM 4.4.1 Quality Management System and its Processes	YES
4.4.2	Does the organization's quality management system address customer and applicable statutory and regulatory requirements? QM 4.4.1 Quality Management System and its Processed	YES
4.4.3	Has the organization:	
4.4.3.1	determined the processes needed for the quality management system and their application throughout the organization? SOP 7.1 Planning for Product Realization	YES
4.4.3.2	determined the inputs required and the outputs expected from these processes? QM 4.4 Quality Management System and its Processed	YES
4.4.3.3	determined the sequence and interaction of these processes? SOP 7.1 Planning for Product Realization	YES
4.4.3.4	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?SOP 8.2.4 Monitoring and Measurement of Product	YES
4.4.3.5	determined the resources needed for these processes and ensure their availability? SOP 7.4.1 Purchasing Process sec. 6.0	YES
4.4.3.6	assigned the responsibilities and authorities for these processes? SOP 7.4.1 Purchasing Process sec. 3.0 Responsibilities	YES
4.4.3.7	addressed the risks and opportunities as determined in accordance with the requirements of 6.1? SOP 7.4.1 Purchasing Process sec. 6.0 Procedure	YES
4.4.3.8	evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results?SOP 8.2.4 Monitoring and Measuring of Product	YES

4.4.3.9	improved the processes and the quality management system? SOP 8.2.4 Monitoring and Measuring of Product	YES
4.4.4	To the extent necessary, does the organization:	
4.4.4.1	maintain documented information to support the operation of its processes? SOP 4.2.3 Document and Data Control	YES
4.4.4.2	retain documented information to have confidence that the processes are being carried out as planned? SOP 4.2.4 Control of Records sec. 6.4 Retention Policy	YES
4.4.5	Has the organization established and maintained documented information that includes the scope of the quality management system and assignment of the responsibilities and authorities? SOP 6.2.2 Competence, Awareness and Training	YES
	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.	
5.	**LEADERSHIP**	
5.1	**Leadership and Commitment**	
5.1.1	Does top management demonstrate leadership and commitment with respect to the quality management system by:	
5.1.1.1	taking accountability for the effectiveness of the quality management system? QM 5.0 Leadership para 5.1.1	YES
5.1.1.2	ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization? QM 5.2 Quality Policy para 5.2.1	YES
5.1.1.3	ensuring the integration of the quality management system requirements into the organization’s processes? QM 5.2.2 Communicating the Quality Policy	YES
5.1.1.4	ensuring that the resources needed for the quality management system are available? QM 7.0 Support para 7.1.1 General	YES
5.1.1.5	communicating the importance of effective quality management and of conforming to the quality management system requirements? QM 5.0 Leadership	YES
5.1.1.6	ensuring that the quality management system achieves its intended results?QM 5.0 Leadership	YES
5.2	**Customer Focus**	
5.2.1	Does top management demonstrate leadership and commitment with respect to customer focus by ensuring that:	
5.2.1.1	customer and applicable statutory and regulatory requirements are determined, understood, and consistently met? QM 5.1.2 Customer Focus	YES

5.2.1.2	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? QM 5.2.1 SOP 8.2.1 Customer Satisfaction	YES
5.3	**Policy**	
5.3.1	**Establishing the Quality Policy**	
5.3.1.1	Has top management established, implemented, and maintained a quality policy that:	
5.3.1.1.1	is appropriate to the purpose and context of the organization and supports its strategic direction? QM 5. Policy	YES
5.3.1.1.2	provides a framework for setting quality objectives? QM 5.2 Policy	YES
5.3.1.1.3	includes a commitment to satisfy applicable requirements? QM 5.2 Policy	YES
5.3.1.1.4	includes a commitment to continual improvement of the quality management system? QM 5.2 Policy	YES
5.3.2	**Communicating the Quality Policy**	
5.3.2.1	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? QM 5.2.2 Communicating the Quality Policy	YES
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? QM 5.3 Organizational Roles, Responsibilities and Authorities	YES
5.4.2	Has top management assigned the responsibility and authority for:	
5.4.2.1	ensuring that the quality management system conforms to the requirements of this checklist? QM 5.3 Organizational Roles, Responsibilities and Authorities	YES
5.4.2.2	ensuring that the processes are delivering their intended outputs? QM 5.3 Organizational Roles, Responsibilities and Authorities	YES
5.4.2.3	reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management? QM 5.3 Organizational Roles, Responsibilities and Authorities	YES
5.4.2.4	ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?QM 5.3 Organizational Roles, Responsibilities and Authorities	YES
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? QM 5.3 Organizational Roles, Responsibilities and Authorities	YES

