EUROPEAN DEFENCE AGENCY

EMAR 21 GUIDE 1.0

IMPLEMENTATION GUIDE FOR NATIONAL MILITARY AIRWORTHINESS AUTHORITIES

EMAR 21 IMPLEMENTATION GUIDE FOR NATIONAL MILITARY AIRWORTHINESS AUTHORITIES

Prepared on 08 October 2021[1]

EUROPEAN DEFENCE AGENCY
RUE DES DRAPIERS 17-23
B-1050 BRUSSELS

[1] The date represents the date when the document was generated.

DOCUMENT CONTROL INFORMATION

DOCUMENT APPROVAL

The table below provides the document approval status:

edition	step	approved by	represented by	date
Edition 1.0	draft	MAWA DPAG	Magnus Johansson DPAG Chairman	25 March2021
	consultation	MAWA Forum F40	Henk CORPORAAL MAWA Forum Chair	13 April 2021
	publication	MAWA Forum F41	Henk CORPORAAL MAWA Forum Chair	5 October 2021

Note:

This EMAR 21 Implantation Guide is intended to be used by authorities, related organisations and personnel engaged in the design, production, maintenance and support of military aircraft and airborne equipment to provide additional guidance on the implementation and application of EMAR 21 requirements.

The first Edition of the Guide addresses the approvals of organisations. The other chapters will be subsequently added.

If language confusion could arise from the use of abbreviated names of months, the following format shall be used for dates: dd/mm/yyyy where dd = 2 digit day, mm = 2 digit month, yyyy = 4 digit year.

REVISION STATUS

REVISION HISTORY

Edition	Approval date	Reason for Document Revision
Edition 1.0	05/10/2021	Initial release

TABLE OF CONTENTS

DOCUMENT CONTROL INFORMATION 3

REVISION STATUS 4
Revision history 4

Table of Contents 5

Chapter I GENERAL 7

1 Abbreviations / Acronyms / Definitions 7

2 Document Scope 7

Chapter II Product related activities 8

Chapter III Organisation related activities 9

1 General considerations 9
1.1 Introduction 9
1.2 Scope of the Procedures 9
1.3 Investigations and audits 9
1.4 References 9

2 Design Organisation Approvals 10
2.1 Initial Design Organisation Approval 10
2.2 Continued Surveillance 16
2.3 Changes within Approved Design Organisations 18

3 Alternative Design Organisation Approvals 19
3.1 Scope and limitation of Alternative Design Organisation Approvals 19
3.2 Coordination between the ADOA assessment team and the PCM 20

4 Production Organisation Approvals 20
4.1 Initial Production Organisation Approval 20
4.2 Continued Surveillance 25
4.3 Changes within the Approved Production Organisation 27

5 Production without Organisation Approval 28
5.1 Letter of Agreement Procedure 29
5.2 Amendment to the Letter of Agreement 33
5.3 Validation of the Statement of conformity (Form 52 & Form 1) 33
5.4 Findings of Non-Compliance 34

6 Additional Provisions 34
6.1 Resolution of Disagreements 34
6.2 Limitation, Suspension and Revocation 34
6.3 Limited Approvals 35

Chapter IV Cross Domain topics 36

Chapter V Considerations for Multinational Cooperation 37

Chapter I GENERAL

1 Abbreviations / Acronyms / Definitions

a) The following Abbreviations and Acronyms are used throughout this document:

DOA	Design Organisation Approval
DOE	Design Organisation Exposition
ICA	Instructions for Continuing Airworthiness
(M)TSO	(Military) Technical Standard Orders
NMAA	National Military Airworthiness Authority
PCM	Project Certification Manager
POA	Production Organisation Approval
PwOA	Production without Organisation Approval
POE	Production Organisation Exposition
TL	Investigation Team Leader

b) The 'Authority' refers to the competent NMAA.

c) Any reference to 'certificates' or approvals shall be understood as certificates or approvals under the scope of the Authority.

d) An 'External Party' refers to an appropriately designated entity outside of the Authority.

e) Any reference made to specific EMAR Requirements should be read across to the equivalent requirement of the applicable national regulation.

f) Any reference made to specific Forms should be read as an EMAR Form or the equivalent Form used in context of the applicable national regulation. For Forms that are not available in EMAR Forms Document, Forms could be derived from the respective EASA Forms.

g) Any reference to the term 'foreign Authority' should be understood as an Authority outside of the Authority's territory or outside of the Authority's competence or legal environment (e.g. civil Authorities should be regarded as being 'foreign' from military regulations perspective).

2 Document Scope

This EMAR 21 Implementation guide presents a collection of practices that can be used by National Military Airworthiness Authorities implementing EMAR 21. It provides additional guidance on how Authorities could carry out activities and may serve as a basis to develop the associated internal procedures for national implementation.

The Guide considers only regulatory frameworks that are based on EMAR 21 compliance. Any deviations, special provisions as well as rights and obligations originating from applicable national regulations and arrangements (e.g. bilateral or multilateral arrangements for recognition) need to be considered separately.

Chapter II Product related activities

(reserved)

Chapter III Organisation related activities

1 General considerations

1.1 Introduction

The objective of this chapter on Organisation Approvals (DOA, ADOA, POA, PwOA) is to establish general principles, which should be followed by a national Authority to process applications for such approvals in accordance with the applicable European Military Airworthiness Requirements or their equivalent national requirements.

1.2 Scope of the Procedures

The recommended procedures for the different organisation approvals in this chapter describe the activities associated with the administrative management of the application, the investigation, the recommendation from the assessment teams, the issuance of the respective approval certificates, and the continued surveillance of the approved organisation. They also describe how an Authority could handle the continuation, change, limitation, suspension, or revocation of approvals in accordance with EMAR 21.

The recommended procedures could also be used by Authorities when acting on behalf of foreign entities on specific request, e.g. in cases where an organisation is applying for an approval to an Authority without having their principle place of business in this Authorities territory, if adequate bilateral arrangements (recognition) exist.

1.3 Investigations and audits

When conducting on desk investigations, due consideration needs to be taken that the relevant entities (Authorities, DO, PO, …) are correctly identified in the different documents and related arrangements (POE, DOE, DO-PO, …) as some entities may be specific to individual programmes. Further Guidance and considerations on the coordination between entities in a multinational environment will be added under Chapter V of this guide at later stage.

1.4 References

- EMAR 21 Certification of Military Aircraft and Related Product, Parts and Appliances, and Design and Production Organisations; including
- EMAR 21 Acceptable Means of Compliance (AMC) and Guidance Material (GM).

2 Design Organisation Approvals

2.1 Initial Design Organisation Approval

The initial approval of an organisation applying for a DOA should be streamlined as much as possible to ensure that all required functions and processes with regards to design activities are present in the applicant's organisation.

5 phases can be identified leading to the issuance of the DOA Certificate as represented in the timeline below. These 5 phases need to be followed regardless of the scope of approval applied for by the applicant. The workload of each phase however may vary depending on the scope of approval.

