International Aerospace Quality Group

# 9100 Auditor Guidance Material

## *« What to look for – What to ask”*

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International Aerospace Quality Group

# 9100 Auditor Guidance Material

## Introduction

This document provides general guidance and potential questions by audit teams when executing the audit process, described by the 9101:2010 standard for 9100:2009 audits.

Any issues identified during audits are to be documented against 9100:2009 requirements. This guidance is not intended to add or take away from the stated standard requirements, but provide examples and thought stimulation on how auditors can:

- identify applicable objective evidence ("What to look for"); and
- ask relevant questions ("What to ask").

Acceptable means of compliance are not limited to those items listed in this document.

NOTES:

- This 'living' document will be regularly updated and posted on the IAQG website.
- This revision does not address 9110 and 9120 audits.
- This is also useful in preparation for an audit.

# Process Auditing Approach

When auditing each process identified by the organization, there are basic questions that should be asked, for example:

- Is the process identified and appropriately defined?
- Is the process identified and appropriately defined (inputs, outputs, resources & controls)?
- Are responsibilities of process owner and process performers assigned?
- Is the process implemented and maintained?
- Is the process effective in achieving the desired results?

Other questions could include the following:

- What is the process? What is it trying to achieve?
- Who is the customer of the process?
- Does the process address applicable customer specific requirements?
- Are competencies identified?
- Is the process operating, as defined?
- What is the desired level of performance?
- Does it reflect specified customer targets / performance requirements?
- What are the measures (key performance indicators, etc.)?
- What is the current level of performance?
- Is the process performance regularly reviewed by Top management?
- Where performance is not being achieved, are improvement plans in place?

NOTE:

See also, the Guidance on the: “Concept and Use of the Process Approach for management systems” available on the ISO website, free of charge (ref : ISO/TC 176/SC2/N544R3) and refer to 9101:2010 § 0.2.

## 4.1 General requirements

### What to look for

Consideration by the organization of:
- describing the activities of the organization in processes: input, output, constraints, resources and measure
- providing visibility, including sequence and interaction of QMS processes defined by the organization (e.g., process model, flow diagram)
- formalizing continual improvement activities/efforts for defined processes
- compliance with customer and applicable statutory and regulatory requirements
- measuring main criteria:
  - How is this measured? (e.g., target setting, trends, on customer complaints, first pass yield, OTD reliability)
  - If out of target, how is this analyzed? How are actions taken?

Examples of objective evidence:
- process map
- list of customer and applicable statutory and regulatory requirements
- identification of process owners
- records on process effectiveness reviews, such as minutes of meetings
- measuring or evaluation methods of processes (how)
- criteria and methods used to ensure both operation & control are effective, e.g., objective of the process, quantitative targets such as first pass yield, max rate non-conforming parts, lead-time, max flow-time, including maximum variation/spread
- availability of resources : man/machine capacity plans (short term and M/LT)
- information needed for each process, e.g., specifications (design), orders, drawings(production), work-orders, job-cards, Monitoring (linked with am objectives/targets)
- data on improving its effectiveness, e.g., statistics on product deficiency rates
- documents, including records, related with outsourced processes, e.g., contracts, conformity statements)

NOTE:
The use of “Turtle diagram” or SIPOC approach is a means of compliance : description of input, output, process, resources, method, measurements

## 4.2 Documentation requirements

### 4.2.1 General

### What to look for

Consideration by the organization of:
- availability of relevant Quality Management System documentation and changes (not only procedures) at all places to be asked all through the audit
- existence of a list of documents, including the documented procedures required by the QMS standard and by the organization itself
- availability of documents in the different work places / shop floors by asking various people
- issue of the documents and regular updates
- samples upwards and downwards showing that the references to and from the procedures are correct (if the documented procedures are not part of the QM)

NOTES:
The list itself is NOT a requirement
The international standard requires, at least, the following documented procedures:
- **4.2.3 Control of documents**
- **4.2.4 Control of records**
- **8.2.2 Internal audits**
- **8.3 Control of nonconforming product**
- **8.5.2 Corrective actions**
- **8.5.3 Preventive actions**

## 4.2 Documentation requirements

### 4.2.2 Quality manual

### What to look for

Examples of objective evidence:
- scope of the QMS with respect to the scope of certification (coverage)
- justifiable exclusions (only to clause 7, ensure that exclusions are mentioned in the scope of certification) and their justification
- Quality manual and procedure references, issue

### What to ask

Recommended questions :
- Are the processes of the QMS explicitly mentioned and descried in the QM?
- Are the process interactions described? In what manner?

| IAQG | *What to look for / What to ask* |
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| **4.2** | **Documentation requirements**<br>**4.2.3 Control of documents**<br><br>**What to look for**<br><br>Consideration by the organization of:<br>• who is responsible for development, approval, distribution, …<br>• issue control (date, number, ...) - update<br>• procedures, instructions, definition / manufacturing / maintenance files, templates, purchasing contracts, change notes, ...<br>• use of electronic tools for documents validation by workflow<br><br>Examples of objective evidence:<br>• the documentation approval status and update status/issue control<br>• if not valid documents (paper or electronic) can be in use during product realization (sampling)<br><br>**What to ask**<br><br>Recommended questions :<br>• How are documents of external origin controlled? (Take some samples and verify the currency, e.g., customer contracts/specifications, supplier certificates of conformity, …)<br>• Are there retention requirements? If yes, how are they retained? (Take some samples on retrieval, based on the retention requirements) |
| **4.2** | **4.2.4 Control of records**<br><br>**What to look for**<br><br>Consideration by the organization of:<br>• how record formats are identified and controlled, including record ID's<br>• retention times and conditions including the storage area<br>• who is responsible for storage of records<br>• are records legible<br>• filing of records<br>• destruction<br><br>**What to ask**<br><br>Recommended questions :<br>• Ask for electronic versus paper records<br>• How long are records kept regarding the statutory, regulatory and customer's requirements?<br>• Is the method for controlling records of supplier's part of the documented procedure?<br>• How are records communicated to the supplier, e.g., in supplier contracts?<br>• Existence of samples on retrieval, based on the retention requirements? |

## 5.1 Management commitment

### What to look for

Consideration by the organization of:
- written management statement, e.g., in the quality manual or separate
- the way(s) it is communicated, e.g., in the QM, posters, newsletters, etc.
- attendance to top management reviews
- improvement plans
- involvement of management in Management reviews
- is management involved on a regular basis?

Typical examples of evidence of commitment:
- top management meetings, activities, …, regarding Quality
- policies and objectives are effective and understood throughout the organization
- policies and objectives are appropriate for continual improvement of the Quality Management System and for the achievement of customer satisfaction

### What to ask

Top management interview {including Business Unit manager(s)} – Recommended questions:
- names and positions of top managers?
- is top management aware of and committed to Quality?
- do employees understand the quality policy and how they contribute to objectives?
- are quality objectives measurable (see 5.4.1)?
- are top managers involved in management reviews?
- does top management answer the most important questions linked with his commitment and involvement or does he delegate this to his Quality manager?

