

Procedure for approval of an FSTD Operator

Reference: Commission Regulation (EU) No 1178/2011, as amended.

CIVIL AVIATION DIRECTORATE

Transport Malta, Malta Transport Centre, Pantar Road, Lija LA 2021 Malta. Tel: +356 2555 5000 cadpel.tm@transport.gov.mt www.transport.gov.mt

1.0 INTRODUCTION

The European Regulation (EU) 1178/2011, as amended, details the rules for the FSTDs. Part-ORA contains information with regards to the approval of FSTD Operators.

1.1 Purpose of This Document

The documents has been established to serve the following purposes:

- Give guidance to new organisations to ensure that an application made for the initial approval will satisfy EASA Part-ORA requirements
- Give guidance of administrative arrangements and legal matters particular to Malta
- ensure the process and procedures are understood by the organisation TM-CAD regulates and to ensure continued compliance

1.2 General

All FSTD operators to which information in this document relates must be approved as an FSTD Operator.

Organisation seeking approval are to be in possession of the latest version of EASA Aircrew Regulation Part-FCL, Part-ARA, Part-ORA, CS-FSTD and the Basic Regulation.

1.3 Who can apply

An FSTD operator must be approved in order to provide FSTDs for the use of training as per Regulation 1178/2011 and 965/2012.

Organisations that wish to apply for a Malta FSTD Operator approval must have their principal place of business located in Malta.

Definition of principal place of business

Commission Regulation No. 1178/2011 defines what constitutes an Organisation's principal place of business as follows. This is as follows:

“principal place of business” of an organisation means the head office or registered office of the organisation within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised;

TMCAD's interpretation of the meaning of the above provision is set out below.

In order for TMCAD to assume responsibility for regulatory safety oversight as the Competent Authority, the Organisation will need to meet the following criteria regarding corporate structure and effective operational and financial control to constitute evidence of their principal place of business being established in Malta:

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1. It must be evident that matters affecting existing operational and financial control, relevant to the organisation's activities in accordance with the applicable requirements, are controlled, decided and directed by the appointed nominated post holders, including the accountable manager, as a result of management meetings held in Malta as often as effective relevant decision-making requires; (Refer to Appendix 2 for GUIDANCE MATERIAL)
2. Organisation must be registered within the Malta Business Register;
3. Organisation must be in possession of a Malta VAT number;
Operational correspondence must be processed at the organisation's Malta head office address; (Refer to Appendix 2 for GUIDANCE MATERIAL)
4. Pricing of services must be processed at the organisation's Malta head office address;
5. Necessary human resources must be present at the organisation's Malta head office address, to ensure compliance with the organisation requirements and to meet the safety objectives; (Refer to Appendix 2 for GUIDANCE MATERIAL)
6. All records regarding the operational and financial decisions affecting the direction, control and coordination of the organisation's activities and operations, within the scope of the applicable regulation, must be available for an on-site inspection at the Malta head office.

It should be noted that the principal place of business may not necessarily be where the approved activity itself takes place, such as where the FSTD devices are located.

Note: In the case where the activity takes place in a country other than that in which the principal place of business is located, to ensure effective oversight of the organisation, co-operative oversight arrangements may be made between Competent Authorities/ EASA.

For organisations that have their "principal place of business" outside of the member states of the European Union the approval must be issued by EASA.

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2.0 PREPARATION FOR INITIAL APPROVAL OR VARIATION TO AN EXISTING APPROVAL

2.1 Prior to Application

The following information shall be considered prior to application:

- The organisation must first determine if the application of the FSTD Operator is for a complex or non-complex organisation according to AMC1 ORA.GEN.200(b).
- Where FSTDs are at multiple locations, all sites will be subject to approval and oversight (included contracted organisations)

2.2 Applying

The process flow chart in Appendix 1 shall be followed for the initial application. In detail guidance shall be provided by TM-CAD PEL department upon application.

2.3 Fees

Fees and charges are published under the 16th Schedule of the Malta ANO and are payable upon application, thereafter a continuation charge is made on the 1st week of each year. Please note for reasons of security only e-banking transfer to our account are accepted or by visiting our accounts department in person with a cheque or an EPOS for credit/debit card transaction.

2.4 Timescale

When making an application for initial approval, or to vary an existing approval the organisation shall ensure that any documents provided are compliant to the EASA regulation, manufacturer documentation (if applicable), national health and safety requirements and to TM-CAD procedures. Applications are processed in order of receipt. If documentation is not compliant this will delay the approval process.

2.5 Language

TM-CAD will only approve documentation in the English language.