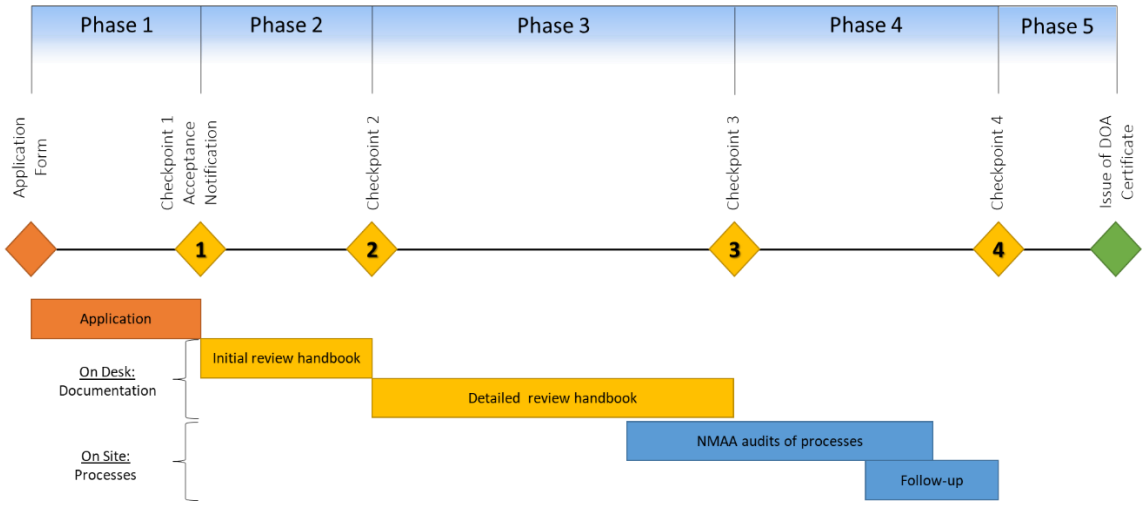

Figure 1: Design Organisation Process - Phases

2.1.1 Phase 1: Application and determination of the DOA Team

An organisation applying for DOA should do so through the submission of a completed Form 80 (EMAR Form or a national equivalent). Following receipt of the Form 80 the Authority should be able to determine the requested scope of approval and consequently to establish the adequate DOA Team to conduct the investigations with the aim to issue a DOA Certificate. The Form 80 should be used exclusively for new applications. Applications for changes to approvals should make use of a Form 82.

Ideally these applications should be accompanied by the Design Organisation Exposition (DOE)/Handbook but at minimum an outline of the contents of the DOE/Handbook. To allow for a timely review, the DOE/Handbook must be submitted at the latest during the kick-off meeting.

When the applicant has already an existing DOA (civil/military) issued by a foreign Authority, e.g. when the application is made by an organisation located outside of the Authority's territory, the Authority should liaise with the foreign Authority.

The Authority should acknowledge receipt of an application, informing the applicant about a kick-off meeting to finalise the application acceptance (Phase 1) that will be held after the DOA team designation. The Authority should verify the application. Where incorrect or incomplete information is supplied, the Authority should notify the applicant as soon as possible by a letter detailing the omissions and errors.

2.1.1.1 Allocation of technical investigation tasks

After receipt of the application, the Authority should check if the application shall be further processed internally or if the technical investigation should be allocated to an external party.

In cases where the technical investigation shall be allocated to an external party, which will handle the technical investigation on behalf of the Authority, the selected external party should be designated in accordance with relevant procedures (e.g. regulation, contract, accreditation process). The external party should be responsible for complying with these procedures.

It is advisable for the Authority to have at least one representative taking part in the activities of the external party.

The Authority or external party should establish an appropriate DOA Team.

The DOA Team should be provided with any necessary information needed for the effective performance of the technical investigation tasks. When the investigation is allocated to an external party, a single point of contact for liaison with the Authority should be appointed.

2.1.1.2 Determination of the DOA Team

The Authority should nominate a team leader and the members of the DOA Team to carry out the investigation process, considering the necessary training, competence, previously accumulated experience, and the available capacity in accordance with the Authority's specific requirements. The composition and size of the team can consist of only the DOA Team Leader (DOA TL) but may vary and is dependent on:

- Size of the applicant's organisation,
- Complexity of the organisation approval applied for,
- Number of sites covered by the approval,
- Nature of the services to be covered by the DOA & its direct impact to aviation safety.

For specific technical investigations, the team may receive assistance from appropriate technical experts. Trainees may participate in investigation teams in accordance with Authority procedures.

2.1.1.3 Kick- Off Meeting

Once the DOA Team is designated and, within reasonable time frame, the Authority should plan and hold a kick-off meeting with the applicant (preferably at the Authority's location) for:

- a general presentation of the applicant,
- a general presentation of the investigation process by the Authority.

After the meeting, minutes of the meeting should be sent to the applicant, additionally notifying the applicant of the following:

- whether its application is accepted, needs improvement, or is refused,
- the designation of the audit team,
- preliminary approval number (e.g. adding a suffix "P" indicating the pending status of the approval, for example [Authority].[21J].[XXXXP]),
- information on the follow-on steps of the process and clarifications on the requirement interpretation and associated acceptable means of compliance.

The NMAA approvals database should be updated with all the relevant information. In case of need for improvement or refusal of an application, the Authority should add in this notification the reasons thereto. Where relevant and if national regulations apply, a reference to the possibility for appeal as specified in national regulations should also be included.

2.1.2 Phase 2: Initial review of the Exposition

The initial review of the Exposition serves a dual purpose for the DOA Team:

1) Verification of the presence of the constituent parts of the organisation.
2) Elaboration of the DOA Team checklist in preparation of the detailed review of the exposition and on-site audit.

The DOA Team Leader should assign subtasks to its team members in the activities to achieve the objectives above. Each member should ideally focus on one constituent part and determine what requirements must be met and should be audited in detail on desk and on site. This will help the DOA Team Lead to establish the DOA compliance checklist, which will serve as a guide towards the issuance of a DOA Certificate.

2.1.2.1 Presence of the constituent parts of the organisation

As defined in EMAR 21 Subpart J, a design organisation must have certain elements in place for an approval to be granted, regardless of its scope of approval.

1) A Design Assurance System (ref. 21.A.239): The Design Assurance System should have the 3 elements present as described in 21.A.239.
2) An Organisation exposition (ref. 21.A.243): This Exposition/Handbook shall describe the organisation and identify the procedures for the scope of work covered by the MDOA and include or give reference to a Compliance Matrix (linking the EMAR 21 requirements to the relevant paragraphs in the Exposition).
3) The right people, at the right place with the right means (ref. 21.A.243 and 21.A.245): Key personnel must be nominated, being appropriately qualified and having the appropriate authority within the organisation to execute its functions and responsibilities.
4) Terms of Approval (ref. 21.A.251 and 21.A.263) defining the technical scope, category of products and privileges according to 21.A.263 as requested by the applicant.

2.1.2.2 Elaboration of the DOA compliance checklist

As the scope of work of every applicant will vary from applicant to applicant, so will the list of requirements to be adhered to. Subpart J is the core of every design organisation but through the application to become an approved Design Organisation, other subparts of EMAR 21 will be subject of the audit review as well to ensure the responsibilities in relation to the activity in question are properly discharged by the organisation. These activities together with the constituent parts define the core processes to be verified and are listed below:

Constituent core process	Scope of work driven core process
– Management of DO (21.A.243 (d) and 21.A.245 (a)) – Independent System Monitoring (21.A.239 (a) 3. and (b)) – Occurrence reporting (21.A.265 (e)) – Competences (21.A.245 (a)) – Suppliers Control (21.A.245 (b)) – Configuration Control (21.A.239 (a) 1.) – DO - PO coordination / arrangements – Periodical Activity Reporting	– Type Certification – Changes – Repairs – Supplemental Type Certification – Permit to Fly – MTSO – Manuals / ICA

Table 1: DOA Core processes

Hence, following the initial review and through the analysis of the presence of the constituent parts the DOA TL should be able to establish a tailored DOA compliance checklist to be completed during the detailed DOE/Handbook review and the on-site audit of the applicant.

Once the checklist is tailored and the required DO activities identified, the DOA TL can proceed to Phase 3 and start the detailed review of the Exposition.

2.1.3 Phase 3 detailed review of the Exposition

Based on the Checklist established in Phase 2, every core process should be analysed in detail within the DOE/Handbook and all its references. The DOA TL should assign core processes to be reviewed to team members in the interest of efficiency.

The review of the core process should focus on the compliance to the requirements in the relevant subpart with regards to obligations on the execution of the relevant scope of work / core process. Questions should be recorded and collected by the DOA Team Leader to be handed over for reply to the applicant.

The DOA team members should determine whether a core process needs a process audit on site based on the information found in the DOE/Handbook.

The collection of questions with associated answers and the recommendation of the DOA team members to execute a process audit should enable the DOA Team Leader to establish an audit plan to be executed during Phase 4.

The checklist should be completed with the references to the DOE/Handbook chapters and mention any question and reply issued during the detailed review of the Handbook / Exposition. The DOA TL should establish an audit plan detailing the different timings and activities to be performed during the audit.