5.4.4	Does the management representative have the organizational freedom and unrestricted access to top management to resolve quality management issues? QM 5.3 Organizational Roles, Responsibilities and Authorities *NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.*	YES
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 4.2.1.2 and determine the risks and opportunities that need to be addressed? QM 6.0 Planning sec. 6.1.1	YES
6.1.2	Does the organization plan actions to address these risks and opportunities? QM 6.0 Planning sec. 6.1.2	YES
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?QM 6.2.1 Quality Objectives and Planning to Achieve Them	YES
6.2.2	Are the quality objectives:	
6.2.2.1	consistent with the quality policy? QM 6.2 Quality Objectives and Planning to Achieve Them	YES
6.2.2.2	measurable? Qm 6.2 Quality Objectives and Planning to Achieve Them	YES
6.2.2.3	taking into account applicable requirements? QM 6.2 Quality Objectives and Planning to Achieve Them	YES
6.2.2.4	relevant to conformity of products and services and to enhancement of customer satisfaction? QM 6.2 Quality Objectives and Planning to Achieve Them	YES
6.2.2.5	monitored? QM 6.2 Quality Objectives and Planning to Achieve Them	YES
6.2.2.6	communicated? QM 6.2 Quality Objectives and Planning to Achieve Them	YES
6.2.2.7	updated, as appropriate? QM 6.2 Quality Objectives and Planning to Achieve Them	YES
6.2.3	Does the organization maintain documented information on the quality objectives? QUA-1183 Rev. 1/13/20 Monthly Quality Objectives Log	YES

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)? QM 6.3 Planning of Changes *NOTE: The organization may consider:* *a. the purpose of the changes and their potential consequences;* *b. the integrity of the quality management system;* *c. the availability of resources;* d. the allocation or reallocation of responsibilities and authorities.	YES
7.	**SUPPORT**	
7.1	**Resources**	
7.1.1	Has the organization determined and provided the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system? QM 7.0 Support sec 7.1.1 General	YES
7.2	**People**	
7.2.1	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? QM 7.1.2 People	YES
7.3	**Infrastructure**	
7.3.1	Has the organization determined, provided, and maintained the infrastructure necessary for the operation of its processes and to achieve conformity of products and services? QM 7.1.3 Infrastructure *NOTE: Infrastructure can include: buildings and associated utilities; equipment, including hardware and software; transportation resources; information and communication technology.*	YES
7.4	**Environment for the Operation of Processes**	
7.4.1	Has the organization determined, provided, and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services? QM 7.1.4 Environment for the Operation of Processes	YES
7.5	**Monitoring and Measuring Resources** 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:	

7.5.1.1	are suitable for the specific type of monitoring and measurement activities being undertaken? QM 7.5.1.2 Measurement Traceability	YES
7.5.1.2	are maintained to ensure their continuing suitability for their purpose? SOP 7.6 Control of Monitoring and Measurment of Product	YES
7.5.1.3	Does the organization retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources? SOP 7.6 Control of Monitoring and Measurment of Product	YES
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:	
7.6.1.1	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? SOP 7.6 Control of Monitoring and Measuring Equipment sec. 6.0 Procedure	YES
7.6.1.2	identified in order to determine their status? SOP 7.6 Control of Monitoring and Measuring Equipment sec. 6.0 sub. sec. 6.1.2	YES
7.6.1.3	safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results? SOP Control of Monitoring and Measuring Equipment sec. 6.4 Safegaurds	YES
7.6.2	Has the organization established, implemented, and maintained a process for the recall of monitoring and measuring equipment requiring calibration or verification? SOP 7.6 Control of Measuring and Monitoring Equipment Calibration Process	YES
7.6.2.1	Does the organization maintain a register of the monitoring and measuring equipment?SOP 7.6 Control of Monitoring and Measuring Equipment sec. 6.0 procedure sub sec. 6.1.1	YES

7.6.3	Does the register include the equipment type, unique identification, and the calibration or verification method, frequency, and acceptance criteria? SOP 7.6 Control of Monitoring and Measuring Equipment sec. 6.0 Procedure sub sec. 6.1.1 *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.*	YES
7.6.4	Is calibration or verification of monitoring and measuring equipment carried out under suitable environmental conditions (see 7.4.1)? Control of Monitoring and Measuring Equipment sec. 6.1.10	YES
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? SOP 7.6 Control of Monitoring and Measuring Equipment sec. 6.1.8	YES

7.7	**Competence**	
7.7.1	Does the organization:	
7.7.1.1	determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system? SOP 6.2.2 Competence, Awareness and Training	YES
7.7.1.2	ensure that these persons are competent on the basis of appropriate education, training, or experience? SOP 6.2.2 Competence, Awareness and Training sec. 6.2 sub sec. 6.2.3	YES
7.7.1.3	where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken? SOP 6.2.2 Competence, Awareness and Training sec. 6.3	YES
7.7.1.4	retain appropriate documented information as evidence of competence? SOP 6.2.2 Competence, Awareness and Training sec. 6.0 sub sec. 6.1.3 *NOTE: Consideration should be given for the periodic review of the necessary competence.* *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.*	YES
7.8	**Awareness**	
7.8.1	Does the organization ensure that persons doing work under the organization's control are aware of:	
7.8.1.1	the quality policy? SOP 6.2.2 Competence, Awareness and Training sec 6.2.2 Proficiency Checklist	YES
7.8.1.2	relevant quality objectives? QUA-0001 Rev. 7/18/13	YES
7.8.1.3	their contribution to the effectiveness of the quality management system, including the benefits of improved performance? QUA-0001 7/18/13	YES
7.8.1.4	the implications of not conforming with the quality management system requirements? Employee Handbook	YES
7.8.1.5	relevant quality management system documented information and changes? SOP 4.2.3 Document and Data Control sec. 6.14 Document Review	YES
7.8.1.6	their contribution to product or service conformity? SOP 6.2.2 Competence, Awareness and Training sec 6.2 Proficiency Checklist	YES
7.8.1.7	their contribution to product safety? SOP 6.2.2 Competence Awareness and Training sec. 6.2	YES
7.8.1.8	the importance of ethical behavior? SOP 6.2.2 Competence Awareness and Training sec.	YES

