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AUDIT CRITERIA

AC7004 REV F Δ1

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Superseding AC7004 Rev E

Nadcap
AUDIT CRITERIA FOR
QUALITY MANAGEMENT SYSTEM

TO BE USED ON AUDITS STARTING ON OR AFTER 31-DEC-2017

1. SCOPE

This audit criteria (AC) is to be used to verify compliance with Nadcap 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, AS/EN/JISQ 9100 or AS/EN 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 AS/EN/JISQ 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 make the self-audit available to the assigned auditor 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 – Public Documents – Aerospace Quality System – Word Copies of Checklist

There is an Audit Handbook available for the AQS AC7004 checklist. Resources – Documents – Public Documents – 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 _____

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 _____

3.1.1 Audit Contacts

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

NAME	TITLE

3.2 Approvals (Quality System, Subscriber, Other)

Certifying Agency	Approval Criteria	Certificate Issue Date	Certificate Expiration Date

3.3	**Verification**			
3.3.1	Did the Auditee make a copy of their completed self-audit available to the auditor at least 30 days prior to the audit date - 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	NO	
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	NO	
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**.*	YES	NO	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.*	YES	NO	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	NO	NA

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	Does the organization monitor and review information about these external and internal issues? *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	NO
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?	YES	NO
4.2.1.2	the requirements of these interested parties that are relevant to the quality management system?	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	When determining this scope, has the organization considered:		
4.3.2.1	the external and internal issues referred to in 4.1.1?	YES	NO
4.3.2.2	the requirements of relevant interested parties referred to in 4.2.1.2?	YES	NO
4.3.2.3	the products and services of the organization?	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

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? *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	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:		
4.4.3.1	determined the processes needed for the quality management system and their application throughout the organization?	YES	NO
4.4.3.2	determined the inputs required and the outputs expected from these processes?	YES	NO
4.4.3.3	determined the sequence and interaction of these processes?	YES	NO
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?	YES	NO
4.4.3.5	determined the resources needed for these processes and ensure their availability?	YES	NO
4.4.3.6	assigned the responsibilities and authorities for these processes?	YES	NO
4.4.3.7	addressed the risks and opportunities as determined in accordance with the requirements of 6.1?	YES	NO
4.4.3.8	evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results?	YES	NO
4.4.3.9	improved the processes and the quality management system?	YES	NO
4.4.4	To the extent necessary, does the organization:		
4.4.4.1	maintain documented information to support the operation of its processes?	YES	NO

4.4.4.2	retain documented information to have confidence that the processes are being carried out as planned?	YES	NO
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? *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.*	YES	NO
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?	YES	NO
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?	YES	NO
5.1.1.3	ensuring the integration of the quality management system requirements into the organization's processes?	YES	NO
5.1.1.4	ensuring that the resources needed for the quality management system are available?	YES	NO
5.1.1.5	communicating the importance of effective quality management and of conforming to the quality management system requirements?	YES	NO
5.1.1.6	ensuring that the quality management system achieves its intended results?	YES	NO
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?	YES	NO
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?	YES	NO

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?	YES	NO
5.3.1.1.2	provides a framework for setting quality objectives?	YES	NO
5.3.1.1.3	includes a commitment to satisfy applicable requirements?	YES	NO
5.3.1.1.4	includes a commitment to continual improvement of the quality management system?	YES	NO
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?	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:		
5.4.2.1	ensuring that the quality management system conforms to the requirements of this checklist?	YES	NO
5.4.2.2	ensuring that the processes are delivering their intended outputs?	YES	NO
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?	YES	NO
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?	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? *NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.*	YES	NO
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?	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:		
6.2.2.1	consistent with the quality policy?	YES	NO
6.2.2.2	measurable?	YES	NO
6.2.2.3	taking into account applicable requirements?	YES	NO
6.2.2.4	relevant to conformity of products and services and to enhancement of customer satisfaction?	YES	NO
6.2.2.5	monitored?	YES	NO
6.2.2.6	communicated?	YES	NO
6.2.2.7	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**

When the organization determines the need for changes to the quality management system, are they changes carried out in a planned manner (see 4.4)? YES NO

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.

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? YES NO

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? YES NO

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? YES NO

NOTE: Infrastructure can include: buildings and associated utilities; equipment, including hardware and software; transportation resources; information and communication technology.