Once the detailed review of the DOE/Handbook is satisfactory completed, the DOA TL should:

– liaise with organisation for scheduling the audit(s),

– agree with the applicant on the on-site investigation plan, locations/suppliers needing investigation and approximate time scale,

- provide an audit questionnaire,
- request and agree on sample (product) projects for process assessment.

2.1.4 Phase 4: Authority audits of DO processes

The DOA TL should start the on-site audit with an opening meeting with the auditee's management and, where possible, with the Accountable Manager.

The following points should be considered when carrying out the meeting:

1) Confirmation of the audit schedule (including the scope of the audit).
2) Explanation on the method for handling findings.

The following on site activities should be carried out:

1) Audits of the organisation, its organisational structure, and its procedures for compliance with EMAR 21 Subpart J. The details of this auditing of working processes and procedures should be documented using compliance audit reports / checklists. The constituent parts and identified DO core processes shall all be covered.
2) Interview of the key personnel nominated by Form 4.
3) Checking that the DOE/Handbook reflects the organisation, its procedures, practices, and all requirements in accordance with 21.A.243.
4) Verifying that the DOE/Handbook is known and used as a basic working document.
5) Sample (product) audits at working level to verify that:
    a) Work is performed in accordance with the procedure described in the DOE/Handbook and its associated procedures.
    b) Facilities, working conditions, equipment and tools are in accordance with the DOE/Handbook and appropriate for the work being performed.
    c) Competence and number of personnel is appropriate for the work being performed.

At an advanced stage of the investigation the DOA TL should review the other audit results and matters arising, in order to determine any additional areas requiring investigation.

The Accountable Manager should be seen at least once during the investigation process, preferably during the conclusion meeting and where possible also during the initiation meeting because he or she is ultimately responsible for ensuring compliance with the requirements for initial grant and subsequent maintenance of the design organisation approval.

Findings made during the investigation process could be classified according to 21.A.258 and handled by the DOA TL according to Section B of EMAR 21 subpart J, where applicable.

A closing meeting chaired by the DOA TL should be held to present the audit findings and conclusions to the auditees to ensure that they are understood. The auditees should be given the opportunity to discuss any non-compliance identified and suggest corrective actions and a timeframe for implementation. For an initial approval, all level 1 and 2 findings, as defined in 21.A.258, should be solved prior to approval recommendation to the Authority and for level 3 findings a corrective action plan should be considered as a minimum.

The formal notification of the findings should be sent by the Authority to the organisation ideally within a maximum of two weeks from the closing meeting of the audit.

The organisation should produce a corrective action plan and submit it to the DOA TL for acceptance.

Note: It is highly recommended for the applicant to submit the corrective action plan for the finding to be sure that it is in line with DOA TL expectations.

The implementation of a corrective action plan without prior agreement by the DOA TL could lead to the rejection of the corrective action and delay the finding closure.

Failure to close the findings within the agreed target date could lead the Authority to terminate the application.

After all planned investigations have been performed; the DOA TL should hold a team meeting to review findings and observations. Depending on the extent and nature of findings and the related corrective actions, an additional audit may be necessary.

When the need is felt, additional audits in specific areas may be planned before a final agreed file on the investigations is compiled, together with an overview of all open and already closed findings.

A report in accordance with the associated and completed checklist should be produced including the audit findings and finding resolutions.

The DOA TL should follow up the closure of all findings identified during the audit(s). When the DOA TL is satisfied with the actions that have been taken by the organisation in respect of the finding raised during the audit, the DOA TL / Authority should notify the organisation in writing that the non-compliances are considered closed.

On completion of the investigation a conclusion meeting with the applicant should be held. The meeting should be chaired by the DOA TL and should agree on the remaining findings, corrective action time scales, and preliminary arrangements for any follow up that may be necessary.

2.1.5 Phase 5: Approval Issuance

Once compliance of the applicant with EMAR 21 Subpart J and associated subparts in accordance with the scope of work has been established, the DOA TL should recommend to the Authority the approval of the design organisation, including management personnel acceptance. This report should also substantiate the granting of privileges by the Authority.

For that purpose, DOA TL should submit a recommendation package (DOA compliance checklist, accepted Form 4, privilege granting substantiation, Terms of Approval (ToA)) for Authority review.

In the case of task allocation to an external party, this package should be reviewed for quality check by the External Organisation POC (within the Authority) before being submitted to the Authority for review.

The recommendation package should be reviewed by the Authority for compliance and accuracy. It is accepted that some level 3 findings are not fully closed because corrective actions are still in progress.

Once satisfied, the Authority should sign the Certificate (Form 83a) and the Terms of Approval (Form 83b).

When the DOA Certificate is issued, the approval number is updated (e.g. by removing the “P” from the approval reference).

Note: Limited approvals can be granted in accordance with 6.3 if not all requirements have been complied with.

2.2 Continued Surveillance

After the DOA Certificate is issued and to ensure continuous and complete compliance with EMAR 21 Section A Subpart J and any other applicable requirement of EMAR 21, the Authority should appoint a DOA TL in charge of the continued surveillance of the DO.

By default, the surveillance should be performed by the assigned initial investigation team. However, should it become necessary or more appropriate to change, the Authority may decide to allocate the continued surveillance to another team.

In any case, the presence of technical experts is still required during the continued surveillance to support the investigation by analysing audit samples provided by the approved DO and provide feedback to the audit team for audit preparation.

The continued surveillance is carried out over a cycle, typically 36 months, in accordance with the continued surveillance plan established by the Authority. This continued surveillance plan should be communicated to the DO.

The continued surveillance activities will be controlled by the Authority according to the predefined investigation plan, and the Authority should notify the approved DO about planned audits in a timely manner.

The following activities should be carried out:

- planned continued surveillance, consisting of several audits (at least one per year) to check compliance with EMAR 21 Subpart J and the effectiveness of the DOE/Handbook and associated procedures.
- sample (product) audits at working level to verify:
  - that work is performed in accordance with the procedures described in the DOE/Handbook and its associated documents;
  - the correct application of processes used in the scope of the granted privileges (classification of changes, approval process, repair approval process etc.);
  - the proper functioning of the Independent Monitoring and Design Assurance System are functioning;
  - the execution of the supplier control;
  - the proper management and control of configuration data;
  - the proper management of continued airworthiness functions;
  - the proper management of changes to the instructions for continuing airworthiness;
  - that facilities, working conditions, equipment and tools are in accordance with the DOE/Handbook and are appropriate for the work being performed;
  - that the competence and number of personnel is appropriate for the work being performed;
  - that coordination between production and design as well as between design organisations and where relevant between the design organisation and maintenance organisation (modification of in-service aircraft) are documented and satisfactory;
- unscheduled DOA audits related to surveillance findings or external needs.

- at least once a year the DOA TL should have a meeting with the Accountable Manager where the general situation regarding the Design Assurance System of the organisation will be reviewed, based on audit results and corrective actions taken by the organisation.

Normally the frequency of visits for continued surveillance should be one visit per 12-month period as a minimum, starting from the date on which the DOA Certificate was granted. This may be varied, when agreed by the Authority. The criteria to be reviewed by the Authority for changing audit visit frequency are as follows:

- Follow up of audits / findings,
- Change to the approval,
- Incident response,
- Request by the NMAA,
- Large complex organisation,
- Complex product,
- Multiple locations.

Each finding should be documented against detailed references to EMAR 21 requirements or the approved DOE/Handbook and associated procedures. All audit reports should be communicated to the organisation. In case of suspected level 1 or level 2 finding impacting the approval, the DOA TL or External Party will have to liaise with the Authority for a confirmation of the finding level.

When the level 1 finding is confirmed, the DOA TL or External Party should not transmit the audit report to the organisation directly. However, he/she should transmit the audit report with their recommendation to the Authority. The Authority should notify the finding(s) to the organisation together with the decision against the approval.

The DOA TL or External Party POC should inform the Authority regarding any level 1 finding made against the DOA holder together with actions it has taken. In case of a level 1 finding, the Authority should review the finding and take appropriate action.

In some cases, the DOA TL or External Party can raise level 2 finding impacting the validity of the approval. In such circumstances, the DOA TL or External Party POC should also inform the Authority, who should review the finding and take appropriate action.