7.9	**Documented Information**	
7.9.1	**General**	
7.9.1.1	Does the organization's quality management system include:	
7.9.1.1.1	documented information required by this checklist? SOP 4.2.3 Document and Data Control	YES
7.9.1.1.2	documented information determined by the organization as being necessary for the effectiveness of the quality management system? SOP 4.2.3 Documente and Data Control *NOTE: The extent of documented information for a quality management system can differ from one organization to another due to:* *- 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
7.9.2	**Creating and Updating**	
7.9.2.1	When creating and updating documented information, does the organization ensure appropriate:	
7.9.2.1.1	identification and description (for example: a title, date, author, or reference number)? SOP 4.2.3 Document and Data Control sec. 6.1 sub sec. 6.1.2	YES
7.9.2.1.2	format (for example: language, software version, graphics) and media (for example: paper, electronic)? SOP 4.2.3 Document and Data Control sec. 6.0 Procedure	YES
7.9.2.1.3	review and approval for suitability and adequacy? SOP 4.2.3 Document and Data Control sec. 6.1 sub sec. 6.1.1	YES
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:	
7.9.3.1.1	it is available and suitable for use, where and when it is needed? SOP 4.2.4 Control of Records sec. 6.0 sub sec. 6.1	YES
7.9.3.1.2	it is adequately protected (for example: from loss of confidentiality, improper use, or loss of integrity)? SOP 4.2.4 Coontrol of Records sec. 6.3 Legibility, Storage and Retrieval	YES
7.9.3.2	For the control of documented information, does the organization address the following activities, as applicable:	
7.9.3.2.1	distribution, access, retrieval, and use? SOP 4.2.3 sec. 6.0 Procedure sub sec. 6.3	YES
7.9.3.2.2	storage and preservation, including preservation of legibility? SOP 4.2.4 Control of Records sec. 6.3	YES

7.9.3.2.3	control of changes (for example: version control)? SOP 4.2.4 Control of Records sec. 6.0 Procedure	YES
7.9.3.2.4	retention and disposition? SOP 4.2.4 Control of Records sec. 6.0 Procedure sub sec 6.4	YES
7.9.3.2.5	prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose? SOP 4.2.3 Document and Data Control sec. 6.1 sub sec. 6.1.3	YES
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)? SOP 4.2.4 Control of Records sec. 6.3 sub sec. 6.3.1 *Audit Note: NA would apply if there is no electronic information.*	YES
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? SOP 4.2.3 Document and Data Control sec. 6.7	YES
7.9.3.5	Is documented information retained as evidence of conformity protected from unintended alterations? SOP 4.2.3 Document and Data Control sec. 6.0 sub sec. 6.1.2	YES
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:	
8.1.1.1	determining the requirements for the products and services? SOP 7.1 Planning for Product Realization	YES
8.1.1.2	establishing criteria for the processes and the acceptance of products and services? SOP 7.1 Planning for Product Realization sec. 6.2 Planning sub sec. 6.2.4 *NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:* *- process control;* *• selection and verification of key characteristics;* *• process capability measurements;* *• statistical process control;* *• design of experiments;* *- verification;* *- failure mode, effects, and criticality analysis.*	YES
8.1.1.3	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? QM 8.0 Operational Planning and Control	YES

8.1.1.4	determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services? QM 8.0 Operation Planning and Control	YES
8.1.1.5	implementing control of the processes in accordance with the criteria as established in 8.1.1.2? SOP 7.1 Planning for Product Realization sec. 6.0 Procedure sub sec. 6.1.3	YES
8.1.1.6	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? SOP 4.2.3 Document and Data Control sec. 6.0 Procedure sub sec. 6.1.2	YES
8.1.1.7	determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified? SOP 7.5.1 Control of Production and Service Provision sec. 6.2 Work Order sub 6.2.1	YES
8.1.1.8	engaging representatives of affected organization functions for operational planning and control? SOP 7.2 Customer Related Processes sec. 3.0 Responsibilities	YES
8.1.1.9	determining the products and services to be obtained from external providers? SOP 7.2 Customer Related Processes sec. 3.0 Responsibilities	YES
8.1.1.10	establishing the controls needed to prevent the delivery of nonconforming products and services to the customer?SOP 8.3 Control of Nonconforming Product sec. 6.2 In Process Inspection	YES

