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AUDIT CRITERIA

AC7004 REV. E

Issued July 1996

Revised September 2010

Superseding AC7004 Rev D

TO BE USED ON AUDITS CONDUCTED ON OR AFTER JANUARY 1, 2011

QUALITY MANAGEMENT SYSTEM
Requirements for Nadcap Accreditation

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 SAE AS7003, approval to AC7004 will be granted. Approval to PRI AC7004 shall not be granted unless supported by at least one Nadcap commodity accreditation.

The scope of this checklist does not include quality system requirements for design and development. The numbers within the parenthesis are references to the paragraph found within AS 9100C.

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.

The list of procedures provided by the organization must be verified by the auditor at the time of the audit. Any corrections or updates to the list must be identified using notes, inserted at the applicable criterion.

All negative responses require an NCR or explanation. All N/A responses must be explained.

The audit results 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 should complete a self-audit using this checklist in preparation for this audit. All internally identified nonconformances should be corrected prior to the actual audit. All “NO” and “N/A” answers must be explained. 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.

The organization should forward the following (and subsequent revisions) as instructed by PRI 30 days prior to the scheduled audit:

a. AC7004 completed by organization during a self-audit in preparation for this audit.
b. Quality control manual (uncontrolled copy which PRI will return or destroy as specified by organization)
c. List of quality department personnel
d. List of current quality systems approvals (by primes, registrars, etc)
e. List of procedures (index/table of contents only)

2.2.2 During the Audit

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

Working space for the auditor with desks or tables, chairs, telephone, etc. Clerical, typing and reproduction services are to be provided as required. This is not a full time assignment.

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 proposed corrective action or to provide any additional information. NOTE: The Nadcap 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.

2.2.3 Following the Audit

The auditor will advise the organization when the audit report will be eligible for review and when the corrective action will be due. 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.

The organization has 21 days from the audit submittal date to submit corrective action for each Nonconformance Report (NCR). This response shall be submitted as instructed by the auditor. If there are zero (0) nonconformances found during the audit, the organization has 3 days from the audit submittal date to complete and submit the Supplier Feedback form in eAuditNet.

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.

PRI Staff or the Task Group may, after review of your audit report, require additional information from you 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 Contacts for the Audit (Name/Title)

Name	Title

3.2 QUALITY SYSTEM APPROVALS

Identify any current approvals related to quality system compliance with AS9100 or other Quality Standards.

Auditing/Certifying Agency	Audit Criteria	Certificate Issue Date	Certificate Expiration Date

3.3 VERIFICATION OF CORRECTIVE ACTIONS

Have corrective actions from the previous audit been verified and found to be effective? YES NO NA

3.4 SCOPE OF THE AUDIT / RELATED AUDITS

Complete the following table for all audits conducted concurrently, and supported by this Quality Systems Audit. For each audit, indicate if this was an initial audit or re-accreditation audit, and enter the current audit number.

Commodity	Audit Number	Audit Date	Audit Type

If Other, Please Describe.

_____

4.1 General requirements

4.1.1	(4.1) The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this Checklist.	**YES**	**NO**
4.1.2	(4.1) The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.	**YES**	**NO**

4.2 Documentation Requirements

4.2.1 General

4.2.1.1	(4.2.1) The quality management system documentation shall include: a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures and records required by this Checklist, and d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.	**YES**	**NO**
4.2.1.2	(4.2.1) The organization shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes. NOTE 1 Where the term "documented procedure" appears within this Checklist, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document. NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to: a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. NOTE 3 The documentation can be in any form or type of medium.	**YES**	**NO**

4.2.2 Quality Manual

4.2.2.1	(4.2.2) The organization shall establish and maintain a quality manual that includes: a) the scope of the quality management system, b) the documented procedures established for the quality management system, or reference to them.	**YES**	**NO**

4.2.3 Control of Documents

4.2.3.1	(4.2.3) Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.	**YES**	**NO**