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? YES NO

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?	YES	NO
7.5.1.2	are maintained to ensure their continuing suitability for their purpose?	YES	NO
7.5.1.3	Does the organization retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources?	YES	NO
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?	YES	NO
7.6.1.2	identified in order to determine their status?	YES	NO
7.6.1.3	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? *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	NO
7.6.4	Is calibration or verification of monitoring and measuring equipment carried out under suitable environmental conditions (see 7.4.1)?	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:		
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?	YES	NO
7.7.1.2	ensure that these persons are competent on the basis of appropriate education, training, or experience?	YES	NO
7.7.1.3	where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken?	YES	NO
7.7.1.4	retain appropriate documented information as evidence of competence?	YES	NO
	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.		
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?	YES	NO
7.8.1.2	relevant quality objectives?	YES	NO
7.8.1.3	their contribution to the effectiveness of the quality management system, including the benefits of improved performance?	YES	NO
7.8.1.4	the implications of not conforming with the quality management system requirements?	YES	NO
7.8.1.5	relevant quality management system documented information and changes?	YES	NO
7.8.1.6	their contribution to product or service conformity?	YES	NO
7.8.1.7	their contribution to product safety?	YES	NO
7.8.1.8	the importance of ethical behavior?	YES	NO
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?	YES	NO	
7.9.1.1.2	documented information determined by the organization as being necessary for the effectiveness of the quality management system?	YES	NO	
	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.*			
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)?	YES	NO	
7.9.2.1.2	format (for example: language, software version, graphics) and media (for example: paper, electronic)?	YES	NO	
7.9.2.1.3	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:			
7.9.3.1.1	it is available and suitable for use, where and when it is needed?	YES	NO	
7.9.3.1.2	it is adequately protected (for example: from loss of confidentiality, improper use, or loss of integrity)?	YES	NO	
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?	YES	NO	
7.9.3.2.2	storage and preservation, including preservation of legibility?	YES	NO	
7.9.3.2.3	control of changes (for example: version control)?	YES	NO	
7.9.3.2.4	retention and disposition?	YES	NO	
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?	YES	NO	
7.9.3.3	When documented information is managed electronically, are data protection processes defined (for example: protection from loss,	YES	NO	NA

	unauthorized changes, unintended alteration, corruption, physical damage)? *Audit Note: NA would apply if there is no electronic information.*		
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
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?	YES	NO
8.1.1.2	establishing criteria for the processes and the acceptance of products and services? *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	NO
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?	YES	NO
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?	YES	NO
8.1.1.5	implementing control of the processes in accordance with the criteria as established in 8.1.1.2?	YES	NO
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?	YES	NO

8.1.1.7	determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified?	YES	NO	
8.1.1.8	engaging representatives of affected organization functions for operational planning and control?	YES	NO	
8.1.1.9	determining the products and services to be obtained from external providers?	YES	NO	
8.1.1.10	establishing the controls needed to prevent the delivery of nonconforming products and services to the customer?	YES	NO	
8.1.2	Is the output of this planning suitable for the organization's operations?	YES	NO	
	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.			
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	Does the organization ensure that outsourced processes are controlled (see 8.4)?	YES	NO	NA
	Audit Note: NA applies when no processes are outsourced.			
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	
8.1.6	Does the process ensure that work transfer impacts and risks are managed?	YES	NO	
	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.			
8.2	**Configuration Management**			
	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?	YES	NO	
	Does this process:			
8.2.2.1	control product identity and traceability to requirements, including the implementation of identified changes?	YES	NO	

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?	YES	NO
8.3	**Requirements for Products and Services**		
8.3.1	**Customer Communication**		
8.3.1.1	Does communication with customers include:		
8.3.1.1.1	providing information relating to products and services?	YES	NO
8.3.1.1.2	handling enquiries, contracts, or orders, including changes?	YES	NO
8.3.1.1.3	obtaining customer feedback relating to products and services, including customer complaints?	YES	NO
8.3.1.1.4	handling or controlling customer property?	YES	NO
8.3.1.1.5	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:		
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?	YES	NO
8.3.2.1.2	the organization can meet the claims for the products and services it offers?	YES	NO
8.3.2.1.3	special requirements of the products and services are determined?	YES	NO
8.3.2.1.4	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:		
8.3.3.2.1	requirements specified by the customer, including the requirements for delivery and post-delivery activities?	YES	NO
8.3.3.2.2	requirements not stated by the customer, but necessary for the specified or intended use, when known?	YES	NO
8.3.3.2.3	requirements specified by the organization?	YES	NO