8.1.2	Is the output of this planning suitable for the organization's operations? SOP 7.5.1 Control of Production and Service Provision sec. 6.2 Work Order *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*.	YES
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? QM 8.1.3 Product Safety	YES
8.1.4	Does the organization ensure that outsourced processes are controlled (see 8.4)? ATG does not outsource processes *Audit Note: NA applies when no processes are outsourced.*	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? ATG does not transfer work *Audit Note:* *1. NA is only supported if there is no potential to move work from the external to external, external to internal, or internal to external.* *2. NA is only applicable if the internal to internal transfer does not affect form, fit, or function and does not deviate from the established process/planning.*	NA
8.1.6	Does the process ensure that work transfer impacts and risks are managed? ATG does not transfere work *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.* *Audit Note: NA only applies if NA applied to 8.1.5*	NA
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 and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle? Does not apply to ATG	N/A
8.2.2	Does this process:	
8.2.2.1	control product identity and traceability to requirements, including the implementation of identified changes? Does not apply to ATG	N/A
8.2.2.2	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? Does not apply to ATG	N/A

8.3	**Requirements for Products and Services**	
8.3.1	**Customer Communication**	
8.3.1.1	Does communication with customers include: SOP 8.2.1	
8.3.1.1.1	providing information relating to products and services? SOP 8.2.1 Customer Communication	YES
8.3.1.1.2	handling enquiries, contracts, or orders, including changes? SOP 8.2.1 Customer Communication	YES
8.3.1.1.3	obtaining customer feedback relating to products and services, including customer complaints? QM 8.3 Requirements for Products and Services	YES
8.3.1.1.4	handling or controlling customer property? QM 8.3 Requirements for Products and Services	YES
8.3.1.1.5	establishing specific requirements for contingency actions, when relevant? QM 8.3 Requirements for Products and Services	YES
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:	
8.3.2.1.1	the requirements for the products and services are defined, including: any applicable statutory and regulatory requirements and those considered necessary by the organization? QM 8.2.2 Determining the Requirement for Products and Services	YES
8.3.2.1.2	the organization can meet the claims for the products and services it offers? SOP 4.2.3 Control of Records, sec. 6.3 legibility and retrieval	YES
8.3.2.1.3	special requirements of the products and services are determined? QM 8.2.2 Determining the requirements for products and services	YES
8.3.2.1.4	operational risks (for example: new technology, ability and capacity to provide, short delivery time frame) have been identified? QM 8.2.2 Determining the requirements for products and services	YES
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? SOP 7.2 Customer related processed sec. 6.2.1	YES
8.3.3.2	Does the organization conduct a review before committing to supply products and services to the customer, including:	
8.3.3.2.1	requirements specified by the customer, including the requirements for delivery and post-delivery activities? QM 8.2.3 Review of the requirements for product and services	YES

8.3.3.2.2	requirements not stated by the customer, but necessary for the specified or intended use, when known? QM 8.2.3 Review of the requirements for product and services	YES
8.3.3.2.3	requirements specified by the organization? QM 8.2.3 Review of the requirements for products and services	YES
8.3.3.2.4	statutory and regulatory requirements applicable to the products and services? QM 8.2.3 Review ow the requirements for products and services	YES
8.3.3.2.5	contract or order requirements differing from those previously expressed? SOP 7.2 Customer related processes sec. 6.2.2	YES
8.3.3.3	Is this review coordinated with applicable functions of the organization? SOP 7.2 Customer Related Processed sec. 6.2.2	YES
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? SOP 7.1 Planning for Product Realization sec. 6.2.4	YES
8.3.3.5	Does the organization ensure that contract or order requirements differing from those previously defined are resolved? SOP 7.1 Planning for Product Realization sec. 6.2.4	YES
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? SOP 7.1 Planning for Product Realization sec. 6.2.4	YES
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? SOP 7.2 Customer Related Processes sec. 6.4 “records” sub. 6.4.2	YES
8.3.4	**Changes to Requirements for Products and Services**	
8.3.4.1	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? SOP 4.2.3 sec. 6.9 sub. Sec. 6.9.2	YES
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? QM 8.3 Design and Development of Product and Services	YES
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? QM 8.3 Design and Development of Product and Services	YES
8.4.1.3	Has the organization ensured, when required, that customer-designated or approved external providers, including process sources (for example: special	YES

	processes), are used? QM 8.3 Design and Development of Product and Services	
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)? QM 8.3 Design and Development of Product and Services	YES
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? QM 8.3 Design and Development of Product and Services	YES
8.4.1.6	Has the organization determined the controls to be applied to externally provided processes, products, and services when:	
8.4.1.6.1	products and services from external providers are intended for incorporation into the organization's own products and services? QM 8.3 Design and Development of Products and Services	YES
8.4.1.6.2	products and services are provided directly to the customer(s) by external providers on behalf of the organization? QM 8.3 Design and Development of Products and Services	YES
8.4.1.6.3	a process, or part of a process, is provided by an external provider as a result of a decision by the organization? QM 8.3 Design and Development of Products and Services	YES
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? QM 8.3 Design and Development of Products and Services	YES
8.4.1.8	Does the organization retain documented information of these activities and any necessary actions arising from the evaluations? QM 8.3 Design and Development of Products and Services *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.*	YES
8.4.1.9	Does the organization:	
8.4.1.9.1	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? SOP 7.5.1 Purchasing Process sec. 3.0 Responsibilities	YES
8.4.1.9.2	maintain a register of its external providers that includes approval status (for example: approved, conditional, disapproved) and the scope of the approval	YES