In case of a negative decision by the Authority on the validity of the approval, the Authority should notify the approval holder by letter and, where relevant, in copy the External Party through the POC, detailing the limitation, suspension or revocation of the approval.

Note: For every finding, the quality system of the organisation should propose a corrective action, compiled in a corrective action plan. The design organisation should submit the corrective action plan to the Authority to be sure that it is in line with what the auditors expect. A rejection of the corrective action plan could lead to a delay in the finding closure. Corrective actions should contain a reference to the finding, the root cause, relevant immediate actions, long-term preventive actions and timescales.

The corrective action period granted by the Authority for any finding will need to be appropriate to the nature of the finding. During the debriefing of the audit with the DOA holder, a reasonable period should be determined which should enable the DOA holder to take the corrective action including root cause actions but, in any case, initially, according to EMAR 21, must not be more than 3 months.

In certain circumstances and subject to the complexity and the nature of the finding, the 3 months period may be prolonged subject to a satisfactory corrective action plan agreed with the Authority or the DOA TL where appropriate. This request for extension should formally be submitted, detailing the corrective action plan proposed and the new proposed target date.

Failure to comply within the agreed time scale could lead to provisional suspension of the approval in whole or in part. Every 36 months the DOA TL should summarize the surveillance performed and if satisfied, recommend to the Authority to continue the approval. For that purpose, the TL should prepare a recommendation letter and a continued surveillance plan for the next cycle.

In extraordinary circumstances, the cycle period may be extended by the Authority. This is subject to verification by other means that the procedures are functioning within the DOA holder's organisation. At the time of the continuation, recent findings having not yet reached the deadline may be still open. However, the DOA TL in charge of the recommendation should be satisfied with the corrective action plan of any open finding made at the time of the recommendation.

When continued validity of the certificate is accepted, the Authority should formally notify the approved design organisation and copy the External Party POC, when applicable.

2.3 Changes within Approved Design Organisations

2.3.1 Application for change

The DOA holder should notify to the Authority any changes to the organisation.

All significant changes to the Design Assurance System as detailed in the 21.A.247 or to the terms of approval as referred to in 21.A.253 require an approval from the Authority. The DOA holder can submit a Form 82 (Application for Significant Changes to Design Organisation Approval (DOA)) to the Authority to ask for the change approval.

It must be clear that any significant change should be applied for and requires approval from the authority prior to its implementation.

A Form 82 should also be submitted in the case of a change of the company name.

In the case of a change of a nominated person, the signed Form 4 should be attached to the Form 82 (several changes of nominated personnel can be requested on the single Form 82).

For any significant change, a draft DOE/Handbook update shall be submitted for acceptance together with other related documents that may be affected by the change. In case of change of location, it is advised to send a coordination plan together with the Form 82 to agree transitional arrangements which can allow continuation of the approval. This coordination plan should be accepted by Authority.

2.3.2 Allocation of the investigation team

By default, the investigation should be performed by the assigned initial team. However, should it become necessary or more appropriate, the Authority may decide to allocate the investigation to another team or auditor.

2.3.3 Technical investigation for change and issuance of decision

Changes should be processed as detailed in 2.1. Changes cannot be implemented prior to formal approval. However, the DOA TL or External Party should liaise with the Authority in all cases where

the organisation wishes to continue its operations whilst in a change of location. The DOA TL or External Party should investigate any proposed significant changes according to the checklist established during the initial investigation and subsequent amendments. The DOA TL or External Party should determine the extent of any subsequent review according to the impact of the proposed changes to the organisation and/or its DOE/Handbook and should carry out all necessary actions.

Depending on the significance, the investigation can range from a desk audit to several on site audits. If the investigation of the change falls in a period close to another investigation it may be possible, for the sake of efficiency and effectiveness, to combine the two investigations.

Based on a recommendation issued by the DOA TL or External Party, the Authority should decide how to proceed with the change. The Authority should send the letter for acceptance or rejection of any significant change based on that recommendation. In case of significant change resulting in the issuance of new revision of DOA Certificate, the old certificate must be returned to the Authority at the reception of the new one.

2.3.4 Correspondence and focal points

For any technical issue related to the approval, the design organisation shall contact the designated DOA TL. In case of task allocation to an External Party, the Authority should communicate with the POC. The Authority should directly transmit to the DOA holder or applicant, all documents linked to the approval, (e.g. DOA certificate, Form 83, acceptance of significant changes, approval continuation letter etc.).

3 Alternative Design Organisation Approvals

3.1 Scope and limitation of Alternative Design Organisation Approvals

Alternative Procedures to Design Organisation Approvals (ADOA) can be agreed, at the discretion of the Authority, in accordance with 21.A.14(b), 21.A.112B, 21.A.432B or 21.A.602B and associated AMC&GM, for design activities ranging, for example, from TSO articles, part and appliances to light or small (non-complex) aircraft.

An ADOA approval is the recognition that a design organisation sufficiently complies with requirements of EMAR 21 that are deemed necessary to achieve appropriate design assurance without the need to establish a complete Design Assurance System as required by EMAR 21 Subpart J. This is done by implementing organisation specific procedures setting out the design practices, resources, and sequence of activities necessary to comply with the relevant Subparts of EMAR 21 dealing with design approval processes (Subparts A, B, E, O etc.).

The objective of ADOA is to ensure that the design organisation has understood applicable requirements and will perform relevant activities as expected by the Authority.

Due to its simplified nature, an ADOA does not include privileges as defined by 21.A.263. The establishment of these alternative procedures may also be a starting phase for a Subpart J DOA, allowing at a later stage, to move towards a full Subpart J DOA by the addition of the missing elements.

For the assessment of an ADOA, the principals of Design Organisation Approvals, especially the phase model for the initial assessment as referred to in 2.1, should apply. However, the individual activities requested in those phases, especially Phase 4, need to be adopted to stay adequate to the activities that are pursued by the applicant.

Provided that the implementation of the design organisation procedures is sufficiently transparent, the audits mentioned in Phase 4 can be reduced to an on-site inspection of the design organisation. In these cases, the Project Certification Manager (PCM) needs to verify that the procedures are adequately followed by the organisation during the certification activities.

Findings about non-compliances to the organisation procedures need to be coordinated between the PCM and the ADOA assessment team.

3.2 Coordination between the ADOA assessment team and the PCM

The following needs to be considered when assessing the organisation specific procedures for granting an ADOA.

As the ADOA does not provide privileges as referred to in EMAR 21.A.263, the Project Certification Manager (PCM) - or equivalent - needs to receive all technical documentation and records required by EMAR 21 for the compliance demonstration to the requirements of related airworthiness codes and, in case of MTSO Authorisations - the Minimum Operational Performance Standards (MOPS).

Due to the missing elements of a full Design Assurance System required for a Subpart J DOA, such as the Compliance Verification Engineer (CVE) function, the PCM will usually be responsible to manage the compliance finding process including document evaluation, technical discussions, and test witnessing.

In this regard and unlike the DOA approval process, the ADOA assessment requires good coordination with the relevant Certification Team, especially the PCM.

The level of involvement of the PCM will be quite high, coordinating directly with the design teams and quality management of the design organisation.

Test witnessing is a key element of certification activity under ADOA that requires dedicated planning and coordination between the organisation and the Authority. To ensure this coordination, the PCM shall review the proposed certification approach (or certification plan) as well as the timeline for certification as part of the initial ADOA assessment and agree it with the applicant. Potential deviations against the airworthiness codes or MTSO standards shall be identified early by the applicant and test witnessing activities are to be agreed for major certification and qualification tests.

4 Production Organisation Approvals

4.1 Initial Production Organisation Approval

4.1.1 Acceptance of Application

Applications for a Production Organisation Approval should be sent to the Authority and made in accordance with EMAR 21 and its AMC & GM. Details about format and address are subject to the requirements of the Authority. A Form 50 should be used for new applications. A Form 51 should be used by POA holders for applications for change to their approval. These applications should be handled in accordance with 4.3 of this procedure. When the application is made by an organization located outside of the Authority's territory, and the applicant has already an existing POA, this approval could be re-used based on a recognition arrangement between the Authorities.