8.3.3.2.4	statutory and regulatory requirements applicable to the products and services?	YES	NO
8.3.3.2.5	contract or order requirements differing from those previously expressed?	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
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?	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:		
8.4.1.6.1	products and services from external providers are intended for incorporation into the organization's own products and services?	YES	NO
8.4.1.6.2	products and services are provided directly to the customer(s) by external providers on behalf of the organization?	YES	NO
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?	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? *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	NO
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?	YES	NO
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 (for example: product type, process family)?	YES	NO
8.4.1.9.3	periodically review external provider performance including process, product and service conformity, and on-time delivery performance?	YES	NO
8.4.1.9.4	define the necessary actions to take when dealing with external providers that do not meet requirements?	YES	NO
8.4.1.9.5	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:			
8.4.2.2.1	ensure that externally provided processes remain within the control of its quality management system?	YES	NO	
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? *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	NO	
8.4.2.2.3	determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements?	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 is high risk of nonconformities including counterfeit parts? *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.* *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.*	YES	NO	
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	YES	NO	NA

	to allow recall and replacement if it is subsequently found that the product does not meet requirements? *Audit Note: NA applies when product is never released prior to completion of all requirements.*			
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? *Audit Note: NA applies when the organization does not delegate.*	YES	NO	NA
8.4.2.7	Does the organization periodically monitor the external provider's delegated verification activities? *Audit Note: NA applies when the organization does not delegate.*	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	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)?	YES	NO	
8.4.3.2.2	the approval of: - products and services; - methods, processes, and equipment; - the release of products and services?	YES	NO	
8.4.3.2.3	competence, including any required qualification of persons?	YES	NO	NA
8.4.3.2.4	the external providers' interactions with the organization?	YES	NO	NA
8.4.3.2.5	control and monitoring of the external providers' performance to be applied by the organization?	YES	NO	NA
8.4.3.2.6	verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises?	YES	NO	NA
8.4.3.2.7	special requirements, critical items, or key characteristics?	YES	NO	NA
8.4.3.2.8	test, inspection, and verification (including production process verification)?	YES	NO	NA
8.4.3.2.9	the use of statistical techniques for product acceptance and related instructions for acceptance by the organization?	YES	NO	NA

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?	YES	NO
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?	YES	NO
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	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? *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	NO
8.5.1.2.2	the availability and use of suitable monitoring and measuring resources?	YES	NO
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?	YES	NO

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?	YES	NO	
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)?	YES	NO	NA
8.5.1.2.6	the use of suitable infrastructure and environment for the operation of processes? *NOTE: Suitable infrastructure can include product specific tools (for example: jigs, fixtures, molds) and software programs.*	YES	NO	
8.5.1.2.7	the appointment of competent persons, including any required qualification?	YES	NO	
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? *NOTE: These processes can be referred to as special processes (see 8.5.3).*	YES	NO	
8.5.1.2.9	the establishment of criteria for workmanship (for example: written standards, representative samples, illustrations)?	YES	NO	
8.5.1.2.10	the accountability for all products during production (for example: parts quantities, split orders, nonconforming product)?	YES	NO	
8.5.1.2.11	the control and monitoring of identified critical items, including key characteristics, in accordance with established processes?	YES	NO	NA
8.5.1.2.12	the determination of methods to measure variable data (for example: tooling, on-machine probing, inspection equipment)?	YES	NO	NA
8.5.1.2.13	the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages?	YES	NO	NA
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?	YES	NO	
8.5.1.2.15	the provision for the prevention, detection, and removal of foreign objects?	YES	NO	

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)?	YES	NO	NA
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?	YES	NO	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?	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:			
8.5.3.1.1	definition of criteria for the review and approval of the processes?	YES	NO	
8.5.3.1.2	determination of conditions to maintain the approval?	YES	NO	
8.5.3.1.3	approval of facilities and equipment? *Audit Note: NA applies when special process requirements do not have a requirement for specific approvals.*	YES	NO	NA
8.5.3.1.4	qualification of persons? *Audit Note: NA applies when the special process(es) does not have industry or customer requirements.*	YES	NO	NA
8.5.3.1.5	use of specific methods and procedures for implementation and monitoring the processes?	YES	NO	
8.5.3.1.6	requirements for documented information to be retained?	YES	NO	
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? *NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans*	YES	NO	