	(for example: product type, process family)? SOP 7.5.1 Purchasing Pocess sec. 6.0 Procedure	
8.4.1.9.3	periodically review external provider performance including process, product and service conformity, and on-time delivery performance? SOP 7.4.1 Purchasing Process sec. 6.3 approved supplier	YES
8.4.1.9.4	define the necessary actions to take when dealing with external providers that do not meet requirements? SOP 7.4.1 Purchasing Process sec. 6.4 Emergancy Suppliers	YES
8.4.1.9.5	define the requirements for controlling documented information created by and/or retained by external providers? SOP 7.4.1 Purchasing Process sec. 6.3.2	YES
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? QM 8.4.2 Type and Extent of Control	YES
8.4.2.2	Does the organization:	
8.4.2.2.1	ensure that externally provided processes remain within the control of its quality management system? QM 8.4.2 Type and Extent of Control	YES
8.4.2.2.2	define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output? QM 8.3 Type and Extent of Control *Note: When defining the controls, take into consideration:* *- 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 8.4.1.9.3).*	YES
8.4.2.2.3	determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements? QM 8.4.2 Type and Extent of Control	YES
8.4.2.3	Are verification activities of externally provided processes, products, and services performed according to the risks identified by the organization? QM 8.4.2 Type and Extent of Control	YES
8.4.2.4	Do these verification activities include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts? QM 8.4.2 Type and Extent of Control *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.*	YES

	NOTE 2: Verification activities can include: *- 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;* *- review of the required documentation;* *- review of production part approval process data;* *- inspection of products or verification of services upon receipt;* *- review of delegations of product verification to the external provider.*		
8.4.2.5	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? Product is never released prior to completion of all requirements QM 8.4.2 Type and Extent of Control *Audit Note: NA applies when product is never released prior to completion of all requirements.*		N/A
8.4.2.6	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? SOP 7.6 Control of Monitoring and Measuring Equipment sec. 6.2 Calibration Process *Audit Note: NA applies when the organization does not delegate.*	YES	
8.4.2.7	Does the organization periodically monitor the external provider's delegated verification activities? SOP 7.4.1 sec. 6.3 approved supplier sub sec. 6.3.2 *Audit Note: NA applies when the organization does not delegate.*	YES	
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? QM 8.4.3 Information for External Providers	YES	
8.4.3.2	Does the organization communicate to external providers its requirements for: *Audit Note: NA applies for the following sub-questions where there are no organizational requirements.*		
8.4.3.2.1	the processes, products, and services to be provided including the identification of relevant technical data (for example: specifications, drawings, process requirements, work instructions)? SOP 7.4.2 Purchasing Information sec. 6.0 Procedure	YES	
8.4.3.2.2	the approval of: - products and services; - methods, processes, and equipment; - the release of products and services? SOP 7.4.2 Purchasing Information sec. 6.0 Procedure	YES	

8.4.3.2.3	competence, including any required qualification of persons? QM 8.4.3 Information for External Providers	YES
8.4.3.2.4	the external providers' interactions with the organization? QM 8.4.3 Information for External Providers	YES
8.4.3.2.5	control and monitoring of the external providers' performance to be applied by the organization? QM 8.4.3 Information for External Providers	YES
8.4.3.2.6	verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises? QM 8.4.3 Information for External Providers	YES
8.4.3.2.7	special requirements, critical items, or key characteristics? QM 8.4.3 Information for External Providers	YES
8.4.3.2.8	test, inspection, and verification (including production process verification)? QM 8.4.3 Information for External Providers	YES
8.4.3.2.9	the use of statistical techniques for product acceptance and related instructions for acceptance by the organization? QM 8.4.3 Information for External Providers	YES
8.4.3.2.10	the need to: - implement a quality management system; - use customer-designated or approved external providers, including process sources (for example: special processes); - notify the organization of nonconforming processes, products, or services and obtain approval for their disposition; - prevent the use of counterfeit parts (see 8.1.1.3); - 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? QM 8.4.3 Information for External Providers	YES
8.4.3.2.11	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? QM 8.4.3 Information for External Providers	YES
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? SOP 7.5.1 Control of Production and Service Provision sec. 6.0 Procedure	YES
8.5.1.2	Do the controlled conditions include, as applicable:	

Audit Note: NA may apply for some of the following sub-questions, but not all.

8.5.1.2.1	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? SOP 7.5.1 Control of Products and Service Provision sec. sec. 6.2 Work Order *NOTE: Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts lists, materials, and process specifications.* 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.	YES
8.5.1.2.2	the availability and use of suitable monitoring and measuring resources? SOP 7.5.1 Control of Production and Service Provision	YES
8.5.1.2.3	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? SOP 7.5.1 Control of Production Service Provision sec. 6.2 Work Order	YES
8.5.1.2.4	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? SOP 7.5.1 Control of Production and Service Provision sec. 6.2 Work Order	YES
8.5.1.2.5	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)? SOP 7.5.1 Control of Production and Service Provision sec. 6.2 Work Order	YES
8.5.1.2.6	the use of suitable infrastructure and environment for the operation of processes? SOP 7.5.1 Control of Production and Service Provision *NOTE: Suitable infrastructure can include product specific tools (for example: jigs, fixtures, molds) and software programs.*	YES
8.5.1.2.7	the appointment of competent persons, including any required qualification? SOP 7.5.1 Control of Production and Service Provision	YES
8.5.1.2.8	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? SOP 7.5.1 Control of Production and Service Provision sec. 6.5 Chemical Laboratory	YES

NOTE: These processes can be referred to as special processes (see 8.5.3).

