

EASA Part 145 Quality System Audit (Performance)	
Name Of Auditee	
Date of Audit	
Name of Auditor	
Audit Standard EASA Part 145 IR, AMC & GM	
<p><i>Additional Guidance is shown in Bold Italics – Basic Questions include Management & Oversight –Ownership of Procedures - Competence & Training “as required” Completeness, Compliance & Validity of Procedures. In all cases identify the reference of MOE and Associated Procedure</i></p> <p>Point 145.A.65 (c) requires that the quality system monitors that the activities are being performed in accordance with the approved procedures. The quality system procedures are included within these approved procedures. This implies that quality system must be subject to audits and the part-145 organisation audit programme/plan needs to reflect this.</p> <p>Besides that the audits of the quality system shall satisfy the requirement of independent audits. This is further explained in AMC 145.A.65(c)(1) point 11: the independence of the audits should be established by always ensuring that audits are carried out by personnel not responsible for the functions, procedures or products being checked.</p> <p>So, the quality manager cannot audit the quality system in terms of independence of the audit.</p> <p>Therefore, to audit the quality system, it is acceptable to:</p> <p>Use competent personnel from a different section/department in the same organisation not responsible for the quality function/procedure, or,</p> <p>Contract the independent audit element of the quality system to another organisation or a qualified competent person, or,</p> <p>Have the quality system is monitored and certified against an internationally recognised quality standards by a certification organisation.</p>	
Audit Criteria	Compliant Y or N – Provide MOE /Associated Procedure Reference for Compliance or detail Corrective Action Request & Reference
The way the quality system is going to be audited has to be described in the MOE and approved by the competent authority.	

<p>AMC1 145.A.30(e) Personnel requirements Quality audit staff are able to monitor compliance with Part-145 identifying noncompliance in an effective and timely manner so that the organisation may remain in compliance with Part-145.</p> <p>AMC 145.A.30(c) Personnel requirements Monitoring the quality system includes requesting remedial action as necessary by the accountable manager and the nominated persons referred to in 145.A.30(b).</p>	
<p>GM2 145.A.30(e) Competence assessment procedure</p> <p>The Following elements form the basis of the expectations for a Quality Assurance Professional within the EASA Part 145 Organisation</p> <p><i>For each relevant item shown below reference how this element is demonstrated</i></p> <p>Knowledge of applicable officially recognised standards</p> <p>Knowledge of auditing techniques: planning, conducting and reporting</p> <p>Knowledge of human factors, human performance and limitations</p> <p>Knowledge of organisation capabilities, privileges and limitations</p> <p>Knowledge of Part-M, Part-145 and any other relevant regulation</p> <p>Knowledge of relevant parts of the maintenance organisation exposition and procedures</p> <p>Knowledge of safety risks linked to the working environment</p>	

<p>Knowledge on CDCCL when relevant</p> <p>Knowledge on EWIS when relevant</p> <p>Understanding of professional integrity, behaviour and attitude towards safety</p> <p>Understanding of conditions for ensuring continuing airworthiness of aircraft and components</p> <p>Understanding of his/her own human performance and limitations</p> <p>Understanding of personnel authorisations and limitations</p> <p>Understanding critical maintenance task Ability to identify and rectify existing and potential unsafe conditions</p> <p>Ability to understand work orders, work cards and refer to and use applicable maintenance data</p> <p>Ability to use information systems</p> <p>Adequate communication and literacy skills</p> <p>Analytical and proven auditing skills (for example, objectivity, fairness, open-mindedness, determination, ...)</p> <p>Maintenance error investigation skills</p>	
<p>145.A.65 Safety and quality policy, maintenance procedures and quality system</p> <p>(a) The organisation shall establish a safety and quality policy for the organisation to be included in the exposition under point 145.A.70.</p> <p>(b) The organisation shall establish procedures agreed by the competent authority taking into account human factors and human performance to ensure good maintenance practices and compliance</p>	

with the applicable requirements established in 145.A.25 to 145.A.95.

The procedures under this point shall:

1. ensure that a clear work order or contract has been agreed between the organisation and the organisation requesting maintenance to clearly establish the maintenance to be carried out so that aircraft and components may be released to service in accordance with 145.A.50; and,

2. cover all aspects of carrying out maintenance, including the provision and control of specialised services and lay down the standards to which the organisation intends to work.

(c) The organisation shall establish a quality system that includes the following:

1. Independent audits in order to monitor compliance with required aircraft/aircraft component standards and adequacy of the procedures to ensure that such procedures invoke good maintenance practices and airworthy aircraft/aircraft components.