NOTE:
See also 9101 section 4.1.2.2. Organizational Leadership Approach

## 5.2 Customer focus

### What to look for

Examples of objective evidence:
- Customer identification
- On-Quality Delivery (OQD) and On-Time Delivery (OTD) performance dashboard
- Communication arrangements
- Method of engagement
- Joint improvement efforts
- Campaigns
- Satisfaction surveys

### What to ask

Top management interview – Recommended questions:
- Who are the key customers?
- What is the level of focus relating to product conformity and on time delivery?
- How are they measured? With which periodicity? What are the targets/objectives to compare with? (If out of target, give examples of actions taken)
- Are the methods of measuring also discussed with the major customers, or are there any customer requirements on this?

## 5.3 Quality policy

### What to look for

Consideration by the organization of:
- Management having effectively “translated” the quality policy into understandable words and guidelines at all levels of the organization, with corresponding objectives at each applicable function / level
- Personnel having the required awareness, understanding and knowledge of the way the organization’s quality policy relates to their own activity, regardless of the terms used by such people to express their understanding?

Examples of objective evidence:
- availability and relevance and link of policy and objectives
- method of communication top / down
- effective dissemination of the quality policy by appropriate communication
- periodic review of suitability, e.g., during management review

| | *What to look for / What to ask* |
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| **5.4** | **Planning**<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• objectives are : **S**pecific, **M**easurable, **A**ttainable, **R**ealistic and **T**ime-bound (**SMART**) at all levels of the organization (they should be documented)<br>• Quality objectives are suitably cascaded throughout the organization's structure and processes<br>• linking the top level quality policy and specific operational objectives<br>• overall performance of the organization reflects the aims of the quality policy and reasonably meets the quality objectives<br>• objectives assigned by management are consistent with Aerospace and/or customer requirements (example: On Time Delivery > 95%, Quality default rate < 1%) |
| **5.5** | **Responsibility, authority and communication**<br><br>**What to look for**<br><br>Employee awareness of responsibilities and authorities - Examples of objective evidence:<br>• Organization chart and responsibilities description<br>• procedure or job description (or other standardized document) where the responsibilities are described, including 5.5.2 requirements<br>• communication process effectiveness<br>• Top management, employees at all levels in the organization, contractors, generate, receive and respond to communications<br>• the information to be communicated is clearly defined, appropriate and accurate to the purpose of the communication<br>• the means used for communication is appropriate to the literacy and other skills of those expected to receive and act upon the information provided<br>• monitoring takes place to ensure that the information communicated is acted upon and the desired outcome achieved<br>• the records necessary to demonstrate that communication has occurred, is effective and subject to continual improvement and are readily available<br>• promotion of customer requirements awareness<br>• occurrences of management representative reporting to top management, organizational freedom (prevent delivery of non-conforming parts, stop non-conforming processes, etc.) |
| **5.6** | **Management review**<br><br>**What to look for**<br><br>Consideration by the organization that:<br>• management review input /output are:<br>- consistent with organization identified processes<br>- relevant to the organization's size and complexity and that they are used to improve the business<br>• the management review process includes elements of Quality Management System planning where changes to processes and systems are being considered<br><br>Examples of objective evidence:<br>• availability of input / output data such as: statistical data, graphics, summary tables, reports on product and delivery performance and results of internal and external audits, ...<br>• minutes of meeting<br>• action(s) plan(s) issued from management review<br>• how the organization's management is structured and how the management review process is used within this structure<br>• Evidence that the following points have been considered during the review:<br>- impact of changes to the management system or business as a whole, on other parts of the system or business<br>- proposed changes are evaluated before implementation<br>- the controls needed are identified before the outsourcing of a process starts<br>• how output from top management review are flown-down into organization at operational level<br>• output from the management review: decisions to modify procedures, methods, training of personnel, hiring additional staff, additional process controls/inspections |

| IAQG | *What to look for / What to ask* |
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| **6.1** | **Provision of resources**<br><br>**What to look for**<br><br>Consideration by the organization that:<br>• the adequacy and effective management of the resources to achieve planned results, irrespective of the way the organization is structured and identifies its processes<br>• past and present performance (e.g., using cost-benefit analysis, risk assessment) have been evaluated when deciding what resources are to be allocated<br>• the resources are determined to enhance customer satisfaction, e.g., special customer focal points (independent from the Sales dep., resources for determining customer satisfaction, e.g., by periodic surveys, standardized interviews, ...)<br><br>NOTE:<br>It is recommended that the management of resources is not audited in isolation |
| **6.2** | **Human resources**<br>**6.2.1 General**<br>**6.2.2 Competence, training and awareness**<br><br>**What to look for**<br><br>Consideration by the organization of:<br>• competencies required by personnel performing work which affects quality<br>• personnel already performing the work have the required competencies<br>• what additional competencies are required<br>• how these additional competencies are to be obtained – training of personnel (external or internal), theoretical or practical training, hiring of new competent personnel, assignment of existing competent personnel to different work<br>• training, hiring or reassigning personnel?<br>• reviewing the effectiveness of actions taken to satisfy competence needs<br>• periodically reviewing competence of personnel<br>• a specific training or information for new employee regarding quality:<br>- at company level<br>- at shop-floor level<br>• if commercial airworthiness requirements, people in charge of airworthiness release are aware of regulatory requirements<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• discussions with top management to ensure they understand the importance of identifying the competencies required<br>• people competencies taken into account in risk analysis process<br>• competence requirements included in contract documents where the activities of subcontractors can have an impact on processes and/or product quality characteristics<br>• review of job descriptions, responsibilities and authorities, including education and training requirements<br>• training records and plan (status of the current year and of the previous year)<br>• competence matrix or some other method to understand competency requirements for processes or sub-processes<br>• nonconformity records, audit reports, customer complaints related to competence problems/ issues, e.g., training/instruction is the corrective action<br>• certification records (e.g., NDT, repair, auditors, authorized signatories, ...)<br>NOTE:<br>Ongoing changes in competence requirements may indicate that an organization is proactive in maintaining personnel performance levels |
| **6.3** | **Infrastructure**<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• separation and identification of repair from manufacture<br>• distribution into product line and separation between work station<br>• restricted area<br>• power supply backup<br>• hazardous material handling<br>• sufficient room/facilities for administration where needed<br>• IT systems management (network availability, organization, software revisions, back-up, …) |
| **6.4** | **Work environment**<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• specific work and storage facilities (ex : composite), clean rooms, electro-static protection, temperature and humidity controlled work areas and the related product or process requirements<br>• ventilation system in case of welding, use of solvents, … |

**7.1**

## Planning of product realization

Detailed processes needed for product realization are specific to each organization.
Examples of such processes are :
Marketing and Sales, Purchasing, Production Planning, Parts Manufacturing, Assembly, Warehousing (both of incoming material but also finished products), Maintenance, Design and Development, Delivery, Incoming goods, and Product Support.