The Authority should acknowledge receipt of applications within a reasonable timeframe and should check the applications. Where incorrect or incomplete information is supplied, the Authority should notify the applicant as soon as possible by letter detailing the omissions and errors.

The Authority should make a first check on eligibility according to EMAR 21 and determine how it will proceed with the application communicating this, together with the applicable requirements, to the applicant within a reasonable timeframe following receipt of the correct application.

When eligibility has been fully assessed, the applicant should be informed of the following:

- acceptance or refusal of its application,
- upon acceptance, a preliminary approval number (e.g. adding a suffix "P" indicating the pending status of the approval (for example [Authority].21G.[XXXX]P), and
- information on the follow-on steps of the process.

The approval database should be updated with all the relevant information.

In case of refusal of an application, the Authority should notify this decision in writing to the applicant together with any reasons thereto. Where relevant and if national regulations apply, a reference to the possibility for appeal as specified in national regulations should be included.

4.1.2 Allocation of technical investigation tasks

After eligibility has been fully assessed and acceptance in principle has been given, the Authority should consider whether the application shall be further processed internally or allocated to an External Party.

In cases where the technical investigation will be allocated to an external party which will handle the technical investigation on behalf of the Authority, the selected External Party should be designated in accordance with Authority procedures (e.g. regulation, contract, accreditation process). The External Party should be made responsible for complying with these procedures.

In cases where the technical investigation will be performed internally, the Authority should establish an appropriate POA Team.

The POA Team or External Party should be provided with all information needed for effective performance of the technical investigation tasks. When the investigation is allocated to an External Party, a single point of contact for liaison with the Authority should be appointed.

4.1.3 Determination of the POA Team

The Authority should nominate a team leader and members to carry out the investigation process, considering the required competence, previously accumulated experience, and the available capacity. The composition and size of the team can consist of only the POA Team Leader (POA TL) but may vary and is dependent upon:

- the size of the applicant's organisation,
- the complexity of the organisation approval applied for,
- the number of sites covered by the approval,
- the nature of the services to be covered by the POA and its direct impact to aviation safety.

Trainees may participate in investigation teams in accordance with Authority procedures.

For specific technical investigations, the team may receive assistance from appropriate technical experts.

4.1.4 Investigation for Initial Organisation Approval

4.1.4.1 Preparation of the investigation

The investigation for initial approval can start once the POA TL Team Leader (TL) is designated. The assigned POA TL should provide the applicant with a POA compliance checklist from the Authority (refer to FO.POA.00009 POA Compliance Checklist as an example) and a POE compliance checklist (refer to FO.POA.00015 POE Compliance Checklist as an example), to be completed by the applicant before the investigation starts.

Note: These checklists are serving as cross reference and evidence to show compliance with the regulation and should be made available in advance for potential applicants. In case the Authority does not provide such checklists, it should be considered to ask the applicant to propose a compliance checklist based on the regulations declared applicable by the Authority.

The POA TL should initiate the process by arranging an initiation meeting (Kick Off meeting) with the applicant for a general presentation by the applicant about its organisation and products, parts or appliances. The POA Team should introduce the investigation process and agree on responsible managers from the applicant, who should then be requested to complete a Form 4.

4.1.4.2 On desk investigations

The POA Team should review and, if necessary, give comments on the completed checklists and the latest version of the POE/Handbook and associated documents. The POA TL should forward the comments to the applicant so that they can be used to revise the relevant documents.

As soon as the documents are deemed to be mature enough, the POA TL should:

- liaise with the organisation for scheduling the audit(s),
- agree with the applicant the investigation plan and schedule, including facility locations and suppliers to be investigated.

4.1.4.3 On site investigation(s)

The POA TL should start the on-site audit with an opening meeting with the auditee's management and, where possible, with the Accountable Manager.

The following points should be considered when carrying out the meeting:

- confirmation of the audit schedule (including the scope of the audit).
- explanation on the method for handling findings in accordance with 21.B.225.

The following on site activities should be carried out:

- Audits of the organisation, its organisational structure, and its procedures for compliance with EMAR 21 Subpart G. The details of these working processes and procedures audits should be documented in compliance audit reports / checklists. The full scope of work shall be covered,
- Interviews of key personnel nominated by Form 4,

- Checking that the POE/Handbook reflects the organisation, its procedures, practices, and all requirements in accordance with 21.A.143,
- Coordination between production and design is documented and satisfactorily implemented,
- Sample (product) audits at working level to verify that:
  - work is performed in accordance with the procedure described in the POE/Handbook and its associated procedures.
  - Products, parts, appliances or material produced by the organisation are in conformity with the applicable design data (21.A.131), including management of the applicable design data and clarifications on the method used for managing non-conformities.
  - Facilities, working conditions, equipment and tools are in accordance with the POE and appropriate for the work being performed.
  - the Level of competence and numbers of personnel is appropriate for the work being performed.

At an advanced stage of the investigation the POA TL should review the audit results and matters arising, to determine any additional areas requiring investigation.

The Accountable Manager should participate at least once during the investigation process, preferably during the conclusion meeting and, where possible, also during the initiation meeting because he or she is ultimately responsible for ensuring compliance with the requirements for initial grant and subsequent maintenance of the production organization approval.

Findings made during the investigation process should be classified in accordance with 21.A.158 and handled by the POA TL in accordance with EMAR 21 Section B Subpart G.

A closing meeting chaired by the POA TL should be held to present the audit findings and conclusions to the auditees to ensure that they are understood. The auditees should be given the opportunity to discuss any non-compliance identified and to suggest corrective actions and a timeframe for their implementation. In normal cases, a maximum of three months should be allowable to take corrective action for each finding raised during the initial audit.

The formal notification of the findings should be sent to the organisation by the Authority, ideally within a maximum of two weeks from the closing meeting of the audit.

The organisation should produce a corrective action plan and submit it to the POA TL for acceptance.

Note: It is highly recommended for the applicant to submit the corrective action plan for the finding to be sure that it is in line with POA TL expectations.

An implementation of corrective action plan without prior agreement by the POA TL could lead to rejection of the corrective action and delay the finding closure. Failure to close the findings within the agreed timelines may cause the Authority to revoke the application.

After all planned investigations have been performed, the POA TL should conduct a team meeting to review findings and observations. Depending on the extent and nature of findings and the related corrective actions, an additional audit may be necessary.

When the need is felt, additional audits in specific areas may be planned before a final agreed file on the investigations is compiled together with an overview of all open and already closed findings.

A report about the audit should be produced using a Form 56.

The POA TL should follow up the closure of all findings identified during the audit(s). When the POA TL is satisfied with the actions that have been taken by the organisation, the Authority should notify the organisation in writing that the non-compliances are considered closed.

On completion of the investigation a conclusion meeting with the applicant should be held. The meeting should be chaired by the POA TL and should agree on the remaining findings, corrective action time scales, and preliminary arrangements for any follow up that may be necessary.

4.1.4.4 Recommendation

Once compliance of the applicant with EMAR 21 subpart G has been established, the POA TL should recommend to Authority the approval of the production organisation, including recommendation for acceptance of the POE/Handbook and management personnel.

For that purpose, the POA TL should submit a recommendation package (Form 56, accepted Form 4) for Authority review.

In the case of task allocation to an External Party, this package should be reviewed to check quality by the External Party's POC before being submitted to Authority.

4.1.5 Issuance of a POA Certificate

The recommendation package (Form 56, Form 4) should be reviewed by the Authority for compliance and accuracy. In some cases, it may be accepted that some findings are not fully closed because corrective actions are still in progress. The Authority may decide to grant an approval with limitations, according to the following principles:

1) All Findings should be equivalent to maximum level 2, which do not need to be rectified as a matter of urgency within less than three months and should normally not exceed three in number.

2) A corrective action plan, including timescales, should have been accepted and should not require an additional and specific follow-up audit by the Authority.

Once satisfied, the Authority should sign:

- a Form 55a (the Certificate) & Form 55b (Terms of Approval),
- the Letter of Approval, stating the acceptance of the POE/Handbook together with its associated documents and lists.