In the smallest organisations the independent audit part of the quality system may be contracted to another organisation approved under this Part or a person with appropriate technical knowledge and proven satisfactory audit experience; and

2. A quality feedback reporting system to the person or group of persons specified in point 145.A.30(b) and ultimately to the accountable manager that ensures proper and timely corrective action is taken in response to reports resulting from the independent audits established to meet point (1). AMC 145.A.65(a) Safety and quality policy, maintenance procedures and quality system.

The safety and quality policy should as a minimum include a statement committing the organisation to:

Recognise safety as a prime consideration at all times.

Apply Human factors principles.

Encourage personnel to report maintenance related errors/incidents.

Recognise that compliance with procedures, quality standards, safety standards and regulations is the duty of all personnel.

Recognise the need for all personnel to cooperate with the quality auditors.

AMC 145.A.65(b) Safety and quality policy, maintenance procedures and quality system

1. Maintenance procedures should be held current such that they reflect best practice within the organisation.

It is the responsibility of all organisation's employees to report any differences via their organisation's internal occurrence reporting mechanisms.

2. All procedures, and changes to those procedures, should be verified and validated before use where practicable.

3. All technical procedures should be designed and presented in accordance with good human factors principles.

GM 145.A.65(b)(1) Safety and quality policy, maintenance procedures and quality system Appendix XI to AMC M.A.708(c) provides guidance on the elements that need to be considered for the maintenance contract between the CAMO and the maintenance organisation.

The Part-145 organisation should take into account these elements to ensure that a clear contract or work order has been concluded before providing maintenance services.

AMC 145.A.65(b)(2) Safety and quality policy, maintenance procedures and quality system Specialised services include any specialised activity, such as, but not limited to non-destructive testing requiring particular skills and/or qualification.

145.A.30(f) covers the qualification of personnel but, in addition, there is a need to establish maintenance procedures that cover the control of any specialised process.

AMC 145.A.65(c)(1) Safety and quality policy, maintenance procedures and quality system

1. The primary objectives of the quality system are to enable the organisation to ensure that it can deliver a safe product and that organisation remains in compliance with the requirements.
2. An essential element of the quality system is the independent audit.
3. The independent audit is an objective process of routine sample checks of all aspects of the organisation's ability to carry out all maintenance to the required standards and includes some product sampling as this is the end result of the maintenance process.

It represents an objective overview of the complete maintenance related activities and is intended to complement the 145.A.50(a) requirement for certifying staff to be satisfied that all required maintenance has been properly carried out before issue of the certificate of release to service.

<p>Independent audits should include a percentage of random audits carried out on a sample basis when maintenance is being carried out.</p> <p>This means some audits during the night for those organisations that work at night.</p>	
<p>4. Except as specified in sub-paragraphs 7 and 9, the independent audit should ensure that all aspects of Part-145 compliance are checked every 12 months and may be carried out as a complete single exercise or subdivided over the 12 month period in accordance with a scheduled plan.</p> <p>The independent audit does not require each procedure to be checked against each product line when it can be shown that the particular procedure is common to more than one product line and the procedure has been checked every 12 months without resultant findings.</p> <p>Where findings have been identified, the particular procedure should be rechecked against other product lines until the findings have been rectified after which the independent audit procedure may revert back to 12 monthly for the particular procedure.</p>	
<p>5. Except as specified otherwise in subparagraphs 7, the independent audit should sample check one product on each product line every 12 months as a demonstration of the effectiveness of maintenance procedures compliance.</p> <p>It is recommended that procedures and product audits be combined by selecting a specific product example, such as an aircraft or engine or instrument and sample checking all the procedures and requirements associated with the specific product example to ensure that the end result should be an airworthy product.</p>	

For the purpose of the independent audit, a product line includes any product under an Appendix II approval class rating as specified in the approval schedule issued to the particular organisation.

It therefore follows for example that a maintenance organisation approved under Part-145 with a capability to maintain aircraft, repair engines, brakes and autopilots would need to carry out four complete audit sample checks each year except as specified otherwise in subparagraphs 5, 7 or 9.

6. The sample check of a product means to witness any relevant testing and visually inspect the product and associated documentation. The sample check should not involve repeat disassembly or testing unless the sample check identifies findings requiring such action.

7. Except as specified otherwise in subparagraph 9, where the smallest organisation, that is an organisation with a maximum of 10 personnel actively engaged in maintenance, chooses to contract the independent audit element of the quality system in accordance with 145.A.65(c)(1) it is conditional on the audit being carried out twice in every 12 month period.