9100 standard identifies verification, validation, monitoring, measurement, inspection and test as activities, which can be part of organization processes

### What to look for

Taking into account the process map regarding these processes, examples of objective evidence include:

- typical sources for requirements for the product: customer specifications, and/or regulatory requirements
- activities that checks the availability of adequate/capable processes linked with specific customer requirements
- inspection/test plans/policies, …
- resources needed for all processes, including the support process (support to the customer and/or end user)
- the use of suitable enterprise resource planning tools (e.g., Sales and Operations Plan & Master Production Schedule)
- activities to achieve On-Time delivery (e.g., load capacity management, buffering stocks, …)
- product configuration planning (see § 7.1.3)

NOTES:

- The planning of product realization starts during the proposal / contracting process until the end of the product life
- The product life cycle includes design, development, production, support
- The records are required to all the processes of the product realization

**7.1**

## Planning of product realization

### *7.1.1 Project management*

### What to look for

Consideration by the organization of:

**Project planning**

- Management plan (including setting-up, acceptance, consistency of the management plans, ...)
- Project organization
  - Organization requirements
  - Information and communication (including communication requirements, protection of information, ...)
  - Requirements relating to the project process evaluation (including progress report, management of actions, technical and management indicators, ...)
- Work breakdown structure
  - Setting-up of the work breakdown structure (including function tree and product tree structures)
- Phasing and scheduling
  - Acquisition strategies and execution plans (including product customer's acquisition strategy, supplier's execution plans)
  - Project phases and milestones
  - Project management tools (Gantt charts, project plan/schedule or dedicated software tool, …)
  - Requirements relating to the execution plan (processes, execution related documents, schedule)
  - Reviews

**Project realization**

- Technical performance control (including performance optimization, verification and validation, justification and qualification)
- Cost control (including cost estimates, cost budgeting, techniques for cost control)
- Schedule control

NOTE:
Project management is appropriate to the organization and the product

**7.1**

## Planning of product realization

### *7.1.2 Risk management*

### What to look for

Consideration by the organization of:

- maintaining risk management activities during all product life
- the project phases when risk analysis are performed and update
- the assurance that the risk analysis is updated whenever a new component or part or a new or changed process/sub-process or a new or changed supplier is introduced
- taking into account lessons learnt from risk management activities

Examples of objective evidence:

- objectives, input and output of the risk management process are identified
- risks identification include risks regarding human factors
- effectiveness and risk status are monitored
- risk management regarding product, suppliers, program, process is handled
- responsibility for all types of risks (financial industrial, suppliers, product, project, operators, …) is assigned (where applicable, cross functions are involved)
- method used to quantify risk (e.g., FMEA methodology)

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| | • risks and associated mitigation plan are communicated to appropriate level<br>• mitigation plan are reviewed periodically<br>• residual risk levels are assessed and reviewed / approved by management<br>• residual or major risks review is part of Management review<br>• where applicable, customer is informed about residual risks<br><br>NOTES:<br>• Risk management is appropriate to the organization and the product. The method should ensure the identification of all risks liable to disrupt the operational/industrial process and/or achievement of customer expectations<br>The concept of risk can be viewed from two perspectives:<br>• Risk management process can be applied at various levels in an organization (organization, project, process, product, etc.). It can be a stand alone process or integrated into key points of the organization's realization processes<br>• Risk based decisions: once risks are identified (7.1.2.c) from various potential sources (customer, organization, statutory/regulatory, etc.) the risks need to be communicated to various departments or individuals within the organization. As this risk communication is received, an assessment of these risks should be performed to determine potential impacts |
| **7.1** | **Planning of product realization**<br>***7.1.3 Configuration management***<br><br>**What to look for**<br><br>**Configuration planning management**<br>• the configuration management planning scope and the objectives<br>• the product description subject of the management<br>• timetable planning for the significant actions of the configuration management<br>• the means used (IT system, for instance)<br>• the configuration management planning coming from the supplier<br>• the identification of the significant documents and their interrelation<br><br>**Configuration identification**<br>Evidence of the existence of:<br>• the tree of product, specification and other configuration<br>• the identification method of the product and documentation (drawing, spec, ...) and the identification of the change (status of the changes)<br>• the requirement to the traceability such as serial number, lot number, ....<br>• the method of communication to know the configuration status of the product<br><br>**Change controls**<br>Examples of objective evidence:<br>• the system of the management configuration changes to all steps of the design (for example : parts list at the different levels of design- development part list- to be certified part list- certified part list, ...)<br>• the configuration change method, the deviations<br><br>**Configuration status accounting**<br>Examples of objective evidence:<br>• the form of change identifying the data of the changes to be recorded<br>• the routing card, following sheet the serial number, batch number of the part, sub-assembly, assembly<br>• the production operations done by the operator<br><br>NOTE:<br>When traceability is a requirement, traceability level of the parts depends on the part category (e.g., the critical ones should be traceable from the raw material to the assembly, the part should always be with its SN during the production, in addition all the manufacturing history should be recorded). Also, see ISO 10007 |
| **7.1** | **Planning of product realization**<br>***7.1.4 Control of work transfers***<br><br>**What to look for**<br><br>Consideration by the organization that the work transfers process:<br>• applies to transfers through the whole lifecycle (not just for production)<br>• includes the planning of proposed moves<br>• covers permanent (as well as temporary) transfers<br>• includes moves from one supplier to another supplier and moves from one of the organizations facility to another or a supplier<br><br>Examples of objective evidence:<br>• transfer team leader and cross functional team are identified<br>• detailed task based plan with major milestones is defined and periodically reviewed<br>• risks are identified and assessed and mitigation plan provided<br>• technical requirement review and production readiness review are performed<br>• production process verification reports at existing location and at new location |

**7.2**

## Customer related processes

### 7.2.1 Determination of requirements related to the product

**What to look for**

Consideration by the organization of:
- needs and expectations of customers for the product/service
- applicable statutes/regulations and national/international standards
- special requirements identified by the customer or the organization
- technologies needed for the product/service realization
- its current capability
- concept and primary specifications of the product/service based on the needs and expectations of customers
- agreement reached with customer on specifications of product/service
- proposal of structure including partners and plan for development activities
- manufacturing site/style
- delivery timing, and volume of sales

Examples of objective evidence:
- special requirement: new technology application, new work sharing, arrangements, introduction of new processes or machines, new competencies required
- requirements not stated by the customer: catalog parts, standard parts, COTS parts
- regulatory requirements: certification specification e.g., CS 25, TSO, PMA, REACH, ITAR, …

**7.2**

## Customer related processes

### 7.2.2 Review of requirements related to the product

**What to look for**

Evidence that, in planning to realize the specific product/service to be provided to customers, the organization has considered:
- the need to establish processes and documents which is specific to the product/service for realization and the need to provide resources
- required verification, validation, monitoring, inspection and test activities specific to the product/service and the criteria for product/service acceptance
- records needed to provide evidence that the realization processes and resulting product/service meet relevant requirements
- **special requirements**
- result of the review of risks associated with order and/or special requirements, short time delivery, new technology, ramp up, …
- availability of resources

Example of output or results: confirmation that all product requirements are defined and captured:
- recording results : compliance matrix, contract review record, risk analysis and mitigation plans, persons who perform the reviews