4.2.3.2	(4.2.3) A documented procedure shall be established to define the controls needed: a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.	**YES**	**NO**
4.2.4	**Control of Records**		
4.2.4.1	(4.2.4) Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.	**YES**	**NO**
4.2.4.2	(4.2.4) The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.	**YES**	**NO**
4.2.4.3	(4.2.4) The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.	**YES**	**NO**
4.2.4.4	(4.2.4) Records shall remain legible, readily identifiable and retrievable.	**YES**	**NO**
5.0	**Management Responsibility**		
5.1	**Management Commitment**		
5.1.1	(5.1) Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by: a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) conducting management reviews, and c) ensuring the availability of resources.	**YES**	**NO**
5.2	**Responsibility and Authority**		
5.2.1	(5.5.1) Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.	**YES**	**NO**
5.3	**Management Representative**		
5.3.1	(5.5.2) Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes: a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) 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**

5.4	**Management Review**		
5.4.1	(5.6.1) Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.	**YES**	**NO**
5.4.2	(5.6.1) Records from management reviews shall be maintained (see 4.2.4).	**YES**	**NO**
6.0	**Resource Management**		
6.1	**Provision of Resources**		
6.1.1	(6.1) The organization shall determine and provide the resources needed: a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.	**YES**	**NO**
6.2	**Human Resources**		
6.2.1	(6.2.1) Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.	**YES**	**NO**
6.3	**Competence, Training and Awareness**		
6.3.1	(6.2.2) The organization shall: a) determine the necessary competence for personnel performing work affecting conformity to product requirements, b) where applicable, provide training or take other actions to achieve the necessary competence, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4).	**YES**	**NO**
6.4	**Work Environment**		
6.4.1	(6.4) The organization shall determine and manage the work environment needed to achieve conformity to product requirements. NOTE The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather).	**YES**	**NO**
7.0	**Product Realization**		
7.1	**Planning of Product Realization**		
7.1.1	(7.1) The organization shall plan and develop the processes needed for product realization.	**YES**	**NO**

7.1.2	(7.1) In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents, and to provide resources specific to the product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4); e) configuration management appropriate to the product;	**YES**	**NO**
7.2	**Customer-Related Processes**		
7.2.1	**Determination of Requirements Related to the Product**		
7.2.1.1	(7.2.1) The organization shall determine: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements considered necessary by the organization.	**YES**	**NO**
7.2.2	**Review of Requirements Related to the Product**		
7.2.2.1	(7.2.2) The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that: a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, c) the organization has the ability to meet the defined requirements, d) special requirements of the product are determined, and e) risks (e.g., new technology, short delivery time frame) have been identified.	**YES**	**NO**
7.2.2.2	(7.2.2) Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	**YES**	**NO**
7.2.2.3	(7.2.2) Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.	**YES**	**NO**
7.2.2.4	(7.2.2) Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	**YES**	**NO**
7.3	**Purchasing**		
7.3.1	**Purchasing Process**		
7.3.1.1	(7.4.1) The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.	**YES**	**NO**
7.3.1.2	(7.4.1) The organization shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.	**YES**	**NO**

7.3.1.3 (7.4.1) The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4). **YES** **NO**

NOTE One factor that can be used during supplier selection and evaluation is supplier quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, organization approvals from government authorities). Use of such data would be only one component of an organization's supplier control process and the organization remains responsible for verifying that purchased product meets specified purchase requirements.

7.3.1.4 (7.4.1) The organization shall: **YES** **NO**
a) maintain a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family),
b) periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of controls to be implemented,
c) define the necessary actions to take when dealing with suppliers that do not meet requirements,
d) ensure where required that both the organization and all suppliers use customer-approved special process sources,
e) define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on their supplier's approval status.

7.3.2 Purchasing Information

7.3.2.1 (7.4.2) Purchasing information shall describe the product to be purchased, including, where appropriate: **YES** **NO**
a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel,
c) quality management system requirements,
d) the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,
e) requirements for test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics,
f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,
g) requirements regarding the need for the supplier to
- notify the organization of nonconforming product,
- obtain organization approval for nonconforming product disposition,
- notify the organization of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain organization approval, and
- flow down to the supply chain the applicable requirements, including customer requirements

h) records retention requirements, and,
i) right of access by the organization, their customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

7.3.2.2 (7.4.2) The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. **YES** **NO**

7.3.3 Verification of Purchased Product

7.3.3.1 (7.4.3) The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. **YES** **NO**

NOTE1 Customer verification activities performed at any level of the supply chain should not be used by the organization or the supplier as evidence of effective control of quality and does not absolve the organization of its responsibility to provide acceptable product and comply with all requirements.