8.5.1.2.9	the establishment of criteria for workmanship (for example: written standards, representative samples, illustrations)? SOP 7.5.1 Control of Production and Service Provision SOP 7.5.1 Control of Production and Service Provision sec. 6.2 Work Order	YES
8.5.1.2.10	the accountability for all products during production (for example: parts quantities, split orders, nonconforming product)? SOP 7.5.1 Control of Production and Service Provision sec. 6.0 sub sec. 6.2.4 split order quantities	YES
8.5.1.2.11	the control and monitoring of identified critical items, including key characteristics, in accordance with established processes? SOP 7.5.1 Control of Production and Service Provision sec. 6.2 Work Order	YES
8.5.1.2.12	the determination of methods to measure variable data (for example: tooling, on-machine probing, inspection equipment)? SOP 7.5.1 Control of Production and Service Provision sec 6.2 Work Order	YES
8.5.1.2.13	the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages? SOP 7.5.1 Control of Production and Service Provision sec. 6.2 Work Order	YES
8.5.1.2.14	the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized? SOP 4.2.4 Control of Records, sec. 6.3 Legibility, Storage and Retention	YES
8.5.1.2.15	the provision for the prevention, detection, and removal of foreign objects? SOP 7.5.1 Control of Production and Service Provision sec. 6.3	YES
8.5.1.2.16	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)? SOP 7.5.1 Control of Production and Service Provision sec. 6.3	YES
8.5.1.2.17	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? Product is not released pending completion	NA
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? SOP 7.5.1 Control of Procuction and Service Provision sec. 7.2	YES
8.5.2.2	Are storage requirements defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks? SOP 7.5.1 Control of Production and Service Provision sec. 7.2	YES

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:	
8.5.3.1.1	definition of criteria for the review and approval of the processes? QM 8.5.1.2 Validation and Control of Special Processes	YES
8.5.3.1.2	determination of conditions to maintain the approval? QM 8.5.1.2 Validation and Control of Special Processes	YES
8.5.3.1.3	approval of facilities and equipment? QM 8.5.1.2 Validation and Control of Special Processes *Audit Note: NA applies when special process requirements do not have a requirement for specific approvals.*	YES
8.5.3.1.4	qualification of persons? QM 8.5.1.2 Validation and Control of Special Processes *Audit Note: NA applies when the special process(es) does not have industry or customer requirements.*	YES
8.5.3.1.5	use of specific methods and procedures for implementation and monitoring the processes? QM 8.5.1.2 Validation and Control of Special Processes	YES
8.5.3.1.6	requirements for documented information to be retained? QM 8.5.1.2 Validation and Control of Special Processes	YES
8.5.4	**Production Process Verification, Including Control of Changes**	
8.5.4.1	Has the organization implemented production process verification activities to ensure the production process is able to produce products that meet requirements, , including when changed? QM 8.5.1.3 Production Process Verification *NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans*	YES
8.5.4.2	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? QM 8.5.1.3 Production Process Verification *NOTE: This activity can be referred to as First Article Inspection (FAI).* *Audit Note: NA applies when not required by the customer.*	YES
8.5.4.3	Is this activity repeated when changes occur that invalidate the original results? QM 8.5.1.3 Production Process Verification *NOTE: Production or service provision changes can include engineering changes or the changes affecting processes, production equipment, tools, or software programs.*	YES

Audit Note: NA applies when not required by the customer.

8.5.4.4	Are persons authorized to approve production or service provision changes identified? SOP 7.1 Planning for Product Realization sec. 3.0 Responsibilities	YES	
8.5.4.5	Does the organization retain documented information on the results of production process verification? SOP 4.2.4 Control of Records sec. 6.3 Legibility, Storage and Retrieval	YES	
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? QM 8.5.2 Identification and Traceability	YES	
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? QM 8.5.2 Identification and Traceability	YES	
8.5.5.3	Does the organization identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision? QM 8.5.2 Identification and Traceability	YES	
8.5.5.4	When acceptance authority media are used (for example: stamps, electronic signatures, passwords), does the organization establish controls for the media? Acceptance Media is not used *Audit Note: NA applies when media is not used.*		N/A
8.5.5.5	Does the organization control the unique identification of the outputs when traceability is a requirement, and retain the documented information necessary to enable traceability? QM 8.5.2 Identification and Traceability *NOTE: Traceability requirements can include:* - *the identification to be maintained throughout the product life;* - *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);* - *for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;* - *for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.*	YES	
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? QM 8.5.3 Property Belonging to Customers or External Providers	YES	
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? QM 8.5.3 Property Belonging to Customers or External Providers	YES	