NOTE:
Determination for competence and authority for requirements review (see 6.2)

**7.2**

## Customer related processes

### 7.2.3 Customer communication

**What to look for**

Examples of objective evidence:
- the organization's customer communication channels promote an adequate awareness of the process by which customers can provide feedback
- inputs to the customer feedback process include relevant, representative and reliable data
- this data is analyzed effectively
- the output from this process provides useful information to the management review and other QMS processes
- the use / knowledge of the customer's web portals/web sites to enhance customer satisfaction and drive continual improvement

Other examples of objective evidence:
- inquiries, contracts or order handling, including amendments
- quotations, order forms, confirmation of order, amendment to order
- delivery documentation, invoices, credit notes
- e-mail & general correspondence, visit reports or notes to/from customer

Customer feedback and complaints management process:
- letters in response to complaints
- acknowledgments
- management of the complaint process e.g., complaints log, control of timely response and adequate actions

Communication with the customer:
- ordering process: when the customer provides no documented statement of requirement, the organization needs to have a system in place to obtain or confirm these customer requirements before the organization accepts the order
- design/development process: there may be considerable communication between the organization and the customer during this phase
- process of authorizing the use of non conforming product by release or acceptance under concession: by a relevant authority and, where applicable, by the customer

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| | Examples of standardized communication: coordination memos, contact persons, customer specific, complaint process, information pertaining to OTD & OQD |
| **7.3** | **Design and development (D&D)**<br>**7.3.1 Design and development planning**<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• a work breakdown structure has to be done<br>• work packages and their content are identified<br><br>NOTE:<br>It is emphasized that:<br>• as part of the design input and to be integrated in the requirements related to the product, functional and operational requirements have to be foreseen including reliability, safety, maintainability and availability as far as statutory and regulatory requirements<br>• design and development planning should enable product equipment industrialization, testability, maintainability/reparability, etc. and associated risks to be mitigated from the early design stage<br><br>**What to ask**<br><br>Recommended questions:<br>• What is the overall flow of the design planning process?<br>• How is it described?<br>• What resources and competencies are required?<br>• What part of the design will be outsourced and how is this controlled?<br>• Who is responsible and are the authorities defined?<br>• How are (internal and external) interfaces between various groups identified and managed?<br>• Are the required verification, validation and review points defined?<br>• Are the main milestones and timelines identified?<br>• Is the implementation and effectiveness of the plan monitored?<br>• Is the plan updated and communicated to all relevant functions as necessary? |
| **7.3** | **Design and development (D&D)**<br>**7.3.2 Design and development inputs**<br><br>**What to look for**<br><br>Consideration by the organization of having identified its own inputs, based on:<br>• the organization's products and processes<br>• financial, environmental, health and safety issues<br>• organizational risks and impacts<br>• customer's requirements and expectations<br>• statutory and regulatory requirements applicable to the product<br><br>Evidence that the organization evaluates the risks, the possible implications for customer satisfaction and issues that the organization may encounter if some relevant inputs are not considered |
| **7.3** | **Design and development (D&D)**<br>**7.3.3 Design and development outputs**<br><br>**What to look for**<br><br>Consideration by the organization that:<br>• information regarding the completion of design and development stages is available<br>• the design and development process has been completed for the stage under review<br>• design and development outputs have been confirmed<br><br>Recommended questions:<br>• are there any critical items defined?<br>• are there any key characteristics defined (e.g., on the product drawing or another way)<br>NOTE:<br>See IAQG Special Requirement/Critical Items (SR/CI) Guide, included into the Supply Chain Management Handbook (SCMH) |

| IAQG | *What to look for / What to ask* |
|---|---|
| **7.3** | **Design and development (D&D)**<br>**7.3.4 Design and development review**<br><br>**What to ask**<br><br>Recommended questions on the review process:<br>• do reviews occur at planned stages throughout the design process?<br>• are the reviews carried out in a systematic way involving representatives of the functions concerned with the stage(s) being reviewed?<br>• have all original and any new inputs been considered ?<br>• are the original outputs still relevant or have revised outputs been identified?<br>• have revised inputs and outputs been reviewed and approved by those with the relevant responsibility and authority (including the customer where appropriate)?<br>• does the output demonstrate the suitability, adequacy and effectiveness of the designed product?<br>• are the relevant design objectives being achieved?<br>• are there adequate records of reviews and follow-up of actions defined? |
| **7.3** | **Design and development (D&D)**<br>**7.3.5 Design and development verification**<br><br>**What to look for**<br><br>Consideration by the organization that the design and development verification activities provide confidence that:<br>• required verifications are planned and that verification is performed as appropriate during the design and development process<br>• the completed design or development is acceptable and the results are consistent with and traceable to the initial requirements<br>• the completed design or development is the result of implementation of a proper sequence of events<br>• inputs, outputs, interfaces, logic flow, allocation of timing, etc.<br>• the design or development provides safety, security, and compliance with other requirements and design inputs<br>• evidence is available to demonstrate that the verification results and any further actions have been recorded and confirmed when actions are completed<br>Evidence that only verified design and development outputs have been submitted to the next stage, as appropriate |
| **7.3** | **Design and development (D&D)**<br>**7.3.6 Design and development validation**<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• there are records to confirm that the validations have been carried out<br>• the validation was carried out in accordance with the planned arrangements for validation<br>• the validation indicates that the resulting product is capable of meeting the requirements of the specification<br>• wherever practical, the validation has been carried out prior to delivery or implementation; and that<br>• there are records of any actions necessary to correct non-compliance with the design and development inputs and the reasons for these deviations |
| **7.3** | ***7.3.6.1 Design and development verification and validation testing***<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• all tests to be carried out are planned<br>• tests were carried out in accordance with planned arrangements<br>• responsibilities are defined (to perform test, to review and to validate test result)<br>• product configuration is reviewed and recorded,<br>• test procedure, resources needed and acceptance criteria are defined for all tests,<br>• disposals are defined in case of failed test (repair, ,,,)<br>• there is a final test plan review with formal acceptation<br>• there are records of any actions necessary to correct non-compliance with the design and development inputs and the reasons for these deviations |
| **7.3** | ***7.3.6.2 Design and development verification and validation documentation***<br><br>**What to look for**<br><br>Example of objective evidence: a compliance matrix between all specification requirements and verification and validation activities carried out<br>Recommended question: are discrepancies (if any) accepted by customer? |
| **7.3** | **Design and development (D&D)**<br>**7.3.7 Control of design and development changes**<br><br>**What to ask**<br><br>Recommended questions : |