2.6 Items Required for Submission for Initial Application

- 3 year Business plan
- Application Form TM/CAD/0360 completed and signed
- Manuals
- Fee according to ANO
- Application Form TM/CAD/0404 completed and signed for each nominated person including CVs and relevant certificates
- TM-CAD completed checklists
- Proof of agreements with Contracted Organisations
- Simulator qualification certificates (if previously approved with another authority or EASA or if currently approved by another authority or EASA)

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2.7 Nominated persons

The key personnel in an organisation must be notified to TM-CAD. See flow chart in Appendix 1 and PEL Notice 86 for documentation needed and the guidance from the EASA regulations with regards to requirements for nominated person positions. TM-CAD interviews the below persons:

Accountable Manager

The requirements and qualifications for the Accountable Manager can be found in Part-ORA.GEN.210 and PEL notice 86.

Safety Manager

The requirements and qualifications for the Safety Manager can be found in PEL notice 86.

Compliance Monitoring Manager

The requirements and qualifications for the Compliance Monitoring Manager can be found in AMC1 ORA.GEN.200(a)(6)(3)(iii) and GM1 ORA.FSTD.100.

Assigned Person

The requirements and qualifications for the Assigned Person can be found in ORA.FSTD.225 and PEL notice 86. Complex organisations may have different assigned persons for different locations or for different devices.

2.8 Records

Management (CMS related) records shall be maintained in Malta and these shall be easily accessible for inspections, including any ad-hoc inspections. Records related to devices shall be kept at the location of the device.

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3.0 PROGRESS OF APPLICATION

3.1 Review of manual and Supporting Documentation

Manuals put forward for initial approval shall be in electronic format and placed through Centrik system (Access codes will be provided once application is received).

3.2 Inspection of Facilities

Prior to the approval an inspection of the facilities shall be conducted to ensure full compliance with the applicable requirements, namely ORA.FSTD.115. When more than one facility is applied for then the inspection shall be conducted at all facilities.

3.3 Inspection of FSTD and FSTD Operator

Refer to PEL Notice 96

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4.0 CONTINUED OVERSIGHT

Once an FSTD Operator has been issued with an approval it is subject to continued oversight of the management system, documentation, FSTDs and other areas required by TM-CAD.

4.1 Oversight Planning Cycle

The frequency of the management system audit is based on a risk-based concept. Nevertheless, the first oversight inspection will be conducted after 12 months of the issue date of the FSTD operator.

4.2 Desk-top audits, Ad-Hoc / Unannounced Inspections

TM-CAD may, at any point, conduct unannounced or adhoc inspections as required by the oversight programme.

In accordance with national laws, Regulation (EU) No. 2018/1139 and its relevant implementing rules, organisations shall provide full access to any documentation, records, equipment, aircraft and facilities which the Director may wish to inspect or examine.

In this regard the interpretation of providing access to documentation for the of purpose of examining or inspecting data, may mean one or more of the below:

1. Onsite physical access to documents, records, data, a system, simulator, facility, etc.
2. Direct access to a database or system through password access (NB: only viewing rights are required) for retrieval of data, documents, records, etc.
3. Submission to TM-CAD, electronic or physical copies of the data, documents or records for an analysis to be conducted offsite.

The means of access to the above shall be agreed upon by TM-CAD with the organisation. If access cannot be given a non-compliance shall be issued.

4.3 Changes to the organisation

All organisational changes requiring prior approval must be submitted to the authority for approval. For other changes not-requiring prior approval, the FSTD Operator must have a procedure in the manual for these changes in accordance with ORA.GEN.130.

4.4 Procedure for Approval of FSTDs

FSTDs will be checked in accordance with 1178/2011 and CS-FSTD regulation. Refer to PEL Notice 96.

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5.0 REVOCATION, SUSPENSION OR VARIATION/ LIMITATION OF AN APPROVAL

In case of any significant non-compliance to the regulations or with the terms of approval which reduces safety or seriously hazards flight safety (ARA.GEN.350(b) and/or ARA.GEN.330(b)) TM-CAD will raise a Level 1 finding and thus TM-CAD will prohibit, limit or suspend activities of the organisation. When the non-compliance “could” reduce safety or hazard flight safety as indicated in ARA.GEN.350(c), the competent authority will raise a Level 2 finding.

5.1 Non-compliances

Any Findings shall be issued and addressed through Centrik. Access codes shall be provided upon approval of the FSTD Operator.

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6.0 CONTINUATION OF APPROVAL

6.1 Approval validity period

Organisation approvals are non-expiring, however this is subject to a continuation recommendation every 12 or 24 months from the date of issue. This is raised by the TM-CAD Inspector following the CMS audit programme.

