

CIVIL AVIATION DIRECTORATE

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

0.0 PURPOSE OF THIS DOCUMENT

This policy document is designed to ensure commonality and transparency by TMCAD assessors in the evaluation of nominees for key positions within an Aero Medical Centre under the oversight of TMCAD Aero Medical Section.

The following is an explanatory list of terms used in this policy:

- TMCAD - The competent authority in Malta.
- AMS – Aero Medical Section.
- Organisation - The AeMC holder or an entity that is in the process of applying for an AeMC.
- Sponsor - The organisation nominating a candidate for acceptance in a key position by TMCAD.
- Assessor(s) - TMCAD personnel conducting assessments for the purpose evaluating the suitability of nominees for key posts.
- Nominee / Candidate - A person, sponsored by an organisation for acceptance by TMCAD in a key position within the organisation.
- Key Position/ Person - One or a combination of incumbencies within the organisation and includes:
 - Accountable Manager (AM)
 - Head of AeMC
 - Safety Manager (SM)
 - Compliance Monitoring Manager (CMM)
 - Common Responsible Person (CRP)

1.0 INTRODUCTION

To achieve an adequate level of safety, both the TMCAD and the organisations holding AeMC certificates must work in a consistent manner towards a common goal. To ensure compliance with the regulation, TMCAD must establish means to oversee standards expected from the organisation. The assessment of the standard and competence of the organisation's personnel in key positions falls within the remit of the TMCAD.

Although the responsibility for the induction of personnel in key positions rests with the organisation, the regulation obliges the competent authority to oversee that the required acceptance standards are met. This policy is embedded in the AMS Manual and outlines the process to be applied to ensure transparency and consistency in the assessment/acceptance by TMCAD, of persons in key positions sponsored by an organisation. Essentially, nominees for key positions will be expected to satisfy to TMCAD that they possess the experience and qualification required for them to be able to fulfil their role within the management organisation of their sponsor and to ensure compliance with the regulation.

2.0 ACCEPTANCE PRE-REQUISITES

Nominated persons in accordance with ORA.GEN.200 (and its AMCs) and IS.I.OR.240 shall be nominated and expected to possess the experience and meet the provisions that are listed hereunder.

2.1 Accountable Manager (AM)

The Accountable Manager is responsible for establishing and maintaining an effective management system, ensuring also that all activities can be financed and carried out in accordance with the appropriate requirements. The post holder shall have a proven track record in same or similar post.

2.2 Head of AeMC

The Head of AeMC is responsible for the overall management, clinical oversight, and regulatory compliance of the Aeromedical Centre. This includes ensuring that all operations comply with applicable aviation medical regulations namely Part-MED and Part-ATCO.MED, as well as national procedures established by the competent authority. The Head of AeMC is also accountable for maintaining the integrity, confidentiality, and accuracy of medical records, facilitating internal audits, and liaising with regulatory bodies.

The Deputy Head of the AeMC shall undertake the duties and responsibilities of the Head of the AeMC during periods of deputization. Refer to Section 8.0 for further details.

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2.3 Compliance Monitoring Manager (CMM)

The Compliance Monitoring Manager shall undertake the function to monitor compliance of the organisation with the relevant requirements.

The recommendation from TMCAD is that the key person has a proven track record of audit planning and 24 months experience as auditor or 12 months CMM experience.

2.4 Safety Manager (SM)

The Safety Manager is responsible to coordinate the safety management system of the organisation.

The recommendation from TMCAD is that the key person has a proven track record of safety and knowledge of safety risk assessment and qualified in incident investigation and follow-up, with 24 months experience working in the Safety unit or 12 months experience as a SM.

2.5 Common Responsible Person (CRP)

The accountable manager or the common responsible person, shall have corporate authority to establish and maintain the organisational structures, policies, processes and procedures necessary to implement point IS.I.OR.200.

3.0 PROCESS FOR THE NOMINATION OF PERSON IN KEY POSITION(S)

In the case of, Accountable Manager, Safety Manager or Compliance Manager, the sponsoring organisation shall submit through Centrik, not less than ten (10) working days prior to proposed date of assessment:

- i. A formal application of proposal for nomination;
- ii. Completed TMCAD Form 374;
- iii. Manpower Plan;
- iv. Management of Change (if this is a change of key person).

The application shall be accompanied by the following documents:

- i. Curriculum Vitae;
- ii. Relevant Qualifications

4.0 PROCESS FOR ASSESSMENT

- The assessment will be conducted at the offices of TMCAD. It is expected that the candidate has the organisation manual suite available with them.
- Assessors shall be AMS/Personnel Licensing Inspectors/Inspecting Officers. For the nominated position of Head of AeMC, one of the assessors shall be a medical assessor.
- Two assessors will be present during the session.
- The decision on the outcome of the assessment by the TMCAD assessors must be unanimous.
- If the candidate is not accepted by the TMCAD, s/he shall not be permitted to reapply for the same post with the sponsoring organisation for a minimum period of 12 months.
- A list of topics (not exhaustive) for discussion can be found in Appendix A of this document.

For the avoidance of doubt, previous employment of a Key Person in a similar position with another organisation will not result in automatic acceptance by TMCAD within the new organisation. The decision of the TMCAD assessors will be final and not subject to appeal.