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| | • are the sources and requests for changes properly identified and communicated?<br>• is the impact of any change evaluated?<br>• is any additional design proving or testing undertaken where appropriate?<br>• are the effects of the changes on constituent parts and product already delivered evaluated?<br>• has appropriate approval been given before a change is implemented (this could include statutory or regulatory approval or approval by the customer)?<br>• are the changes fully documented and do records include information regarding any necessary additional actions?<br><br>Also see §7.1.3 Configuration management |
| **7.4** | **Purchasing**<br>**7.4.1 Purchasing process**<br><br>**What to look for**<br><br>Consideration by the organization of:<br>• formal purchasing process description, procedure or job description where the responsibilities are described<br>• how the suppliers ability is determined: use of questionnaires, use of ability audits, use of test specimens<br>• supplier evaluation including ability to deliver on time product<br>• supplier register (status and approval scope)<br>• if service provider suppliers (calibration, test, logistics,...) and customer defined suppliers are included in supplier register<br>• supplier performance review used to set up improvement plan<br>• supplier risk analysis performed and recorded<br>• responsibilities and authorities are defined<br><br>Examples of objective evidence:<br>• key performance indicators - objectives - improvement plan<br>• supplier classification, linked to product and supplier risk, e.g., standard parts versus subcontracted special processes or critical products<br>• rules for selection / de-selection of suppliers per type of purchase (select one or more suppliers per type of product or service purchased)<br><br>**Purchasing**<br>**7.4.1 Purchasing process (continued)**<br><br>• updated register of supplier with scope and status including customer defined sources<br>• supplier evaluation and re-evaluation results<br>• supplier performance indicators<br>• improvement plan issued by the organization and/or the supplier<br>• suppliers risk analysis and associated mitigation plan<br><br>**What to ask**<br><br>Recommended questions:<br>• Are steps taken to prevent use of suspended or conditional suppliers?<br>• Are supplier performances (quality and on-time delivery) reviewed periodically (review period should be in accordance with customer requirement if applicable)? |
| **7.4** | **Purchasing**<br>**7.4.2 Purchasing information**<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• contractual documents or reference documents clearly defining what changes planned or implemented by supplier are submitted to the organization for review and/or approval<br>• supplier furnished acknowledgement of POs to the organization<br>• issue control of documents specified on purchase order<br><br>NOTE:<br>The organization should obtain and use as much reliable supplier performance data as possible when making a selection decision and provide a number of examples where this data might be found. The accountability remains the responsibility of the organization, independent of where this performance data was obtained |
| **7.4** | **Purchasing**<br>**7.4.3 Verification of purchased product**<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• accompanying document are in accordance with PO<br>• all documentation needed (drawing, specification, PO) to perform incoming inspection is at the right issue and used<br>• test and measurement equipment used have valid calibration |

- formal verification process description or procedure
- register of delegation (if applicable)

### What to ask

Recommended questions:
- Are specific skills required for incoming inspectors?
- Are OEM certificates of conformity (CoC) provided with parts procured from retailers? (organization and customer requirement regarding OEM CoC)
- Is Level of incoming inspection taking into account supplier performance and identified risks?

NOTES:
It is recommended to:
- look for the rules for incoming inspection.
- perform interview with incoming inspectors to verify that rules are applied (select different types of purchased product)

## 7.5 Production and service provision

### 7.5.1 Control of production and service provision

### What to look for

Examples of objective evidence, if available (and controlled) at the point of use, as applicable:

a. design definitions, arrangement drawings, component drawings (final/stage), identification of key characteristics, parts lists, material specifications (raw material, consumables, standard parts etc.), process specifications (metal joining, thermal processing, coating, plating, bonding, fitting)

b. manufacturing/assembly/test instructions, process data cards, standard operating procedures, process flow charts, set up diagrams, tooling lists, works order, batch cards, routers, travelers, inspection/test procedure cards, inspection/test history cards, ...

c. jigs, fixtures, cutting tools, moulds, form tools, hand tools, machine tool programs, inspection/test programs (if "Special to Product" - check the identity/correlation of equipment/programs in accordance with planning instructions)

d. gauges and measuring equipment (manual/electronic), computerized measuring machines/equipment and testing facilities

e. definition of when and how in the production/service cycle monitoring and measurement is required and that records exist to prove that checks are being undertaken in accordance with the defined instructions

f. final inspection records, customer eyes over-check, release notes, delivery notes, certificates of conformity, material transfer notes, packing lists, labels, user instructions, equipment log books, delivery receipt documents, delivery tracking system, invoices, customer queries and problem resolution

g. production history records (batch cards, routers, travelers, electronic systems, …). account for all product in the batch (e.g., the recorded quantity aligns to the batch size)
If product is split after launch then evidence should be available to identify when the split took place, the reason why, update/reissue of production documentation, together with relevant authority/approval
NOTE: Any electronic systems (where used) should have been updated accordingly to reflect the production status

h. production, inspection and test records indicate that all operations have been completed in accordance with instructions, typical evidence includes the accounting for work via the use of signatures, stamps, electronic work booking, ...
Where completion of an operation is not in accordance with instructions then check that the reason is documented together with appropriate disposition and authorization/approval

i. organization campaigns on FOD prevention (posters, briefings, training, customer feedback, quality alerts etc.)
Production documentation includes reference to the detecting and removal of foreign objects, in particular for those products that have entrapment features. Special checks may be needed to determine FOD that may not be apparent (e.g., the use of instrascopes, boroscopes, x-ray techniques, ...)
Control of tooling and equipment may also be evident in assembly, packaging and dispatch areas, (e.g., booking in/out of tooling at the point of use, use of shadow boards and standard tool boxes, brightly painted slave equipment, ...)

j. regular checks of utilities, supplies, chemicals that have an impact on the product including contamination, cleanliness, chemical strength/constituency, air pressure, voltage supply etc. Instructions should define what needs to be checked (work instruction, standard operating procedure etc.) the frequency (daily, weekly, monthly, annually, ...) and how the check should be performed
Confirmation that the check has been performed should be in evidence together with the steps taken to recover out of specification conditions, including any requirements to perform any product recheck/rework
Data is typically used to monitor process performance, for example plotting of recorded values on control charts that are in turn used to improve process control and determine future levels of checking

k. Written instructions, photographs, diagrams, illustrations ..., captured in standard operating procedures, manufacturing/assembly instructions, quality acceptance standards, training material
Physical samples may also be used to represent the acceptable condition - these are controlled specimens used for comparison purposes and should be identified, protected, maintained and readily available

NOTES:

- Essential items taken into account during planning also includes defining the requirements necessary to control-key characteristics. This typically includes identification of the key characteristics usually via the component definition and/or process control document/plan, application of process mapping techniques, process failure modes and effects analysis, use of control charts, data analysis and determination of process capability …

- Measurement systems are determined to ensure the appropriate selection and application of tooling/gauging via the use of capability studies. Capable tooling/gauging is acquired and where necessary special to product tooling/gauging may be required and as such provision will be made to design and manufacture such items. In all cases reference to the tooling/gauging needed to measure variable data should be included within the manufacturing instruction

- In process verification/inspection points are determined at the planning stage in particular when conformance checks cannot be performed at a later stage in the production cycle, for example features that become inaccessible after further processing e.g., permanent assembly of detail parts, treatment of surfaces (coating, painting, ...), un-restraining of flexible parts, removal of slave