Once the approval is issued, the approval number should be updated (e.g. by removing the "P" from the approval reference).

4.1.6 Basic time frame

The normal time frame to process an EMAR 21 subpart G approval is about 8 months from the application date. The time taken largely depends on the ability of the applicant to produce the required documentation and to rectify any non-conformity identified during the approval process. Unless duly justified, failure to stay within this time frame would cause the Authority to revoke the application.

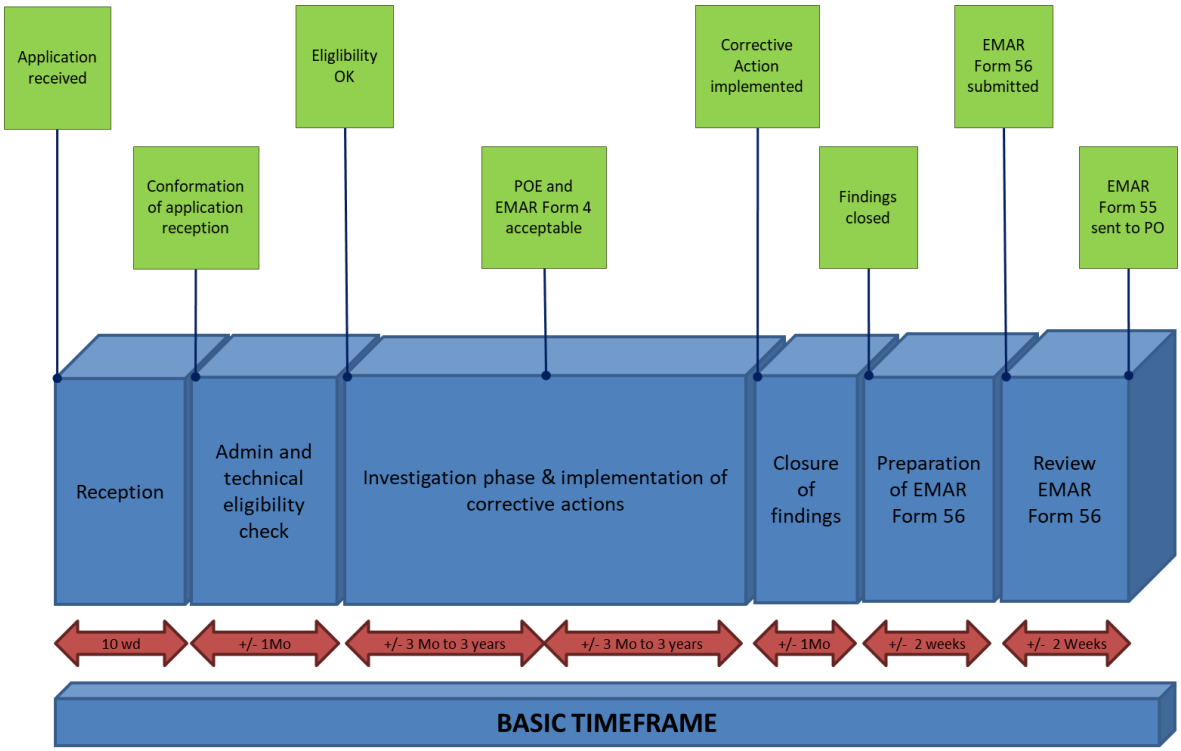

Figure 2: proposed POA timeline

Note: The timings in Figure 2 are to be understood as a reference to guide Authorities only.

If there are still blocking points for a recommendation for approval after this period, the organisation should inform the POA TL or External Party of any delays and propose an action plan to close all remaining findings. The POA TL or External Party should report to the Authority the situation in case of a delay. The Authority should then decide on the way to proceed further.

4.2 Continued Surveillance

After the POA Certificate is issued and to ensure continuous and complete compliance with EMAR 21 Section A Subpart G and any other applicable requirements of EMAR 21, a POA TL in charge of the approval should be appointed by the Authority.

By default, the surveillance should be performed by the assigned initial investigation team. However, should it become necessary or more appropriate to change it, the Authority may decide to allocate the continued surveillance to another team.

The continued surveillance is carried out over a cycle, typically 24 months, in accordance with the continued surveillance plan established by the Authority. This continued surveillance plan should be communicated to the PO.

The continued surveillance activities will be controlled by the Authority according to the predefined investigation plan.

The following activities should be carried out:

- Planned continued surveillance, consisting of several audits (at least one per year) to check compliance with EMAR 21 Subpart G and the effectiveness of the POE/Handbook and associated procedures.
- Sample (product) audits at working level to verify that:
  - work is performed in accordance with the procedures described in the POE/Handbook and its associated procedures.
  - products, parts, appliances, or material produced by the organisation are in conformity with the applicable design data.
  - facilities, working conditions, equipment and tools are in accordance with the POE/handbook and appropriate for the work being performed.
  - the competence and number of personnel is appropriate for the work being performed;
  - coordination between production and design is documented and satisfactory;
- Unscheduled POA audits related to surveillance findings or external needs
- At least once a year the POA TL will have a meeting with the Accountable Manager where the general situation regarding the Quality System of the organisation will be reviewed based on audit results and corrective actions taken by the organisation.

Normally the frequency of visits for continued surveillance should be one visit per 12-month period as a minimum, starting from the date on which the POA Certificate was granted. This may be varied, when agreed by the Authority. The criteria to be reviewed by the Authority for changing audit visit frequency are as follows:

- Follow up of audits / findings,
- Change to the approval,
- Incident response,
- Request by the Authority,
- Large complex organisation,
- Complex product.

Each finding should be documented against detailed references to EMAR 21 requirements or the organisations' POE/handbook and associated procedures. All audit reports should be communicated to the organisation. In case of suspected level 1 or level 2 finding impacting the approval, the POA TL or External Party will have to liaise with the Authority for confirmation of the finding level.

When the level 1 finding is confirmed, the POA TL or External Party should not transmit the audit report to the organisation directly. However, he/she should transmit the audit report with their recommendation to the Authority. The Authority should notify the finding(s) to the organisation together with the decision against the approval.

The POA TL or External Party POC should inform the Authority regarding any level 1 finding made against the POA holder together with any actions it has taken. In case of a level 1 finding, the Authority should review the finding and take appropriate action.

In some cases, the POA TL or External Party can raise level 2 finding impacting the validity of the approval. In such circumstances, the POA TL or External party POC should also inform the Authority, who should review the finding and take appropriate action.

In case of a negative decision by the Authority on the validity of approval, the Authority should notify the POA holder in writing and where relevant put the External Party POC in copy, detailing the limitation, suspension, or revocation of the approval.

Note: For every finding, the production organisation should propose a corrective action plan. The organisation should submit the corrective action plan to the Authority to be sure that it is in line with what the auditors expect. A rejection of the corrective action plan could lead to a delay in the finding closure. Corrective actions should contain a reference to the finding, the root cause, relevant immediate actions, long-term preventive actions and timescales.

The corrective action period granted by the Authority for any finding will need to be appropriate to the nature of the finding. During the debriefing of the audit with the POA holder, a reasonable period should be determined which should enable the POA holder to take the corrective action including root cause actions. This period must not be more than 3 months.

In certain circumstances and subject to the complexity and the nature of the finding, the 3 months period may be prolonged, subject to a satisfactory corrective action plan agreed with the Authority. The request for extension should formally be submitted by the quality manager detailing the corrective action plan proposed and the new proposed target date.

Failure to comply within an agreed time scale could lead to provisional suspension of the approval as a whole or in part. Every 24 months the POA TL should summarize the surveillance performed and if satisfied, recommend to the Authority to continue the approval. For that purpose, the TL should prepare a recommendation letter (Form 56) and a continued surveillance plan for the next cycle.

In extraordinary circumstances, the cycle period may be extended by the Authority. This is subject to verification by other means that the procedures are functioning within the POA holder's organisation. At the time of the continuation, recent findings having not yet reached the deadline may be still open. However, the POA TL in charge of the recommendation should be satisfied with the corrective action plan of any open finding made at the time of the recommendation.