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? *NOTE: This activity can be referred to as First Article Inspection (FAI).* *Audit Note: NA applies when not required by the customer.*	YES	NO	NA
8.5.4.3	Is this activity repeated when changes occur that invalidate the original results? *NOTE: Production or service provision changes can include engineering changes or the changes affecting processes, production equipment, tools, or software programs.* *Audit Note: NA applies when not required by the customer.*	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? *Audit Note: NA applies when media is not used.*	YES	NO	NA
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? *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);*	YES	NO	

- *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.*

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	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? *NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property, and personal data.*	YES	NO	
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? *NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.*	YES	NO	
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?	YES	NO	NA
8.5.7.2.2	prevention, detection, and removal of foreign objects?	YES	NO	
8.5.7.2.3	special handling and storage for sensitive products?	YES	NO	NA
8.5.7.2.4	marking and labeling, including safety warnings and cautions?	YES	NO	NA
8.5.7.2.5	shelf life control and stock rotation?	YES	NO	NA
8.5.7.2.6	special handling and storage for hazardous materials?	YES	NO	NA

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:		
8.6.4.1	evidence of conformity with the acceptance criteria?	YES	NO
8.6.4.2	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? *NOTE: The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.*	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:		
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?	YES	NO
8.7.4.2	taking actions necessary to contain the effect of the nonconformity on other processes, products, or services?	YES	NO

8.7.4.3	timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties?	YES	NO	
8.7.4.4	defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2)? *NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.*	YES	NO	
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?	YES	NO	
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? *Audit Note: NA is allowable when dispositions of use-as-is or repair are prohibited either internally or by customer.*	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:			
8.7.10.1	describes the nonconformity?	YES	NO	
8.7.10.2	describes the actions taken?	YES	NO	
8.7.10.3	describes any concessions obtained?	YES	NO	
8.7.10.4	identifies the authority deciding the action in respect of the nonconformity?	YES	NO	

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?	YES	NO
9.1.1.2	the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results?	YES	NO
9.1.1.3	when the monitoring and measuring shall be performed?	YES	NO
9.1.1.4	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
9.1.3	Does the organization retain appropriate documented information as evidence of the results?	YES	NO
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? *NOTE: The organization's own requirements should include customer and applicable statutory and regulatory quality management system requirements.*	YES	NO
9.2.1.2	is effectively implemented and maintained? *NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.*	YES	NO
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?	YES	NO
9.2.2.2	define the audit criteria and scope for each audit?	YES	NO
9.2.2.3	select auditors and conduct audits to ensure objectivity and the impartiality of the audit process?	YES	NO

9.2.2.4	ensure that the results of the audits are reported to relevant management?	YES	NO
9.2.2.5	take appropriate correction and corrective actions without undue delay?	YES	NO
9.2.2.6	retain documented information as evidence of the implementation of the audit program and the audit results?	YES	NO
	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?	YES	NO
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?	YES	NO
9.3.2.1.2	changes in external and internal issues that are relevant to the quality management system?	YES	NO
9.3.2.1.3	information on the performance and effectiveness of the quality management system?	YES	NO
9.3.2.1.4	opportunities for improvement?	YES	NO
9.3.2.1.5	adequacy of resources?	YES	NO
9.3.2.1.6	the continuing adequacy and suitability of the quality policy and quality objectives?	YES	NO
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?	YES	NO
9.3.3.1.2	any need for changes to the quality management system?	YES	NO
9.3.3.1.3	other actions?	YES	NO
9.3.3.2	Does the organization retain documented information as evidence of the results of management reviews?	YES	NO

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? *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	NO

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?	YES	NO
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?	YES	NO
10.2.1.3	implement any action needed?	YES	NO
10.2.1.4	review the effectiveness of any corrective action taken?	YES	NO
10.2.1.5	make changes to the quality management system, if necessary?	YES	NO
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?	YES	NO
10.2.1.7	take specific actions when timely and effective corrective actions are not achieved?	YES	NO
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:		
10.2.4.1	the nature of the nonconformities and any subsequent actions taken?	YES	NO
10.2.4.2	the results of any corrective action?	YES	NO