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|---|---|
| | manufacturing features, ... In all cases in process verification/inspection points should be sequenced and identified within the manufacturing instruction<br><br>• Identification and control of special processes is determined at the planning stage, this includes defining and sequencing the process requirements. For each special process the manufacturing instruction typically includes a reference to the process specification, the detail needed to perform the task (process data card, work instruction etc.), identification of any tooling/ equipment (holding fixtures, furnace, welding plant, test pieces, ...), consumable reference (paint, adhesive, chemicals, welding wire, ...) and verification activity (product inspection, non destructive examination, document check etc.) - see also 7.5.2 |
| **7.5** | **Production and service provision**<br>***7.5.1.1 Production process verification***<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• appropriate arrangements are in place to plan for and implement verification of the first production run of a new product or after changes have been implemented<br>• the following evidence is available and readily retrievable as applicable<br>• new or changed products in series production are identified in the workplace as items requiring production process verification to be applied<br>• in cases where nonconformance is identified within the production process verification report, correct disposition are taken and recording of corrective action within the document pack is performed, together with re-application of the process against the affected characteristics<br>• arrangements are in place to indicate when a new production process verification is required and/or an update is required to an existing product (e.g., part of the manufacturing launch plan, signal from production planning and control for a new product, signal from operations/engineering as a result of a source/method change, ...<br>NOTES:<br>• The production process verification document pack (unique to the part) typically contains reason for applying the process (new part, method change, source change etc.), information relating to part identity, serial number (if applicable) and classification, process checklist, part number accountability, materials, tooling, processes, functional testing and product characteristics<br>• Other supporting evidence available to demonstrate satisfactory production process verification includes: design/make launch plan, master parts list, component definition, manufacturing routers, operation lists, process cards, process failure modes and effects analysis report, measurement plan, gauge study, inspection history/results (including CMM print out as applicable), inspection and test procedures / programs, inspection reports, quality control plan, corrective action plan, identification of key characteristics, process control document, control charts, capability assessments and gauge calibration status<br>• Complete and authorized reports confirm that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements<br>• The production process verification report is a quality record (storage, ease of retrieval and document clarity should be checked)<br>• The activity “production process verification” is often referred as “First Article Inspection” |
| **7.5** | **Production and service provision**<br>***7.5.1.2 Control of Production Process Changes***<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• those personnel who are authorized to approve changes to production processes are identified<br>• a record of the change is evident wherever a change to a production process, equipment, tools or software program is made<br>• in each case, documents defining the level of authority are controlled, up to date and approved<br>• for critical parts, when applicable, the change is formally documented at the outset, all relevant approvals are captured on the "Manufacturing Change Request" (or equivalent) and the record of change is included in the relevant Critical part Plan for each part number affected<br>• if the change is to be made permanent then an instruction is in place to flow the change request into the relevant department via the use of a "Production Process Change Request" (or equivalent) document<br>• such change requests are being dealt with in a timely manner by the appropriate department, look for a request tracking system and the number of entries, open/closed status, turnaround time, ...<br>• the original document has been updated in a correct and controlled manner, by following the trail of a completed change request, …<br>• a downstream check is in place to confirm that the production process change continues to meet specification requirements, wherever a change has been incorporated<br>• authority for change may be captured in a variety of ways including individual/generic job descriptions/accountability statements, approved signatories list, document approval matrix, ...<br>• change may be captured by the manual updating of a production document at the point of use including detail of the change, together with the signature(s) of the authorized individual(s) and date<br>• change may include the re-sequencing of production operations, use of an alternative source, amendment to software programs (machine, inspection, testing), replaced equipment/tooling/gauges, update to material/process specifications, revised method, …<br>• checks may include visual/dimensional inspection, non-destructive testing, destructive testing, functional testing, risk assessment, ...<br>• substantiation of the change may also be proven by a series of activities and the issuing of a report |

**7.5**

## Production and service provision

***7.5.1.3 Control of Production Equipment, Tools and Software Programs***

### What to look for

Examples of objective evidence:

- production equipment, tools and software programs that are used in series production have been validated and maintained
- evidence exists to demonstrate that equipment, tools and software programs are identified. Follow an audit trail to confirm that validation has taken place prior to incorporation into the production plan
- the identity and configuration (version/issue number) of the validated equipment, tools and software program is captured and remains traceable in the production process plan
- storage requirements are defined for production equipment and tooling
- items are protected from damage, corrosion etc., including the adequate use of racking, shelving, cupboards, packaging materials, surface treatment, ...
- storage conditions appropriate including space, temperature, humidity, ...
- equipment and tooling is being maintained in accordance with defined requirements (follow an audit trail)
- validation may include results of trials/tests, proof reports, inspection history/ results, process failure modes and effects analysis, gauge R&R study, control charts, capability assessments, first article inspection (see 7.5.1.1), ...
- definitions may include standard operating procedures, local operating procedures, preservation specifications, storage/stock control procedures, individual equipment/tooling specifications, ...

NOTE:
Customer owned equipment and tooling may also be subject to specific requirements contained within an interface procedure

**7.5**

## Production and service provision

***7.5.1.4 Post-delivery support***

In service data contains of statistical information on the use and reliability of parts and components, such as:

- Mean Time Between Failure (MTBF)
- Mean Time Between Unscheduled Removal (MTBUR)
- unexpected shut-off and similar information*.

This information is coming from the operators, and/or maintenance organizations, but also as 'incident/accident' information from Aviation Authorities or Safety organizations

It is recommended that analysis could include comparison of the data with the design specification on the reliability criteria for these parts and components, but also on study and tests (e.g., on failure causes linked with the design specifications)

The actions linked with these are aimed to inform the customers on possible problem.
If an organization has a Design Organization Approval (DOA), this could result in service bulletins, design changes or modified technical documentation

### What to look for

Typical examples of technical documentation are:

- Operation Manuals
- Component Maintenance Manuals (CMM)
- Structural Repair Manuals (SRM)
- Illustrated Parts Catalogues (IPC) and
- Maintenance Instructions

but also changes in the design data such as drawings
NOTES:

- Repair schemes should be approved by the Type Certificate holder
- Control of off-site work should cover the conditions in 7.5.1, as applicable, such as but not limited to the work environment, the use of qualified resources, the use of and the measuring of the work carried out by qualified personnel
- Where relevant, this information should be flown down to suppliers

**7.5**

## Production and service provision

**7.5.2 Validation of processes for production and service provision**

### What to look for

Examples of objective evidence that special processes implemented in the company are:

- identified (including the subcontracted ones)
- managed :
  - Training of the operators and recorded qualification files
  - Capability, validation and periodical re-validation of the facilities with records :
    - Equipments of the facilities to manage the special process parameters
    - Configuration of the installation recorded and managed
    - Follow the validation time
    - Customer approval (by itself or other party)
  - Realization of the special process :
    - Controlled Instruction sheet with the process parameters, these parameters should be with tolerances
    - SP Validation requirements (defined method)
    - Control of the SP parameters changes (defined method)
    - Necessary tools for the PS identified in the process sheet
    - Record the enforced SP parameters during the process
  - Periodical surveillance of the SP parameter equipments such as the requirements of the 9100 standard (see § 7.6)

