Temporary Guidance Material for validation of Products outside Track II and without Working Arrangement

Contents

1. Background, purpose and scope

In accordance with the principles of the Bilateral Aviation Safety Agreement (BASA) between the EU and China signed in Brussels in May 20th 2019, and pending its entry into force, this temporary Guidance Material is developed for any individual project applied or to be applied from both sides which is outside Track II and without a Working Arrangement between CAAC and EASA, as listed in Appendix 1 to this Guidance Material. The following operational procedures will be used to enable acceptance of civil aeronautical products from both sides.

2. Terms and conditions

2.1. Working arrangement

Considering the existing set of concluded Working Arrangements, and the signed BASA, it is agreed that no separate working arrangements are required for the validation of identified products and the issuance of the related certificates by the Validating Authority (VA).

2.2. Status of the guidance material

The purpose of this interim Guidance Material is to provide clarification and guidance for technical teams of both EASA and the CAAC regarding the validation of products outside Working Arrangement as foreseen in the above-mentioned arrangement. The guidance material addresses both the validation process itself and also post-TC activities.
More detailed implementing procedures (TIP) for the validation of products and post-TC activities will be developed in the context of the BASA. Hence the description of validation processes in this document, in particular of post-TC activities, is of preliminary character.
The OSD/AEG content in this guidance material is for information only.

2.3. Consideration of previous experience

The VA will give credit for the experience, understanding and confidence gained in the Certificating Authority's (CA) certification system during previous validation exercises.
In this regard particular attention will be given to the size of the validation team, its scope and level of involvement, the number of visits to the CA and the applicant, and the overall duration of the project.
It is expected that in such cases the VA will significantly reduce its efforts and reduce the overall duration of the validation exercise, compared to a first-time validation.

2.4. Consideration of project status

It will be duly considered whether the validation project takes place in parallel to an on-going certification by the CA or whether it takes place after the CA has completed its certification.
For a validation following a completed certification by the CA (non-concurrent project) the validation exercise will be reasonably streamlined and tailored in terms of schedule, team size, missions and level of involvement. The VA will apply its best efforts to avoid any duplication or repetition of work that the applicant has already performed for the CA. In accordance with common practices, the VA will furthermore consider product delivery schedules of the applicant in its validation programme as far as possible.
For a validation in parallel to an on-going certification the CA and the VA will coordinate their activities in advance for efficiency purposes and in order to minimize additional work for the applicant.

The VA will issue its TC/VTC for a product subject to validation only if the product meets the applicable certification basis of the VA and no unsafe condition exists. For projects where the CA has not completed its certification project (and issued a TC), this must be completed prior to the finalisation of the project by the VA.

2.5. Cooperation of CA and VA technical teams

Both technical teams shall work together in partnership, share experiences and build mutual trust to ensure an efficient validation process in consideration of industry demand.

2.6. Working language

The working language shall be English. This applies to all communication between the VA and the CA, between the VA and the applicant and to all documents (of the CA and the applicant) subject to review by the VA. If original documents are not available in English, courtesy translations need to be provided as required.

2.7. Proprietary information

The VA shall not disclose proprietary information of the applicant to third parties unless with the prior express consent of the applicant.

3. Procedure for products outside Working Arrangement

The procedure outlined below is applicable to aircraft Type Certificate validation projects. For other Type Certificate validation projects (e.g. propellers, engines) and Supplemental Type Certificate (STC) validation projects a simplified approach following the main principles of this procedure can be agreed.
Further simplification should be envisaged in cases where the VA has already gained experience, understanding and confidence in the CA's certification system during previous validation exercises.

It is important to note that some technical areas may be more advanced than others and may be conducted at different steps as described below. This shall not hinder the overall progress of the project. Some determinations by the VA can be made early in the project and are considered an initial position that may be adapted as further insight is gained. Highlights are provided in the text below. In other words, the following tasks should not be executed strictly in a sequential manner. Some work can start for a task n+1 before task n is formally completed.

3.1. Project start

The project will start upon receipt of the related application for validation. The application should be sent by the applicant to the VA through the CA. In the forwarding letter the CA should indicate/allocate a Project Manager as the technical contact for the VA. For Chinese applications to EASA, the CAAC letter should confirm the applicant's intent to derogate from the requirement to hold a Design Organisation Approval (DOA) through the provision provided for in Article 8(2) of Regulation 748/2012.

Note for validations by EASA: Chinese applicants should consider the need for OSD[1]- and/or MRB[2]-applications.