When continued validity of the certificate is accepted, the Authority should formally notify the approved production organisation and copy the External Party POC, when applicable.

4.3 Changes within the Approved Production Organisation

4.3.1 Application for change

All significant changes as detailed in the 21.A.147 or 21.A.148 require a Form 51. The POA holder shall address the Form 51 to the Authority.

It must be clear that any significant change should be applied for and requires approval from the Authority prior to its implementation (refer to 21.A.147(b)).

In the case of a change of Company name a Form 51 should be submitted.

In the case of a change of nominated staff, a Form 4 signed by the organisation shall be attached to the Form 51 (several changes of nominated personnel can be requested on a single Form 51).

For any significant change, a draft POE / handbook update shall be submitted for acceptance together with other related documents that may be affected by the change. In case of change of location, it is advised to send a coordination plan together with the Form 51 to agree transitional arrangements which can allow continuation of the approval. This coordination plan should be accepted by Authority.

4.3.2 Allocation of the investigation team

By default, the investigation should be performed by the assigned initial team. However, should it become necessary or more appropriate, the Authority may decide to allocate the investigation to another team or auditor.

4.3.3 Technical investigation for change and issuance of decision

Changes should be processed as detailed in 4.1.4. Changes cannot be implemented prior to formal approval. However, the POA TL or External Party POC should liaise with the Authority in all cases where the organisation wishes to continue its operations whilst in a change of location. The POA TL or External Party should investigate any proposed significant changes according to 21.B.240. The POA TL or External Party should determine the extent of any subsequent review according to the impact of the proposed changes to the organisation and/or its POE/Handbook and should carry out all necessary actions.

Depending on the significance, the investigation can range from a desk audit to several on site audits. If the investigation of the change falls in a period close to another investigation it may be possible, for the sake of efficiency and effectiveness, to combine the two investigations.

Based on a recommendation issued by the POA TL or External Party, the Authority should decide how to proceed with the change. The Authority should send the letter for acceptance or rejection of any significant change based on that recommendation. In case of significant change resulting in the issuance of new revision of POA Certificate, the old certificate must be returned to the Authority at the reception of the new one.

4.3.4 Correspondence and focal points

For any technical issue related to the approval, the production organisation shall contact the designated POA TL or, in case of task allocation to an External Party, the POC. Authority should communicate with the production organisation via the POA TL or External Party POC. The Authority should directly transmit to the POA holder or applicant, all documents linked to the POA, (e.g. POA certificate, Form 55, acceptance of significant change, approval continuation letter etc.).

5 Production without Organisation Approval

It is important to highlight that the standard recommended practice to authorise manufacturing should be via Production Organisation Approvals. The use of EMAR 21 Subpart F should therefore be considered as an alternative option in certain cases and should therefore be carefully evaluated by the authority before being accepted.

The Authority should consider the following conditions before accepting an application for Production without Organization Approval under Subpart F:

1) The applicant produces or intends to produce aeronautical products, parts and/or appliances intended for airborne use as part of a type-certificated product (this excludes simulators, ground equipment and tools), and

2) the Authority determines that EMAR 21 Section A Subpart G would be inappropriate (impractical, uneconomical). The main difference between EMAR 21 Section A Subparts G and F is that Subpart G requires the existence of a Quality System which provides the Authority with the necessary confidence to grant to the manufacturer the privileges of certifying its own

production. There are situations where a Quality System, including independent monitoring and continuous internal evaluation functions, is not justified and/or not feasible.

In making the determination that Subpart F may apply, the Authority may use one or a combination of the following parameters:

- Whether the production organisation is in the process of obtaining a Subpart G approval;
- Production line output capacity (infrequent or low volume of production);
- Complexity of technology used (use of simple technology enabling effective inspection phases during the manufacturing process);
- Organisation size and complexity (very small organisation with non-complex communication lines may not justify Subpart G approval).

5.1 Letter of Agreement Procedure

5.1.1 Acceptance of Application

Applications for a Letter of Agreement should be made in accordance with relevant requirements, AMC & GM and be sent to the Authority. A Form 60 should be used for new applications as well as amendments to the Letter of Agreement specifying the Authority's contact details and providing the information in accordance with GM 21.A.124(b)(2). If the termination date exceeds a one-year period, an explanation should also be required.

When the application is made by an organisation located outside of the Authority's territory as a whole or in part (i.e. some production facilities that are used are outside of the territory), a recognition arrangement with the other competent (foreign) Authority should be established whenever possible considering the involvement of the other Authority in the production inspection system.

The Authority should acknowledge receipt of applications within reasonable timeframe following the date of receipt at the Authority. The Authority should check the applications and notify the applicant by letter as soon as possible when incorrect or incomplete information is received, detailing the omissions and errors.

The Authority should first check the eligibility according to EMAR 21 and should determine how it will proceed with the application communicating this, together with the applicable requirements, to the applicant within a reasonable timeframe following receipt of the correct application.

To be eligible for PwOA, the application should also detail why it considers Subpart F more suitable than Subpart G and should be compliant to the requirements 21.A.122 and 21.A.124.

When eligibility has been fully assessed, the applicant should be informed of the following:

- acceptance or refusal of its application,
- upon acceptance, a preliminary approval number (e.g. adding a suffix "P" indicating the pending status of the approval (for example [Authority].21F.[XXXX]P), and
- information on the follow-on steps of the process.

The Authority database should be updated with all the relevant information.

In case of refusal of an application, the Authority should notify this decision in writing to the applicant together with the reasons thereto. Where relevant and if national regulations apply a reference to the possibility for appeal as specified in national regulations should be included.

5.1.2 Allocation of technical investigation tasks

After eligibility has been fully assessed and acceptance in principle has been given, the Authority should consider whether the application shall be further processed internally or allocated to an External Party.

In cases where the technical investigation will be allocated to an external party which will handle the technical investigation on behalf of the Authority, the selected External Party should be designated in accordance with Authority procedures (e.g. regulation, contract, accreditation process). The External Party should be made responsible for complying with these procedures.

In cases where the technical investigation will be performed internally, the Authority should establish an appropriate PwOA Team.

The PwOA Team or External Party should be provided with all information needed for effective performance of the technical investigation tasks. When the investigation is allocated to an External Party, a single point of contact for liaison with the Authority should be appointed.

5.1.3 Determination of the PwOA Team

The Authority should nominate a team leader and members to carry out the investigation process, considering the required competence, previously accumulated experience, and the available capacity. The composition and size of the team can consist of only the PwOA Team Leader (PwOA TL) but may vary and is dependent upon:

- the size of the applicant's organisation,
- the complexity of the organisation approval applied for,
- the number of sites covered by the approval,
- the nature of the services to be covered by the Letter of Agreement and its direct impact to aviation safety.

Trainees may participate in investigation teams in accordance with Authority procedures.

For specific technical investigations, the team may receive assistance from appropriate technical experts.

5.1.4 Investigation for issuance of a Letter of Agreement

5.1.4.1 Preparation of the Investigation

The investigation for initial agreement can start once the PwOA TL is designated. The assigned PwOA TL should provide the applicant with a PwOA compliance and a Production Manual compliance checklist where such checklists are available from the Authority (see the checklists that are provided for POA under 4.1.4.1) to be completed by the applicant to serve as a cross reference checklist and evidence for compliance with the regulation before the investigation starts.

Note: These checklists should be made available for potential applicants. In case the Authority does not provide such checklists, it should be considered to ask the applicant to propose a compliance checklist based on the regulations declared applicable by the Authority.

The PwOA TL should initiate the process by arranging an initiation meeting (Kick Off meeting) with the applicant for a general presentation by the applicant about its organisation and products, parts or

appliances. The PwOA Team should introduce the investigation process and confirm the identity of the authorised personnel from the applicant.

5.1.4.2 On desk investigations

The PwOA Team should review and, if necessary, give comments on the completed checklists and the associated latest versions of:

- the presence of DO-PO arrangements.
- the production manual with associated documents (incl. the Production Inspection System as referred to in 21.A.126).