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7.0 USEFUL INFORMATION

Malta ANO

PEL Notice 86

PEL Notice 96

Contact us on:

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PERSONNEL LICENSING SECTION

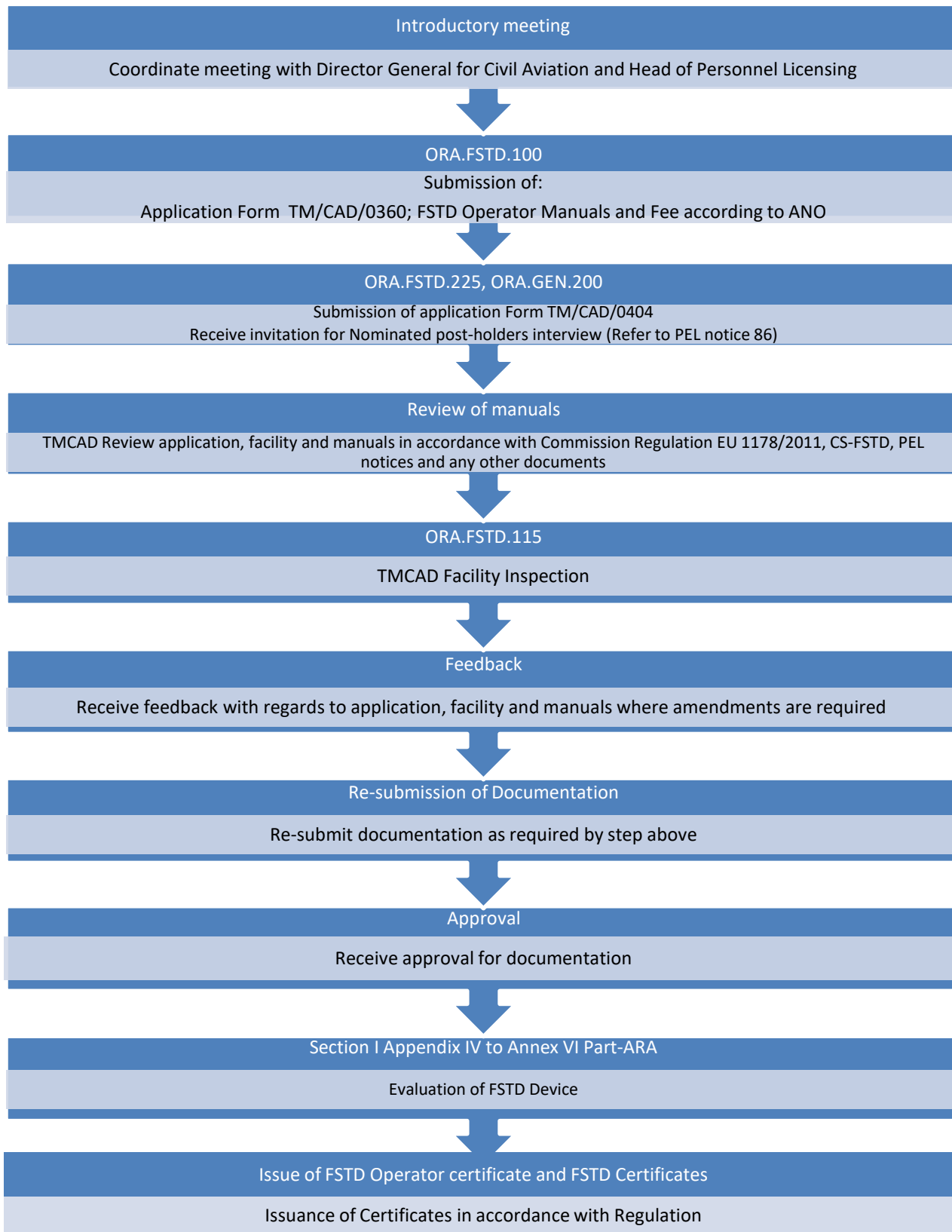
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APPENDIX 1



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APPENDIX 2

THE BELOW IS GUIDANCE MATERIAL

Principal financial functions

The principal financial functions of an organisation comprise of all financial activities which are required to operate and maintain an organisation. These include receiving funds and profits, provide the dividends to shareholders, conduct due payments (salaries, employment benefits, debtors, investments, etc), pay tax or any other financial obligations and so forth.

Principal operational control of its activities

The principal operational control of its activities entails managing operational decisions of the company on a regular basis, as required by the organisation. The determination of the place of operational control of an organisation requires a case-by-case assessment by the authority.

Human Resources

The accountable manager, as the ultimate person responsible for safety and compliance should either reside permanently in the country where the PPOB is or demonstrate to the satisfaction of the Authority that there are suitable means in place for him/her to remain responsible for safety and compliance where he/she resides.

Operational Correspondence

The organisation's key personnel (Assigned person [iaw ORA.FSTD.225] - FSTD Maintenance Manager, Safety Manager, Compliance Monitoring Manager, etc.) are responsible to hold operational management meetings and processing of operational correspondence, that ultimately lead to meeting Safety Manager, Compliance Monitoring Manager, etc.) are responsible to hold operational Ppob, the coordination and processing of operational correspondence may be delegated to a responsible person/s, however the ultimate responsibility shall lie with the nominated person/s.