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| **7.5** | **Production and service provision**<br>**7.5.3 Identification and traceability**<br><br>**What to look for**<br><br>Consideration by the organization of maintaining configuration traceability by the definition change traceability:<br>• all the changes are in accordance with the configuration management required by the 9100 standard § 7.1.3<br>• all the additional changes of a part or sub-assembly and assembly are formalized and recorded ; the duration of the filing depends of the part, sub-assembly, assembly and is defined<br><br>**7.5.3 Identification and traceability (continued)**<br>Examples of objective evidence:<br>• the traceability is in the shop, in case of a part, sub-assembly and assembly is manufactured before the change approval (the actual configuration can be compared to the approved configuration)<br>• the routing card, following sheet, the serial number, batch number of the part, sub-assembly, assembly are written and in accordance with the SN or batch number marking on the part, sub-assembly, assembly<br>• the production operations are done by the operator, inspector is identified in accordance with the applicable rules defined in the AQMS (stamps, signature, ...) often governed by a procedure<br><br>NOTE: When traceability is a requirement, traceability level of the parts depends on the part category (e.g., the critical ones should be traceable from the raw material to the assembly, the part should always be with its SN during the production, in addition all the manufacturing history should be recorded) |
| **7.5** | **Production and service provision**<br>**7.5.4 Customer property**<br><br>**What to look for**<br><br>Examples of objective evidence on :<br>• the storage condition in the warehouse<br>• the intellectual property controls applied (e.g., drawings, models, …)<br>• customer reporting records, when applicable<br>• customer property controls (identification, verification, protection, safeguarding) |
| **7.5** | **Production and service provision**<br>**7.5.5 Preservation of product**<br><br>**What to look for**<br><br>Consideration by the organization of:<br>• inter-operation preservation in the shop (pollution, impact, corrosion, …)<br>• storage of the products and conditions in the warehouse itself:<br>- configuration, survey of storage duration, ESD protection, FIFO, ...<br>- temperature, humidity, cleanliness, restricted access, ...<br>- surveillance of limited life products, ingredients and storage conditions<br>- handling of dangerous products<br>• delivery rules and conditions:<br>- Instruction sheet (parts aspect, packaging process,... ), packaging, preservation |
| **7.6** | **Control of monitoring and measuring equipment**<br><br>**What to look for**<br><br>Examples of objective evidence:<br>• the organization has a process for insuring the capability of measurement system (e.g., Interval Analysis, Resolution Analysis, Gage Repeatable & Reproducibility, …)<br>• links are established with the recognized international / national standard<br>• all measuring equipment are identified regarding calibration status (take some sample in different shops and for different types of equipment<br>• all equipments are recorded in register (can be computer based)<br>• calibration activities are performed without exceeding scheduled dates<br>• if automatic test bench (including software) are used, they are calibrated and validated<br>• capability of measuring equipment / measurement is relevant<br>• traceability is established between measuring equipment used and product measurement |

| IAQG | *What to look for / What to ask* |
|---|---|
| **8.1** | **MEASUREMENT, ANALYSIS AND IMPROVEMENT**<br>**General**<br>Please refer to:<br>a. §8.2.4<br>b. §8.2.2 & §8.2.3<br>c. §8.5<br><br>NOTE:<br>Special attention should be given to the various methods that are used like Cp - Cpk, 6 Sigma, Sample method inspection, FMEA, ... to demonstrate conformity and effectiveness of processes |
| **8.2** | **Monitoring and measurement (M&M)**<br>**8.2.1 Customer satisfaction**<br><br>**What to look for**<br><br>Recommended questions:<br>• What information is actually available on customer perceptions?<br>• Are customer report cards available from the customers and acted upon?<br>• How does management use information to drive improvements to the product, processes and the QMS use this information?<br>• Are all customer categories covered by this information?<br>• How is the data collected to feed the process?<br>• How reliable is the information?<br>• How is the data analyzed?<br>• How does the information generated by this process feedback into the QMS as a whole?<br>• What are the links to other QMS processes?<br><br>Some examples of techniques the organization can use include:<br>• face-to-face evaluations<br>• telephone calls or visits made periodically or after delivery of products and services<br>• questionnaires or surveys carried out by the organization itself, or by independent market researchers<br>• other contacts with customers, for example by service or installation personnel<br>• internal enquiries among the organization's personnel who are in contact with customers<br>• evaluation of repeat business<br>• monitoring accounts receivable, warranty claims, etc.<br>• customer complaints analysis |
| **8.2** | **Monitoring and measurement (M&M)**<br>**8.2.2 Internal audit**<br><br>**What to look for**<br><br>Consideration by the organization for planning of having identified:<br>• its processes that are critical to product quality,<br>• its complex processes, or those that need special attention<br>• its processes that need to be validated<br>• its processes that need personnel to be qualified<br>• its processes that need close monitoring of process parameters<br>• its monitoring and measuring activities that require frequent calibration and/or verification<br>• its activities and processes that occur across multiple locations and/or which are human resource intensive, ...<br>• its processes where problems have occurred or are in risk<br><br>Examples of objective evidence:<br>• list of approved auditors<br>• audit plan (status of the previous year and progress of the current year)<br>• audit records<br>• competencies that are needed for and applied to the audit<br>• the previous period on the auditors department and the audited department<br>• correct grading of findings and the avoidance of 'soft-grading', e.g., observations that should be classified as non-conformities<br>• risk analysis performed by the organization (if any) in planning internal audits<br>• degree of management involvement in the internal audit process<br>• way the outcome of the internal audit process is used by the organization to evaluate<br>• established process performance indicators that define effectiveness measures<br>• effectiveness of its QMS and to identify opportunities for improvements<br>• follow-up of corrective actions<br>• a process for utilizing past audit results in the planning of future internal audits<br><br>**What to ask**<br><br>Recommended question:<br>• How long corrective actions remain open / vs. planning of closure of CA |

**8.2**

## Monitoring and measurement (M&M)

### 8.2.3 Monitoring and measurement of processes

**What to look for**

Recommended questions :

- Are responsibilities of process owner and process performers defined?
- What is the desired level of performance?
- Does it reflect specified customer targets / performance requirements?
- What are the measures? (key performance indicators, …)
- What is the current level of performance?
- Where performance is not being achieved, are improvement plans in place?
- Process Effectiveness

**8.2**

## Monitoring and measurement (M&M)

### 8.2.4 Monitoring and measurement of product

**What to look for**

Consideration by the organization that:

- Inspection instructions are issued. These inspection instructions are available to persons who have to inspect, and/or accept release of product. These instructions may be either generic or product related. When product is found acceptable, evidence of conformity is found either on product (inspection stamp) or on inspection documentation
- Acceptance criteria are clearly shown on inspection instructions
- KC are inspected as per instructions developed in accordance with § 7.5.1
- Sampling plans are established in accordance recognized sampling procedures (e.g., : MIL-STD 105)
- Procedure and records demonstrate that when product is released to next production stages although not all inspection results are available, it is possible to trace use of product all along the production cycle and that final inspection and delivery cannot be done until all inspections results are available. Examples can be found of pre-released product that has been withdrawn from production process once non conformity identified
- Test reports show compliance to the contractual Acceptance Test Procedure, or equivalent
- Written instructions, or check lists are available in dispatch area showing that contractual documentation is delivered together with product, or in accordance with contract
- release documentation (type of document, qualification to release parts and documents, ...) is delivered as required by contract or regulation and existing customers rejections or complaints for non adequate documents are furnished with products delivered