The on-desk audit should verify at minimum:

- the organisation, its organisational structure, and its procedures for compliance with EMAR 21 Subpart F.
- the Production Manual reflects the organisation, its procedures, practices and all requirements as referred to in 21.A.125A,
- the Production Inspection System as referred to in 21.A.126
- the detailed working processes and procedures as referred to in 21.A.127 and/or 21.A.128
- the presence of an occurrence reporting system as referred to in 21.A.3A.

As soon as the documents are deemed to be mature enough, the PwOA TL should:

- liaise with organisation for scheduling of the closure meeting and if required on-site audit(s), and
- agree with the applicant on the investigation plan, locations/suppliers needing investigation and approximate time scale.

Comments on documents made during the investigation process should be handled by the PwOA TL.

5.1.4.3 On site investigation(s)

After having identified the location(s) needing on-site investigation, the PwOA TL should start the on-site audit with an opening meeting with the auditee's management and, where possible, with the accountable personnel.

The following points should be considered when carrying out the meeting:

- Confirmation of the audit schedule (including the scope of the audit).
- Explanation on the method for handling findings as referred to in 21.B.125.

The following on site activities should be carried out:

- audits of the organisation, its organisational structure, and its procedures for compliance with EMAR 21 Subpart F. The details of these working processes and procedures audits should be documented in compliance audit reports / checklists. The full scope of work shall be covered.
- Interview of the key personnel being the authorised personnel signing the statement of conformity (21.A.130).
- Checking that the Production Manual as referred to in 21.A.125A, reflects the organisation, its procedures, and practices.

- Coordination between production and design is documented and satisfactorily implemented (as referred to in 21.A.122),
- Audits at working level to verify that:
  - Work is performed in accordance with the procedures described in the Manual and its associated documents.
  - Products, parts, appliances or material produced by the organisation are in conformity with the applicable design data (GM 21.A.121), including, management of the applicable design data and clarifications on the method used for managing non-conformities.
  - Facilities, working conditions, equipment and tools are in accordance with the Manual and appropriate for the work being performed.
  - Competence and numbers of personnel is appropriate for the work being performed.

At an advanced stage of the investigation the PwOA TL should review the audit results and matters arising, to determine any additional areas requiring investigation.

The accountable manager should be seen at least once during the investigation process, preferably during the conclusion meeting and where possible also during the initiation meeting because he or she is ultimately responsible for ensuring compliance with the requirements for initial grant and subsequent maintenance of the Letter of Agreement.

Findings made during the investigation process should be classified in accordance with 21.A.125B and handled by the PwOA TL in accordance with EMAR 21 Section B Subpart F.

A closing meeting chaired by the PwOA TL should be held to present the audit findings and conclusions to the auditees to ensure that they are understood. The auditees should be given the opportunity to discuss any non-compliance identified and suggest corrective actions and a timeframe for implementation. In normal cases, a maximum of three months should be allowed to take corrective action for each finding raised during the initial audit.

The formal notification of the findings should be sent by the Authority to the organisation ideally within a maximum of two weeks from the closing meeting of the audit.

The organisation should produce a corrective action plan and submit it to the PwOA TL for acceptance.

Note: It is highly recommended for the applicant to submit the corrective action plan for the finding to be sure that it is in line with PwOA TL expectations.

An implementation of corrective action plan without prior agreement by the PwOA TL could lead to rejection of the corrective action and delay the finding closure. Failure to close the findings within the agreed timelines may cause the Authority to revoke the application.

After all planned investigations have been performed, the PwOA TL should conduct a team meeting to review findings and observations. Depending on the extent and nature of findings and the related corrective actions, an additional audit may be necessary.

When the need is felt, additional audits in specific areas may be planned before a final agreed file on the investigations is compiled together with an overview of all open and already closed findings.

A report about the audit should be produced by the PwOA TL.

The PwOA TL should follow up the closure of all findings identified during the audit(s). When the TL is satisfied with the actions that have been taken by the organisation in respect of the finding raised during the audit, the Authority should notify the organisation in writing that the findings are considered closed.

5.1.4.4 Recommendation

Once compliance of the applicant with EMAR 21 subpart F has been established, the PwOA TL should submit a recommendation package (Form 65) to the Authority for the issuance of a Letter of Agreement, containing:

- The application form,
- The Scope of the Agreement,
- Termination Date / Conditions,
- Limitations,
- The Production Manual,
- Reference to the Inspection Plan as part of the Production Inspection System.

In the case of task allocation to an External Party, this package should be reviewed to check quality by the External Party's POC before being submitted to Authority.

5.1.4.5 Issuance of a Letter of Agreement

The recommendation package should be reviewed by the Authority for compliance and accuracy. Once satisfied, the Authority should sign:

- the Letter of Agreement (Form 65),
- the associated documents (Production Manual) and lists (capability list).

Once the Letter of Agreement is issued, the Agreement number should be updated (e.g. by removing the "P" from the Agreement reference).

5.1.4.6 Basic time frame

The normal time frame to process an EMAR 21 Subpart F agreement is dependent on different factors and difficult to estimate on average. However, the amount of time taken should not exceed 6 months taking into consideration the ability of the applicant to produce the documentation required and to rectify any non-conformity that may be identified during the approval process.

5.2 Amendment to the Letter of Agreement

The Authority must be satisfied that any change affecting a Letter of Agreement comply with the requirements of EMAR 21 Section A Subpart F before their implementation can start. A plan for the change should be agreed with the applicant in accordance with AMC 21.B.130. If the change affects the content of the Letter of Agreement, a new application (Form 60) should be filed and an amended/revised Letter of Agreement should be obtained subsequently.

5.3 Validation of the Statement of conformity (Form 52 & Form 1)

The Authority should appoint a Production Inspector authorised to validate the Statements of Conformity. The Production Inspector should be appropriately qualified (refer to 21.A.145 (d)). The Authority shall maintain a record of all authorised Production Inspectors.

Prior to the validation of the Statement of Conformity, the Production Inspector should verify that:

- the product is covered by the Letter of Agreement;
- the Statement of Conformity has been issued in accordance with the Production Manual, being in the change status as referenced in the Letter of Agreement;
- the product has been produced under the conditions prescribed in the Letter of Agreement;
- inspections and tests (including flight tests, if appropriate), as per 21.A.130(b)(2) and/or (b)(3), have been carried out under the condition prescribed in the Letter of Agreement.
- the requirements of 21.A.130 have been complied with.

If any of the points above has not been met, a finding of non-compliance should be raised by the Production Inspector and the Statement of Conformity shall not be countersigned.

5.4 Findings of Non-Compliance

When during audits, inspections for validation or by other means, objective evidence is found by the Authority showing non-compliance of the holder of a Letter of Agreement with the applicable requirements EMAR 21 Section A, this finding shall be classified in accordance with 21.A.125B.

Note: For every finding, the holder of a Letter of Agreement should propose a corrective action plan. He should submit the corrective action plan to the Authority to be sure that it is in line with what the Authority expect. A rejection of the corrective action plan could lead to a delay in the finding closure or a revocation of the Letter of Agreement. Corrective actions should contain a reference to the finding, the root cause, relevant immediate actions, long-term preventive actions and timescales.

6 Additional Provisions

6.1 Resolution of Disagreements

Every effort should be made to resolve all kinds of disputes or disagreements between investigation teams, External Parties, and the applicants for or approval holders at the lowest possible level. The investigation teams should be in charge to manage disputes or disagreements with the applicants or approval holders in accordance with procedures available from the Authority, which should contain adequate instructions for escalation. Unresolved disputes or disagreements will be brought to the attention of the Authority for further action in accordance with applicable Authority procedures.

6.2 Limitation, Suspension and Revocation

Approval should be limited, suspended, or revoked by the Authority if the certificate becomes invalid under the conditions specified in EMAR 21. The Authority should notify the approval holder in writing about the limitation, suspension or revocation including the reasons therefore and notifying the right to appeal against its decision in accordance with applicable national regulations.

6.3 Limited Approvals

During initial application investigations an Authority may issue limited approvals in case not all applicable requirements have been complied with. This will allow the organisation to exercise a limited scope of activities to be agreed with the Authority pending further investigations

Chapter IV Cross Domain topics

(reserved)

Chapter V Considerations for Multinational Cooperation

(reserved)