Note for validations by CAAC: EU applicants should consider the need for AEG[3] evaluation applications and they need to apply for CSV[4] to EASA.

The VA should acknowledge receipt of the application and notify the applicant with copy to the CA of any additional requirements (e.g. fees and charges) for the processing of the application. After a first review of the application the VA should nominate a Project Manager and notify the applicant with copy to the CA of its formal acceptance of the application.

3.2. Definition and agreement of working methods

After formal acceptance of the application by the VA the allocated Project Managers of the CA and VA should contact the applicant establishing communication lines and perform the following tasks.

3.2.1. Applicant presentation to VA management – general familiarisation

Dependent on the kind and size of project (i.e. for large aeroplane TCs, for small aeroplane TCs, and for rotorcraft TCs) the applicant should deliver a high-level presentation of the project to the VA Certification Management.

The objective of this general familiarisation is to give an overview of the product, the main technologies utilised and any unusual characteristics, also including a high-level project schedule to enable the VA Management to endorse the plan and establish the project team.

Attendance to the presentation will be defined as necessary: typically, the VA's Project Manager and responsible certification management, supported as required by technical experts.

Note for validations by EASA: even if an application for OSD elements is delayed, the EASA Chief Expert OSD will participate for overall efficiency purposes.

Note for validation by CAAC: The general familiarisation presentations should be available to the responsible AEG Director, even if AEG did not participate in the familiarisation presentation.

Participants from the CA will typically be the CA's Project Manager with additional participants as necessary.

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[1] Operational Suitability Data (OSD)
[2] Maintenance Review Board (MRB)
[3] Aircraft Evaluation Group
[4] Certification Support for Validation (CSV)

3.2.2. Selection of technical teams

Both the VA and CA should select technical teams that have sufficient knowledge of the product category (VA) and the product itself (CA).

For the size and composition of the VA team credit should be given by the VA for the experience, understanding and confidence gained in the CA's certification system during previous validation exercises.

Once the teams have been selected, VA and CA should inform each other and communicate the team compositions to the applicant.

3.3. Technical familiarisation, determination of the VA's certification basis and initial set of validation items (VIs)

The objective of these tasks are to provide detailed technical information about the project to the VA's team to enable the definition of, and agreement on, the VA's initial type certification basis.

3.3.1. Technical familiarisation

The technical familiarisation starts with a project meeting, involving all (*) VA team members, during which the applicant presents in detail the product as well as the overall schedule.

Each design area should be presented to the VA's team, highlighting the architectures, the main (potential) issues, criticalities, new and novel technologies, etc. Therefore the presentation should include detailed information on:

- Any novel design features, novel applications of existing technology, or unconventional uses of the product,
- Any design features where experience has shown that an unsafe condition might occur,
- Any newly proposed interpretations or Means of Compliance (MoCs) for existing standards.

The technical familiarization meeting should allow the VA's team to get an overall view of the project. Afterwards individual meetings of expert panels might be organized which allow a deeper investigation of specific items. The need for such meetings and the number of meetings should be appropriate to the size and scope of the project.

For optimal efficiency credit will be given by the VA for the experience, understanding and confidence gained in the CA's certification system during previous validation exercise(s) when determining the number and the scope of meetings and visits of the VA with/to the CA and with/to the applicant.

Following the technical familiarization meeting the validation team should be able to identify an initial set of applicable generic and project specific validation items (VIs).

(*) Note: considering experience it may be difficult to organize meetings with the entire VA team. Therefore the Technical familiarisation could be achieved through multiple meetings. However, depending on the complexity of the project, expert domains sharing interfaces should attend common presentations.

3.3.2. Initial VA's certification basis and environmental protection requirements (and OSD certification basis for validation by EASA in case of application for OSD)

During the validation project, a dedicated VA Type Certification Basis Paper (e.g. CRI A-01 for EASA, IP G-1 for CAAC) should be produced by the VA in cooperation with the CA and the applicant that records certification basis of the VA. The initial VA's certification basis needs to be notified to the applicant and to the CA by the VA. It should be established at an early stage in the project and will be updated during the life of the product as required.

The VA's certification basis should consist of the following items:

For establishing the VA's certification basis, the Validating Authority shall refer to the airworthiness standards for a similar product of its own that were in effect on the effective certification application date established by the Certificating Authority complemented when applicable by additional technical conditions.

The environmental protection requirements used for the type validation shall be the applicable VA requirements in effect on the date of application for validation to the VA.