NOTE 2 Verification activities can include:
- obtaining objective evidence of the conformity of the product from the supplier (e.g., accompanying documentation, certificate of conformity, test records, statistical records, process control records),
- inspection and audit at the supplier's premises,
- review of the required documentation,
- inspection of products upon receipt, and
- delegation of verification to the supplier, or supplier certification.

7.3.3.2 (7.4.3) Where purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements. **YES** **NO**

7.3.3.3 (7.4.3) Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained. **YES** **NO** **N/A**

7.3.3.4 (7.4.3) Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. **YES** **NO** **N/A**

7.4 Production Provision

7.4.1 Control of Production Provision

7.4.1.1 (7.5.1) The organization shall plan and carry out production provision under controlled conditions. Controlled conditions shall include, as applicable: **YES** **NO**
a) the availability of information that describes the characteristics of the product,
NOTE This information can include drawings, parts lists, materials and process specifications.
b) the availability of work instructions, as necessary,
NOTE Work instructions can include process flow charts, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards) and inspection documents.
c) the use of suitable equipment,
NOTE Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and software programs.
d) the availability and use of monitoring and measuring equipment,
e) the implementation of monitoring and measurement,
f) the implementation of product release, delivery and post-delivery activities,
g) accountability for all product during production (e.g., parts quantities, split orders, nonconforming product),
h) evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,
i) provision for the prevention, detection and removal of foreign objects,
j) monitoring and control of utilities and supplies (e.g., water, compressed air,

electricity, chemical products) to the extent they affect conformity to product requirements, and
k) criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).

7.4.1.2	(7.5.1) Planning shall consider, as applicable: - establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified, - designing, manufacturing and using tooling to measure variable data, - identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and - special processes.	**YES**	**NO**
7.4.2	**Control of Production Process Changes**		
7.4.2.1	(7.5.1.2) Personnel authorized to approve changes to production processes shall be identified.	**YES**	**NO**
7.4.2.2	(7.5.1.2) The organization shall control and document changes affecting processes, production equipment, tools, or software programs.	**YES**	**NO**
7.4.2.3	(7.5.1.2) The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.	**YES**	**NO**
7.4.3	**Control of Production Equipment, Tools and Software Programs**		
7.4.3.1	(7.5.1.3) Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.	**YES**	**NO**
7.4.3.2	(7.5.1.3) Storage requirements, including periodic preservation/condition checks, shall be defined for production equipment or tooling in storage.	**YES**	**NO**
7.4.4	**Validation of Processes for Production Provision**		
7.4.4.1	(7.5.2) The organization shall validate any processes for production provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or has been delivered. NOTE These processes are often referred to as special processes.	**YES**	**NO**
7.4.4.2	(7.5.2) Validation shall demonstrate the ability of these processes to achieve planned results.	**YES**	**NO**
7.4.4.3	(7.5.2) The organization shall establish arrangements for these processes including, as applicable: a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.	**YES**	**NO**

7.4.5 Identification and Traceability

7.4.5.1	(7.5.3) Where appropriate, the organization shall identify the product by suitable means throughout product realization.	**YES**	**NO**	
7.4.5.2	(7.5.3) The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.	**YES**	**NO**	
7.4.5.3	(7.5.3) When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish appropriate controls for the media.	**YES**	**NO**	**N/A**
7.4.5.4	(7.5.3) Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4). NOTE Traceability requirements can include − 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 (e.g., delivery, scrap), − for an assembly, the ability to trace its components to the assembly and then to the next higher assembly, and − for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.	**YES**	**NO**	

7.4.6 Customer Property

7.4.6.1	(7.5.4) The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4). NOTE Customer property can include intellectual property and personal data.	**YES**	**NO**	

7.4.7 Preservation of Product

7.4.7.1	(7.5.5) The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	**YES**	**NO**	
7.4.7.2	(7.5.5) Preservation of product shall also include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for: a) cleaning, b) prevention, detection and removal of foreign objects, c) special handling for sensitive products, d) marking and labeling including safety warnings, e) shelf life control and stock rotation, and f) special handling for hazardous materials.	**YES**	**NO**	