8. Except as specified otherwise in subparagraph 9, where the organisation has line stations listed as per 145.A.75(d) the quality system should describe how these are integrated into the system and include a plan to audit each listed line station at a frequency consistent with the extent of flight activity at the particular line station. Except as specified otherwise in subparagraph 9 the maximum period between audits of a particular line station should not exceed 24 months.

9. Except as specified otherwise in subparagraph 5, the competent authority may

agree to increase any of the audit time periods specified in this AMC 145.A.65(c)(1) by up to 100% provided that there are no safety related findings and subject to being satisfied that the organisation has a good record of rectifying findings in a timely manner.

10. A report should be raised each time an audit is carried out describing what was checked and the resulting findings against applicable requirements, procedures and products.

11. The independence of the audit should be established by always ensuring that audits are carried out by personnel not responsible for the function, procedure or products being checked.

It therefore follows that a large maintenance organisation approved under Part-145, being an organisation with more than about 500 maintenance staff should have a dedicated quality audit group whose sole function is to conduct audits, raise finding reports and follow up to check that findings are being rectified.

For the medium sized maintenance organisation approved under Part-145, being an organisation with less than about 500 maintenance staff, it is acceptable to use competent personnel from one section /department not responsible for the production function, procedure or product to audit the section/department that is responsible subject to the overall planning and implementation being under the control of the quality manager.

Organisations with a maximum of 10 maintenance staff actively engaged in carrying out maintenance may contract the independent audit element of the quality system to another organisation or a qualified and competent person approved by the

competent authority. GM 145.A.65(c)(1)
 Safety and quality policy, maintenance procedures and quality system

1. The purpose of this GM is to give guidance on just one acceptable working audit plan to meet part of the needs of 145.A.65(c)1. There is any number of other acceptable working audit plans.
2. The proposed plan lists the subject matter that should be covered by the audit and attempts to indicate applicability in the various types of workshops and aircraft facilities.

The list should therefore be tailored for the particular situation and more than one list may be necessary.

Each list should be shown against a timetable to indicate when the particular item is scheduled for audit and when the audit was completed.

AMC 145.A.65(c)(2) Safety and quality policy, maintenance procedures and quality system

1. An essential element of the quality system is the quality feedback system.
2. The quality feedback system may not be contracted to outside persons.

The principal function of the quality feedback system is to ensure that all findings resulting from the independent quality audits of the organisation are properly investigated and corrected in a timely manner and to enable the accountable manager to be kept informed of any safety issues and the extent of compliance with Part-145.

3. The independent quality audit reports referenced in AMC 145.A.65(c)(1) subparagraph 10 should be sent to the

<p>relevant department(s) for rectification action giving target rectification dates.</p> <p>Rectification dates should be discussed with such department(s) before the quality department or nominated quality auditor confirms such dates in the report.</p> <p>The relevant department(s) are required by 145.A.65(c)(2) to rectify findings and inform the quality department or nominated quality auditor of such rectification.</p>	
<p>4. The accountable manager should hold regular meetings with staff to check progress on rectification except that in the large organisations such meetings may be delegated on a day to day basis to the quality manager subject to the accountable manager meeting at least twice per year with the senior staff involved to review the overall performance and receiving at least a half yearly summary report on findings of non-compliance.</p> <p>5. All records pertaining to the independent quality audit and the quality feedback system should be retained for at least 2 years after the date of clearance of the finding to which they refer or for such periods as to support changes to the AMC 145.A.65(c)(1) sub-paragraph 9 audit time periods, whichever is the longer.</p>	
<p>Guidance Notes Concerning PART 3 – QUALITY SYSTEM PROCEDURES.</p> <p>3.1 Quality Audit of Organisation Procedures.</p> <p>Part 145.A.65 (a) - Part 145.A.65 (c) (1), (2) / AMC 145.A.65 (c) (1)</p> <p>This chapter must explain how the audit of internal procedures is organised and managed i.a.w. PART 145.A.65 and AMC 145.A.65.</p>	

In particular this chapter shall describe how the requirements for system/procedure audit are complied with and the methodology of the audit.

Small organisation may choose to subcontract the audits to another organisation or an outside person with satisfactory technical knowledge and satisfactory audit experience (link to chapter 3.6).

Definition of the Quality System:

Independence of the quality compliance monitoring staff (e.g. quality auditor)

Access to Accountable Manager
Composition and functions of management quality group

Definition of the "system/procedure" audit (ref. AMC 145.A.65 (c).(1).3&4)16

Common audit procedures for several lines of product

Specific audit procedure by line of product

Single exercise audit or subdivided over 12 months

Findings classification (ref. 145.A.95)

Procedures to manage findings and related due dates to be entered in MOE chapter

3.3 "System/procedure" Audit programme

System/procedure audit plan (refer to GM 145.A.65.(c).(1))

Principles of annual audit procedure planning

Grouping of audits

Dates and timescales.