Based on this principle and as an alternate method, CAAC establishes its certification basis for validation by accepting the EASA certification basis for civil aviation products and identifying Additional Technical Conditions (ATC) based on, and not limited to, the difference between the referred CAAC airworthiness standards and environmental protection requirements and those defined in the EASA certification basis.

3.4. Agreement of validation program and level of involvement

The objective of this task is the definition of and the agreement on the proposed means of compliance for each requirement of the VA's certification basis and the identification of the validation team's level of involvement (LoI) in each technical discipline of the project.

3.4.1. VA validation program

The applicant should propose to the VA a validation program, commensurate with the complexity of the product, detailing the means and methods for the compliance demonstration. The validation program should be coordinated with the CA and accepted by the VA.

The review of the validation program should allow the VA to establish its level of involvement.

In order to define the appropriate level of involvement, the VA should take into account its experience gained during previous validation programmes. Support may be provided by the applicant to identify details of previous validation activities with the VA in the same product category.
To facilitate this exercise the CA should, in agreement with the applicant, propose to the VA those areas where an in-depth technical involvement of the VA should take place.

The Level of Involvement should be documented either in the validation program or in a dedicated document (e.g. Certification Action Item (CAI), IP). It should detail which certification documents are retained, which tests will be witnessed, which audits will be performed, etc.

The review by VA of the proposed validation program can already start in parallel with the technical familiarisation of the project before notification of the first issue of the initial VA's certification basis.

The validation program may be composed of several documents. The exact organization of the validation program is up to the applicant (e.g. by ATA chapter, subpart of certification requirements etc.) in agreement with the VA and CA.

Review and acceptance of the validation program should be duly documented and coordinated by the applicant and the Project Managers of the CA and VA.

The Validation Program should be kept up to date during the whole validation process.

3.5. Compliance determination

The objective of this task is for the applicant to demonstrate compliance with the applicable certification basis of the VA and to declare that it has demonstrated compliance with all applicable requirements according to the validation program.

The objective for VA is to verify compliance with the applicable requirements in accordance with the LoI determined per the Validation Program.

3.5.1. VA team investigation

During the verification of compliance the VA should rely on the CA as much as technically justifiable. For this purpose the CA should eventually verify compliance with VA's certification basis and confirm to the VA that the applicant has demonstrated full compliance.

In this task, the VA should review, as necessary, the relevant certification documents, manuals, tests and audits.
The progress of the VA's investigation should be managed by its Project Manager in coordination with the Project Manager of the CA, and the LoI records should be kept up-to-date, identifying completed and pending actions, as well as the owner of each action.

In practice there may be overlaps between familiarisation and VA investigation e.g. since design and compliance are more complex in some areas than others.

For concurrent projects, particular attention needs to be paid by the both VA and CA to late design changes and the configuration control mechanisms of the applicant.

3.5.2. Final Check and TC/VTC issuance

Upon completion of the previous tasks and following a positive decision by the VA the VA Project Manager should check the following items before initiating TC/VTC issuance:

- The type design definition is identified;
- All retained compliance documents, as defined by the VA LoI, have been submitted and accepted by the VA, as reflected in the accepted validation program and/or CAIs;
- If necessary, TCs/VTCs for required related products (e.g. engine, propeller, APU ETSO) have been granted by the VA;
- All VIs are closed;
- The VA Type Certification Basis Paper (e.g. CRI A-01, IP G-1) is closed and official notification has been sent to the applicant and CA;
- All other pre-TC actions are closed;
- All limitations and conditions are fully defined and agreed by VA, CA and the applicant;
- The Applicant Declaration of Compliance has been received and the applicant has expressly stated that it is prepared to comply with the continued airworthiness requirements;
- As required by the respective procedures, a final Report is issued and the VA has decided to proceed with the issuance of the TC/VTC;
- The TCDS/VTCDS (and TCDSN as required) is ready to be published;
- Additional applicable requirements (e.g. fees and charges) are fulfilled;

When the above prerequisites are complete, the VA will issue the TC/VTC in accordance with its procedures.

Note for validations by EASA:
for OSD relevant products the OSD data can be approved independently of the type certificate issuance before entry into service with an European operator; this may require the re-opening of the VA Type Certification Basis Paper (e.g. CRI A-01) to record late OSD certification basis changes. The TCDS will then be updated to record OSD references.

Note for validations by CAAC:
AEG Evaluation Report will be issued independently of the type certificate issuance before entry into service with a Chinese operator.

3.6. Post TC activities

The project ends with the issuance of the TC. The following general principles for continued airworthiness, changes and repairs have been developed in anticipation of the post-TC task and will be described through more specific implementing procedures.