7.4.8	**Control of Monitoring and Measuring Equipment**			
7.4.8.1	(7.6) The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.	**YES**	**NO**	
7.4.8.2	(7.6) The organization shall maintain a register of the monitoring and measuring equipment and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria. NOTE Monitoring and measuring equipment includes, but is not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.	**YES**	**NO**	
7.4.8.3	(7.6) The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.	**YES**	**NO**	
7.4.8.4	(7.6) The organization shall ensure that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.	**YES**	**NO**	
7.4.8.5	(7.6) Where necessary to ensure valid results, measuring equipment shall: a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4), b) be adjusted or re-adjusted as necessary, c) have identification in order to determine its calibration status, d) be safeguarded from adjustments that would invalidate the measurement result, e) be protected from damage and deterioration during handling, maintenance and storage.	**YES**	**NO**	
7.4.8.6	(7.6) The organization shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.	**YES**	**NO**	
7.4.8.7	(7.6) The organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.	**YES**	**NO**	
7.4.8.8	(7.6) Records of the results of calibration and verification shall be maintained (see 4.2.4).	**YES**	**NO**	**N/A**
7.4.8.9	(7.6) When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.	**YES**	**NO**	

8.0	**Measurement, Analysis, and Improvement**		
8.1	**Internal Audit**		
8.1.1	(8.2.2) The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to the planned arrangements (see 7.1) to the requirements of this checklist and to the quality management system requirements established by the organization, and NOTE Planned arrangements include customer contractual requirements. b) is effectively implemented and maintained.	**YES**	**NO**
8.1.2	(8.2.2) An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.	**YES**	**NO**
8.1.3	(8.2.2) A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.	**YES**	**NO**
8.1.4	(8.2.2) Records of the audits and their results shall be maintained (see 4.2.4).	**YES**	**NO**
8.1.5	(8.2.2) The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2). NOTE See ISO 19011 for guidance.	**YES**	**NO**
8.2	**Monitoring and Measurement of Processes**		
8.2.1	(8.2.3) The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.	**YES**	**NO**
8.2.2	(8.2.3) In the event of process nonconformity, the organization shall: a) take appropriate action to correct the nonconforming process, b) evaluate whether the process nonconformity has resulted in product nonconformity, c) determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and d) identify and control any nonconforming product.	**YES**	**NO**

8.3	**Monitoring and Measurement of Product**			
8.3.1	(8.2.4) The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained.	**YES**	**NO**	**N/A**
8.3.2	(8.2.4) Measurement requirements for product acceptance shall be documented and shall include: a) criteria for acceptance and/or rejection, b) where in the sequence measurement and testing operations are performed, c) required records of the measurement results (at a minimum, indication of acceptance or rejection), and d) any specific measurement instruments required and any specific instructions associated with their use.	**YES**	**NO**	
8.3.3	(8.2.4) When critical items, including key characteristics, have been identified the organization shall ensure they are controlled and monitored in accordance with the established processes.	**YES**	**NO**	**N/A**
8.3.4	(8.2.4) When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be 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**	**N/A**
8.3.5	(8.2.4) Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.	**YES**	**NO**	**N/A**
8.3.6	(8.2.4) Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).	**YES**	**NO**	
8.3.7	(8.2.4) The release of product to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.	**YES**	**NO**	
8.3.8	(8.2.4) The organization shall ensure that all documents required to accompany the product are present at delivery.	**YES**	**NO**	
8.4	**Control of Nonconforming Product**			
8.4.1	(8.3) The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product. NOTE The term “nonconforming product” includes nonconforming product returned by a customer.	**YES**	**NO**	
8.4.2	(8.3) The organization’s documented procedure shall define the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.	**YES**	**NO**	

8.4.3	(8.3) Where applicable, the organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity, b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer, c) by taking action to preclude its original intended use or application, d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started, − The organization's nonconforming product control process shall provide for timely reporting of delivered nonconforming product, NOTE Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors and regulatory authorities. e) by taking actions necessary to contain the effect of the nonconformity on other processes or products.	**YES**	**NO**	
8.4.4	(8.3) The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.	**YES**	**NO**	**N/A**
8.4.5	(8.3) Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.	**YES**	**NO**	**N/A**
8.4.6	(8.3) When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	**YES**	**NO**	
8.4.7	(8.3) Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	**YES**	**NO**	
8.5	**Corrective Action**			
8.5.1	(8.5.2) The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	**YES**	**NO**	
8.5.2	(8.5.2) A documented procedure shall be established to define requirements for: a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), f) reviewing the effectiveness of the corrective action taken, g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity, h) specific actions where timely and/or effective corrective actions are not achieved, and i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.	**YES**	**NO**	