Audit of the Quality system by an independent auditor, being either:

A person employed by the maintenance organisation and working in another department (i.e. production), or;

A person contracted by the maintenance organisation (part-time basis or short time contract based on the 145.A.30 (d) contracted personnel) to perform audits on the quality system procedures.

This case does not mean subcontracting the quality system.

Audit of contracted organisations /Subcontractors/suppliers, as applicable depending to the monitoring criteria defined in MOE chapter 2.1.

Scheduled audits and audits to be carried out at random and to be carried out during maintenance including night shifts.

Validation/internal approval of the audit programme and management of changes to the programme Follow up of the audit program: scheduled, performed, audit report issued, open/close – link with chapter 3.3

Company Audit Policy including compliance audit:

The internal audit plan shall also take into account the applicable Part-M requirements
Part-145 organisations shall take into account the following requirements of Part-M:

M.A.201 (c) – Responsibilities
M.A.402 (a) & (f) – Performance of Maintenance;
M.A.403 (b) – Aircraft defects
M.A.501 (a) & (c) & (d) – Installation
M.A.504 (a) & (b) & (d) & (e) – Control of unserviceable components

In addition, Part-145 refers to the following Appendixes of Part-M:
Appendix II to Part-M (EASA Form 1)
Appendix IV to Part-M (Class and rating system)
Appendix IX to AMC M.A.602 and AMC M.A.702 (EASA Form 2)
Appendix X to AMC M.B.602(a) and AMC M.B.702(a) (EASA Form 4)

The MOE shall be customised by each organisation to demonstrate how they comply with:
For each detailed procedure described within the MOE, the Part 145 organisation should address the following questions:

What must be done?
Who should do it?
When must be done?
Where must it be done?
How must it be done?
Which procedure(s)/form(s) should be used?

Consider the following elements

Audit notification;

Audit reports (documents used, writer, issue, points checked and deviations noted, deadline for rectification)

Reference can be made to MOE chapter 3.3 detailing the process to manage findings

Allocation of resources to the audit (audit team, team leader, etc.)

Principles when deviations are noted on a line of product Quality audit reports retention

Duration (At least duration of 2 years from the date of the findings closure) / location
Type of documents (notification, audit reports, check list, audit programs)

3.2 Quality Audit of Aircraft and/or Components.
Part 145.A.65 (c) (1), (2) / AMC 145.A.65 (c) (1)

This chapter must describe the procedures related to the product audits (aircraft, aircraft component, engine, specialised service) according to PART 145.A.65 (c) 1 and AMC 145.A.65 (c).

Definition of "Product" audit (ref. AMC 145.A.65.(c).(1).5Company "Product" Audit Policy

A dedicated "Product" audit policy may be added, provided it does not conflict with the one describe in the previous chapter.

The Company audit procedure shall include the quality audit of aircraft (and/or component)

"Product" Audit programme

Product samples for each line of product (aircraft and / or components and/or engines and/or specialised services)

Dates and timescales

"Product" Auditing methods

Sampling

"Trail" / "investigation" audits

Records of "Product" audit reports

Duration (At least duration of 2 years from the date of the findings closure) / location

Type of documents (notification, audit reports, check list, audit programs,

Small organisation may choose to subcontract the audits to another organisation or an outside person with satisfactory technical knowledge and satisfactory audit experience (link to chapter 3.6).

Quality Audit Corrective Action Procedure.

Part 145.A.65 (c) (2) / AMC 145.A.65 (c)
(2)

This chapter must describe the procedures of follow up of corrective actions.

Description of the quality audit report feedback system

Corrective action and timescale

Corrective action planning and follow up e.g notified, answered, corrective action accepted,

open/closed

The corrective action plan shall be designed in a way which allows identifying and recording the finding, the root cause, the relevant immediate and long term preventive action with the appropriate timescales.

Management of finding due dates

Alert system, finding database

Extension of the due date Procedure describing the organisation actions when the corrective action deadline has to be postponed or when the answer has not been received on time.

Management responsibilities for corrective action and follow-up Review of the

Quality system overall results Meeting with the Accountable Manager. (including record of meeting procedure)

Regular meetings to check the progress of corrective actions

The follow up of corrective actions cannot be subcontracted.

The revision of the audit planning according to the deviations noted/corrected could be linked to chapter 3.1

All Audit Findings have been transferred to corrective action requests

Signature

Name

Audit Closed QM Signature

Date