3.6.1. Continued Airworthiness

The CA and the VA will cooperate in technical support and information exchange to ensure continued operational safety of the product.

The CA will provide all necessary information for mandatory modifications, required limitations and/or inspections to the VA.

At the request of the VA the CA will assist the VA in determining which VA action is considered necessary for the continued operational safety of the product.

3.6.2. Changes

Where design changes are proposed by the TC Holder, they need to be classified as minor or major in accordance with the CA's applicable rule.

Minor changes to the type design by the TC-holder should be approved by the CA under its normal procedures. Related applications to the VA, if required, should refer to the CA's approval and the VA should issue its approval without technical review.

Generally major changes to the type design by the TC holder should be validated by the VA in accordance with a process defined by the VA. However, the VA may decide to accept the CA's approval without technical review.

3.6.3. Repair designs

For the approval of design data developed by the TC-holder in support of repairs the same principles apply as for design changes (ref. to section 3.6.2).

4. Communication

Validation projects require an efficient and effective communication between the VA, the CA and the applicant.
The teams of the VA, CA and the applicant shall be identified early in the process and updated throughout the validation project.
Formal communication between the VA and the applicant should always involve the CA, but for reasons of efficiency, direct routine communication (e.g. e-mails) between parties is encouraged. The VA and CA Project manager should always stay in copy.

The VA and the CA should as much as possible exchange relevant information and discuss matters at an early stage and without undue delay.

4.1. Communication flow

The Project Managers of the VA and the CA are the focal points for the project for all communication between the VA and the CA. All correspondence between VA- and CA-experts should be copied to the project managers.

The exchange of documentation between the applicant and the VA will be coordinated by the project managers of the CA and the VA.

Formal correspondence should be sent by project managers or their management according to the VA/CA's procedures.

For controversial issues reference is made to chapter 5 (resolution of disagreements).

5. Resolution of disagreements

As a matter of principle all parties should cooperate in partnership, share experiences and build mutual trust to ensure an efficient validation process. .
Particular attention needs to be given to the avoidance of misunderstandings and conflicts arising from cultural differences e.g. in communication practices, traditions, or thought processing.

Potential technical disagreements should be resolved efficiently, in an amicable manner and escalation to higher hierarchical levels should only take place if this is inevitable.

When involving the next hierarchical level, the parties need to duly justify why the position of the other party is considered unacceptable.

5.1. Disagreements between validation team and applicant

In the event of a disagreement between the VA-team and the applicant that cannot be resolved on this level, the VA project manager should address the case with his/her CA counterpart and seek a common position. If no common position can be found and this results in a disagreement between project managers, refer to 5.3.
The case should be recorded by the project managers as appropriate.

5.2. Disagreements between validation team experts and certification team experts

In the event of a disagreement between VA- and CA-teams on expert level that cannot be resolved on this level, team-members should report to their project manager. The VA/CA project manager should address the matter with his/her counterpart and try to find a solution. If the disagreement persists refer to 5.3.
The case should be recorded by the project managers as appropriate.

5.3. Disagreements between VA project manager and CA project manager

In the event of a disagreement between VA- and CA-project managers that cannot be resolved on this level, both managers need to consult their management to seek a solution. If this cannot be achieved they should report to the Technical Roadmap Implementation Team identified in Annex I to the "Agreement between CAAC and EASA on the Implementation of a Technical Roadmap" for review and follow up as necessary.
The case should be recorded by the project managers.

6. Products Export/Import

The Authorities recognize the agreement reached in the BASA in matters of production and import/export. For the purpose of the projects validated under this Guidance Material, CA and VA will aim to implement the agreed provisions contained in this BASA to the extent possible under the existing legislation of the Authorities at the time of the signature of this Guidance Material.

7. Signature, entry into force, termination and validity of certificates

This Temporary Guidance Material will enter into force upon signatures of the Authorities' duly authorized representatives and will be terminated at the date of entry into force of the Technical Implementation Procedures (TIP) developed in the framework of the BASA and its Annex 1. Such termination will not affect the validity of any certificate and other approval granted by the Authorities under the terms of this Interim Guidance Material. For on-going validation activities of civil aeronautical products initiated under the terms of this interim Guidance Material, which have not yet led to the issuance of VTC, the Authorities will finalise the validation in the framework of the TIP and the work done will be appropriately credited.