8.5.6.3	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? QM 8.5.3 Property Belonging to Customers or External Providers *NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property, and personal data.*	YES
8.5.7	**Preservation**	
8.5.7.1	Does the organization preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements? QM 8.5.4 Preservation *NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.*	YES
8.5.7.2	Does preservation of outputs include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for: *Audit Note: NA applies to the sub-questions when there is no requirement.*	
8.5.7.2.1	cleaning? QM 8.5.4 Preservation	YES
8.5.7.2.2	prevention, detection, and removal of foreign objects? QM 8.5.4 Preservation	YES
8.5.7.2.3	special handling and storage for sensitive products? QM 8.5.4 Preservation	YES
8.5.7.2.4	marking and labeling, including safety warnings and cautions? QM 8.5.4 Preservation	YES
8.5.7.2.5	shelf life control and stock rotation? QM 8.5.4 Preservation	YES
8.5.7.2.6	special handling and storage for hazardous materials? QM 8.5.4 Preservation	YES

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? QM 8.6 Release of Products and Services	YES
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? QM 8.6 Release of Products and Services	YES
8.6.3	Does the organization retain documented information on the release of products and services? QM 8.6 Release of Products and Services	YES
8.6.4	Does the documented information include:	
8.6.4.1	evidence of conformity with the acceptance criteria? QM 8.6 Release of Products and Services	YES
8.6.4.2	traceability to the person(s) authorizing the release? QM .6 Release of Products and Services	YES

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? QM 8.6 Release of Products and Services	YES
8.6.6	Does the organization ensure that all documented information required to accompany the products and services are present at delivery? QM 8.6 Release of Products and Services	YES
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? SOP 8.3 Control of Nonconforming Product sec. 6.0 Procedure sub sec. 6.1.1.2 *NOTE: The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.*	YES
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? SOP 8.3 Control on Nonconforming Product sec. 6.0 sub sec. 6.1.1.1	YES
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? SOP 8.3 Control of Nonconforming Product sec 6.0	YES
8.7.4	Is the organization's nonconformity control process maintained as documented information including the provisions for:	
8.7.4.1	defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions? SOP 8.3 Control of Nonconforming Product sec. 3.0 Responsibilities	YES
8.7.4.2	taking actions necessary to contain the effect of the nonconformity on other processes, products, or services? SOP 8.3 Control of Nonconforming Product sec. 6.2 In Process Inspection	YES

8.7.4.3	timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties? QM 8.7 Control of Nonconforming Product sec. 8.7.1	YES		
8.7.4.4	defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2)? SOP 8.3 Control of Nonconforming Product sec. 6.5 sub sec. 6.5.3 *NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.*	YES		
8.7.5	Does the organization deal with nonconforming outputs in one or more of the following ways: - correction; - segregation, containment, return, or suspension of provision of products and services; - informing the customer; - obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer? QM 8.7 Control of Nonconforming Product sec. 8.7.1	YES		
8.7.6	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? SOP 8.3 Control of Nonconforming Product sec. 6.6 Concessions or Deviation *Audit Note: NA is allowable when dispositions of use-as-is or repair are prohibited either internally or by customer.*			N/A
8.7.7	Is product dispositioned for scrap conspicuously and permanently marked, or positively controlled, until physically rendered unusable or returned to the customer? SOP 7.5.1 Control of Nonconforming Product sec. 6.3.5	YES		
8.7.8	Are counterfeit, or suspect counterfeit, parts controlled to prevent reentry into the supply chain? SOP 8.3 Control of Nonconforming Product sec. 6.6 Concessions or Deviation sub. 6.6.3	YES		
8.7.9	Does the organization ensure that conformity to the requirements are verified when nonconforming outputs are corrected? SOP 8.3 Control of Nonconforming Product sec. 6.2 In-process Inspection sub sec. 6.2.2	YES		
8.7.10	Does the organization retain documented information that:			
8.7.10.1	describes the nonconformity? SOP 8.3 Control of Nonconforming Product sec. 7.0 Records	YES		
8.7.10.2	describes the actions taken? SOP 8.3 Control of Nonconforming Product sec. 7.0 Records	YES	NO	
8.7.10.3	describes any concessions obtained? SOP 8.3 Control of Nonconforming Product sec. 6.6 Concessions or Deviation	YES		

8.7.10.4	identifies the authority deciding the action in respect of the nonconformity? QM 8.7 Control of Nonconforming Product sec. 8.7.2	YES
9.	**PERFORMANCE EVALUATION**	
9.1	**Monitoring, Measurement, Analysis, and Evaluation**	
9.1.1	Does the organization determine:	
9.1.1.1	what needs to be monitored and measured? QM 9.1 Monitoring, Measurment, Analysis, and Evaluation	YES
9.1.1.2	the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results? QM 9.1 Monitoring, Measurement, Analysis, and Evaluation	YES
9.1.1.3	when the monitoring and measuring shall be performed? QM 9 Performance Evaluation, sec. 9.1.1 General	YES
9.1.1.4	when the results from monitoring and measurement shall be analyzed and evaluated? QM 9 Performance Evaluation sec. 9.1.1	YES
9.1.2	Does the organization evaluate the performance and the effectiveness of the quality management system? QM 9 Performance Evaluation, sec. 9.1.1 General	YES
9.1.3	Does the organization retain appropriate documented information as evidence of the results? QM 9.0 Performannce Evaluation sec. 9.1.1 General	YES
9.2	**Internal Audit**	
9.2.1	Does the organization conduct internal audits at planned intervals to provide information on whether the quality management system:	
9.2.1.1	conforms to the organization's own requirements for its quality management system and the requirements of this checklist? QM 9.2 Internal Audit sec. 9.2.1 *NOTE: The organization's own requirements should include customer and applicable statutory and regulatory quality management system requirements.*	YES
9.2.1.2	is effectively implemented and maintained? QM 9.2 sec. 9.2.1 *NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.*	YES
9.2.2	Does the organization:	
9.2.2.1	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? SOP 8.2.2 Internal Auditing sec. 6.0 Procedure	YES