**8.3**

## Control of nonconforming product (NCP)

**What to look for**

For each NC, objective evidence:

- of how the Organization is evaluating the effect of NC on product already delivered (or in process)
- of how responsibilities are defined
- of how NCs are recorded in order to ensure traceability between NC and S/N or manufacturing batch
- that, in case of rework, product have been re-inspected
- that, in case of part or product scrapped, NC product have been marked (labeling) or controlled (specific storage areas,…)
- that, in case of concession request accepted, NC report (or concession report ) are identified on delivery document (including FAA or EASA release Form)

NOTES:

- select random sample from NC database in addition of NC in-progress
- select at least one sample of each of the following types of NC :
  - procurement, manufacturing process (including test/inspection phases),
  - repair (if applicable)
  - Customers.
- if supplier have MRB delegation from Customer, check scope of delegation

**8.4**

## Analysis of data

**What to look for**

Recommended questions:

- How measures are calculated (method, trend, possible interactions between indicators, follow-up of these indicators)?
- Who, how, what actions are taken in case of degradation?
- How does the organization measure the effectiveness of the QMS?

**8.5**

## Improvement

### 8.5.1 Continual improvement

**What to look for**

Consideration by the organization of a process approach to continual improvement. That is to say an interaction and alignment of

processes to enable the achievement of planned results (planned improvement)

- It does not have to be called continual improvement
- It does not have to be documented
- It can be made up of several other processes or parts of other processes within the Quality Management System
- The Quality manual includes a description of the interaction between the processes of the Quality Management System. It should include process interactions that deliver continual improvement

## What to ask

Recommended questions:

- **Planning and objective setting (Plan)**
  - What does the organization want to improve within the approval scope?
    - What are the drivers for the improvement (i.e. why do it)?
    - Will it improve any of: consistency, customer satisfaction, regulatory compliance, realization of their declared policies, compliance with a requirement or prevent possible failure?
    - Who will benefit and how?
  - What is the current performance?
    - How has the organization evaluated current performance?
    - What data is available?
  - What is the target performance/objective?
    - How did the organization decide on the target?
    - How will they monitor or measure performance?
    - What is the timescale for achieving the target?
  - What is the plan to realize the improvement?
    - What resources are needed?
    - Who is doing what, and when?
    - Which processes or functions are involved or affected?
- **Implementation of improvement plans (Do)**
  - Have plans been implemented and maintained?
    - Have actions been taken as planned?
    - Have plans been changed and updated as appropriate?
    - Is implementation progress being maintained?
- **Progress of improvement monitoring (Check)**
  - Has improved performance or progress towards the objective been achieved?
    - What is the current performance?
    - How do the results compare with the targeted performance / objectives?
    - Have any changes been made to the improvement target or objective?
- **Evaluation and maintenance of improvement (Act)**
  - Decision making:
    - Has the target being achieved, taken as far as is viable or overtaken by events and other priorities?
    - Has the desired result been achieved?
    - Who decides and what data is the decision based on?
  - Review and close:
    - Has the system been changed to ensure the improvement is maintained?

Example of objective evidence:

- An area for improvement identified to be pertinent to the organization's approval scope. It may be from:
  - External drivers:
    - regulatory changes, legislation
    - market expectations, competitor activity
    - customer perceptions, including dissatisfaction
  - Internal drivers:
    - poor process effectiveness or efficiency, capability or consistency, risk management
    - business strategy, policy or objectives, expected results and benefits, results of management review
- There could be:
  - Data analysis of performance measures
  - Product or service delivery performance data, customer satisfaction data leading to a list of problems where expected performance is not achieved
  - Audit results, benchmarking, corrective actions, non conforming product, supplier data
- Examples may include:
  - Pareto, cost benefit analysis, competitor research, benchmarking, customer survey
  - Internal and external indicators and measures, process capability, time and resource usage, failure rates
  - time to completion, investment limits – cost and resource
- For the chosen solution, there could be:
  - Resource planning - budgets, time, people, internal and external expenditure
  - Action plans with responsibilities, Gantt charts, critical path analysis
  - Interim decision points and success measures
  - Process analysis, quality function deployment, moments of truth analysis. The impact of the improvement on other processes should be known
- Evidence, records of trials, pilot runs, change documentation, operator training, new tooling or equipment etc.
- Typical evidence would include:
  - Current performance data, elimination or reduction of the initial performance gap
  - Performance data of related processes show no negative effects or trends
  - Revised targets based on results achieved, investment made and re-evaluation of improvement drivers and priorities
- Typical evidence should include:
  - Fact based decision making
  - An authorized person decides to adjust, close, abandon or extend the improvement target and implementation activities
- Typical evidence may include:
  - Improvement realized is maintained over an appropriate time period

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| | - Process controls, performance standards, procedures, documents, training and equipment changed<br>- Lessons learned review, improvement cascaded to related activities, processes or locations<br>- If unsuccessful, what is the organization doing to address the problem?<br>- New or revised objectives |
| **8.5** | **Improvement**<br>**8.5.2 Corrective action**<br><br>**What to look for**<br><br>Example of objective evidence:<br>• samples of non conformities and corrective actions<br>• effectiveness of corrective and preventive actions, possibly by samples<br>• root cause analysis<br><br>Recommended questions:<br>• How CA are managed when they have different interfaces?<br>• What is done in case implementation is belated? |
| **8.5** | **Improvement**<br>**8.5.3 Preventive action**<br><br>**What to look for**<br><br>Consideration by the organization of:<br>• Trend analysis for process and product characteristics (output from the data analysis process)<br>• A worsening trend might indicate that if no action is taken, a non-conformity could occur<br>• Alarms to provide early warning of approaching "out-of-control" operating conditions<br>• Monitoring of customer perception, by both formal or informal feedback systems<br>• Analysis of trends in process capability, using statistical techniques<br>• Ongoing failure mode and effect analysis for processes and products<br>• Evaluation of nonconformities that have occurred in similar circumstances, but for other products, processes, or other parts of the organization, or even in other organizations<br><br>Examples of objective evidence that:<br>• the organization has analyzed the causes of potential nonconformities (use of cause and effect diagrams and other quality tools may be appropriate for this)<br>• the required actions are deployed in all relevant parts of the organization, and in a timely manner<br>• there are clear definitions of the responsibilities for the identification, evaluation, implementation and review of preventive actions.<br><br>NOTE:<br>Methods used in the evaluation could include:<br>• Risk analysis approaches<br>• Failure Mode Effect and Criticality Analysis (FMECA)<br><br>**What to ask**<br><br>Recommended questions:<br>• What is included in preventive actions, including risk management?<br>• How does the organization determine potential nonconformities and their root-causes?<br>• What records are kept?<br>• Are they appropriate, and are they a true reflection of the results?<br>• Are they being controlled in accordance with clause 4.2.4? |