Signatures

Organisation	**Name**	**Signature**	**Date**
CAAC-AAD	**DG Xu Chaogun**	徐超骏	01.08.2019
EASA-CT	**Ms Rachel Daeschler**		22. JULI 2019

Annex 1 – Templates

1. Certification Review Item - CRI
2. Issue Paper - IP
3. Certification Action Item - CAI

Annex 1

1. Template Certification Review Item

EASA / CAAC	CERTIFICATION REVIEW ITEM Airworthiness Code -[enter applicable CS or equivalent] [Identify product category, e.g. small rotorcraft]	CRI: X-NN Issue: ... Date: dd.mm.yyyy Page: 1 of 2 Status: [Open/Closed] Next Action: [enter responsible party]
	APPLICANT: [Enter applicant name] PROJECT No.: [Enter EASA project number] PROJ. TITLE: [Enter type/model name]	

SUBJECT: ...

CATEGORY: Special Condition/Equivalent Safety Finding / Interpretative Material / Means of compliance (as applicable)

REQUIREMENTS: Airworthiness Code -[enter applicable CS or equivalent].[enter paragraph]

ADVISORY MATERIAL: ...

PRIMARY PANEL: ...

SECONDARY PANEL: ...

IDENTIFICATION OF ISSUE:

...

EASA / CAAC POSITION: (Issue 1, dated dd.mm.yyyy)

...

APPLICANT'S POSITION: (Issue 1, dated dd mmm yyyy)

...

EASA POSITION: (Issue 2, dated dd.mm.yyyy)

...

CONCLUSION:

...

SIGNED BY: EASA / CAAC PROJECT MANAGER

CRI - Issue	Remark	Date
Issue 1	Statement of Issue and Initial EASA / CAAC position	dd.mm.yyyy
Issue 2	...	dd.mm.yyyy
Issue 3	...	dd.mm.yyyy

Annex 1

2. Template Issue Paper

Issue Paper

Project: (Manufacturer's name and model. Project No. if available)	Item:
Regulation Ref.:	Stage:
Reference Doc.:	Date: yyyy-mm-dd
Subject:	Status: (open/close)

(Type of Issue Paper)

Statement of Issue: (Stage * - yyyy-mm-dd)

Background: (Stage * - yyyy-mm-dd)

CAAC Position: (Stage * - yyyy-mm-dd)

Applicant Position: (Stage * - yyyy-mm-dd)

EASA Position: (Stage * - yyyy-mm-dd)

Conclusion: (yyyy-mm-dd)

Signature:

CAAC form AAC-120 (03/2011)

Annex 1

3. Template Certification Action Item

Introduction to Certification Action Item (CAI)

The purpose of a CAI is to administer the progress of non-controversial certification actions but requiring special attention.

The need for a CAI will normally be identified by the team, but in some circumstances the applicant may also wish to raise a CAI.

Examples of cases where CAIs may be opened:

a) To request additional information during the familiarisation

b) To record and notify the applicant regarding the team's involvement in the verification of compliance demonstration

c) To review the suitability of and to follow up actions related to compliance demonstrations of selected subjects

d) To follow up a "closed" CRI, when necessary

e) To administer matters interfacing certification and operations.

A CAI defines the characteristic to be checked, the relevant requirements, the interpretations to be used, the action, the responsibilities and the basis for conclusion.

A CAI is closed after it has been agreed by all involved team members.

To manage the action items raised during the certification process, according to complexity of the program, the PCM may choose to use either a single sheet for any action or a table listing all the actions with the relevant description of the issue and identification of the responsibilities.

Certification Action Item (single sheet format) – Template

Project: Regulation ref.: Advisory Material/Policy ref.: Subject:	AI No: Issue No: Date: AI Status: Next Action by: AI Closure Target:

Problem:

Applicant Position: ..... (dated dd.mm.yyyy)

EASA/CAAC Position: ..... (dated dd.mm.yyyy)

Certification Action Item (table format) – Template

LIST UPDATED ON _____

NUMBER	SUBJECT	OPENING DATE	ORIGINATOR	STATUS	NEXT ACTION BY	CLOSURE TARGET DATE	CLOSURE DATE	CLOSURE DOC REF.

NUMBER: WG XX-YY-ZZ
XX: Identification of WG (Working Group)
YY: number of meeting
ZZ: progressive number of the action

SUBJECT: synthetic description of the action

STATUS: OPEN/CLOSED

NEXT ACTION BY: [Applicant/EASA specialist] responsible of the action

CLOSURE REF DOC: evidence (fax, oral) of closing of the action

Appendix I

List of Individual Projects