9.2.2.2	define the audit criteria and scope for each audit? SOP 8.2.2 Internal Auditing sec. 6.0 Procedure sec. 6.1.2	YES
9.2.2.3	select auditors and conduct audits to ensure objectivity and the impartiality of the audit process? SOP 8.2.2 Internal Audit sec. 6.1.5	YES
9.2.2.4	ensure that the results of the audits are reported to relevant management? SOP 8.2.2 Internal Auditing sec. 6.4 Conducting the Audit sub sec. 6.4.3	YES
9.2.2.5	take appropriate correction and corrective actions without undue delay? SOP 8.2.2 Internal Auditing sec. 6.5 Audit findings	YES
9.2.2.6	retain documented information as evidence of the implementation of the audit program and the audit results? SOP 8.2.2 Internal Auditing sec. 6.8 Records	YES
	NOTE: See ISO 19011 for guidance.	
9.3	**Management Review**	
9.3.1	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? QM 9.3 Management Review sec. 9.3.1 General	YES
9.3.2	**Management Review Inputs**	
9.3.2.1	Is the management review planned and carried out taking into consideration:	
9.3.2.1.1	the status of actions from previous management reviews?QM 9.3.2 Managements Review Inputs	YES
9.3.2.1.2	changes in external and internal issues that are relevant to the quality management system? QM 9.3.2 Management Review Inputs	YES
9.3.2.1.3	information on the performance and effectiveness of the quality management system? QM 9.3.2 Management Review Inputs	YES
9.3.2.1.4	opportunities for improvement? QM 9.3.2 Management Review Inputs	YES
9.3.2.1.5	adequacy of resources? QM 9.3.2 Management Review Inputs	YES
9.3.2.1.6	the continuing adequacy and suitability of the quality policy and quality objectives? QM 9.3.2 Management Review Inputs	YES
9.3.3	**Management Review Outputs**	
9.3.3.1	Do the outputs of the management review include decisions and actions related to:	
9.3.3.1.1	opportunities for improvement? QM 9.3.3 Management Review Outputs	YES
9.3.3.1.2	any need for changes to the quality management system? QM 9.3.3 Management Review Outputs	YES
9.3.3.1.3	other actions? QM 9.3.3 Management Review Outputs	YES

9.3.3.2	Does the organization retain documented information as evidence of the results of management reviews? QM 9.3.3 Management Review Outputs	YES
10.	**IMPROVEMENT**	
10.1	**General**	
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? QM 10 sec. 10.1 General *NOTE: These may include:* - *improving products and services to meet requirements as well as to address future needs and expectations;* - *correcting, preventing, or reducing undesired effects;* - *improving the performance and effectiveness of the quality management system.* *NOTE: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation, and reorganization.*	YES
10.2	**Nonconformity and Corrective Action**	
10.2.1	When a nonconformity occurs, including any arising from complaints, does the organization:	
10.2.1.1	react to the nonconformity and, as applicable, take action to control and correct it and deal with the consequences? QM 10.2 Nonconformity and Corrective Action sec. 10.2.1	YES
10.2.1.2	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? QM 10.2 Nonconformity and Corrective Action sec. 10.2.1	YES
10.2.1.3	implement any action needed? QM 10.2 Nonconformity and Corrective Action sec. 10.2.1	YES
10.2.1.4	review the effectiveness of any corrective action taken? QM 10.2 Nonconformity and Corrective Action	YES
10.2.1.5	make changes to the quality management system, if necessary? QM 10.2 Nonconformity and Corrective Action	YES
10.2.1.6	flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity? QM 10.2 Nonconformity and Corrective Action	YES
10.2.1.7	take specific actions when timely and effective corrective actions are not achieved? QM 10.2 Nonconformity and Corrective Action	YES

10.2.2	Are corrective actions appropriate to the effects of the nonconformities encountered? QM 10.2 Nonconformity and Corrective Action	YES
10.2.3	Does the organization maintain documented information that defines the nonconformity and corrective action management processes? QM 10.2 Nonconformity and Corrective Action	YES

10.2.4	Does the organization retain documented information as evidence of:	
10.2.4.1	the nature of the nonconformities and any subsequent actions taken? QM 10.2 Nonconformity and Corrective Action	YES
10.2.4.2	the results of any corrective action? QM 10.2 Nonconformity and Corrective Action	YES