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5.0 PROVISIONAL ACCEPTANCE

TMCAD can provisionally accept sponsored nominees under one of two circumstances:

1. In the event that the nominees are sponsored by an organisation that is in the process of attaining an AeMC, then a full assessment of the nominees' knowledge of the organisation's processes would be limited, particularly since the documentation phase of the AeMC application would be thereto incomplete. Under such circumstances, the TMCAD assessors may provisionally accept the sponsored nominees in their proposed incumbencies for the purpose of assisting with the establishment of the organisation's management system in pursuit of attaining an AeMC.
2. If a candidate is proposed for a key position by an organisation that already holds an AeMC, and during the TMCAD assessment it is determined that the nominee possesses the necessary qualifications but only partially meets other requirements, the candidate may be provisionally accepted—without prejudice to the statutory qualification requirements—provided they are in the process of fulfilling the remaining criteria. In such cases, the assessors will invariably require the candidate to complete specific courses to meet the established standards outlined below and may also request further evaluation.

Under such circumstances, the provisional acceptance shall be for a period not greater than 6 months, until the required criteria are met. This period may be extended for a further period of 6 months if proof has been provided that the qualifying courses have not been available within this period. If within this 12-month period, the nominee has not qualified in the assessed criteria, TMCAD provisional acceptance will lapse and a new assessment by TMCAD will be required.

It will be the responsibility of the organisation's Accountable Manager to notify TMCAD that the organisation is in default of requirements of this policy. The Accountable Manager shall advise TMCAD on how the functions of the post will be fulfilled by the organisation.

6.0 ACCEPTANCE, NOTIFICATION AND CHANGES TO AeMC

The outcome of the assessment will be communicated to the nominee's sponsor via Centrik. If the nominee is accepted by TMCAD with conditions, the sponsor will also receive written confirmation indicating whether the acceptance is provisional and if the nominee's contracted working hours are deemed adequate. Written notification of acceptance (of the nominee) to the organisation shall include the proviso that should the operational situation of the organisation change from the circumstances at the time of acceptance of the nominee, TMCAD is to be immediately informed and reserves the right to review the acceptance criteria of the nominee.

Case in point to this is in organisations where one person holds multiple key positions, erstwhile permissible due to the size and nature of the operation. If the organisation's size and scope of operation varies TMCAD may also determine that a multiple key position holder relinquishes one or more incumbency.

7.0 COMBINATION OF ROLES

The acceptability of one person holding more than one key role will be dependent on the size and scope of the operation as allowed by ORA.GEN.200.

If the key person holds multiple roles, the candidate must fulfil all requirements for all nominations that the organisation applies for, and no credits shall be given for concurrent roles.

Each organisation must declare the minimum working hours for each position. Working hours shall be dependent upon the scale of the operation but limited to the applicable Working Time Directive.

The complexity of the organisation may prevent, or limit, combinations of nominations that may be acceptable in other circumstances.

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7.1 Persons Holding Key Positions with Different AeMCs

A person appointed as a nominated person by an AeMC, may not be appointed as a nominated person of any other AeMC, unless acceptable to the Competent Authorities concerned. Holding a nomination in more than one organisation is acceptable under the following conditions:

- i. The organisation must make arrangements to ensure continuity of supervision in the absence of nominated persons and thus have a declared deputy.
- ii. Nominated persons must be contracted to work sufficient hours to fulfil the management functions associated with the scale and scope of the operation.

A person shall not occupy a key position with more than 2 approved organisation.

8.0 DEPUTIES

Nomination of deputies has to follow the same process as that for key persons. Deputies shall meet the same requirements of the key persons since they will be assuming responsibilities and duties of the concerned function. Refer to Appendix A.

9.0 WITHDRAWAL OF ACCEPTANCE

TMCADs acceptance of a nominee may be withdrawn at any time even after the nominee has embarked on substantive employment with the organisation. This process will only be initiated if a valid reason exists. Reason for such a withdrawal of acceptance include, but not limited to:

- i. Inadequate appropriate interaction with TMCAD;
- ii. Persistent delays in closing audit findings;
- iii. Lack of qualification as a consequence of change in size and scope;
- iv. Culpable infringement of regulations;
- v. Criminal/fraudulent activity.

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APPENDIX A

Assessors have the obligation to ensure that the nominated person/s being interviewed adequately meets the requirements established by the regulation by means of their qualifications and experience. In this respect below are guidelines TMCAD Personnel Licensing officials will use during the assessment, however, questions might not be limited to the below to ensure a thorough assessment.

A.1 Accountable Manager (AM)

Requirements:

- The Accountable Manager is responsible for establishing and maintaining an effective management system, ensuring also that all activities can be financed and carried out in accordance with the appropriate requirements.
- The Accountable Manager must have direct safety accountability for the AeMC and remains ultimately responsible that the AeMC remains in compliance with the applicable regulations
- The Accountable Manager shall be responsible that the AeMC has sufficient qualified personnel, that the AeMC maintains the appropriate staff and that personnel are aware of the rules and procedures to conduct their duties.

Assessment:

- Assess the nominee's knowledge of the elements of the Safety Management System, the principles of the Compliance Monitoring System of the organisation
- Assess the nominee's knowledge of EU regulations governing AeMC
- Assess the nominee's knowledge of his responsibilities as Accountable Manager
- Assess the nominee's knowledge of the role the position he is being nominated for has in Safety Management and Compliance Monitoring
- Assess the nominee's management experience and capabilities
- Assess the nominee's knowledge of AeMC manuals
- Assess the nominee's knowledge of Regulation Part-MED
- Assess the nominee's general attitude towards the regulations and TMCAD

Guidance on Training Requirements for the Position

- Commission Regulation (EU) 1178/2011
- Commission Regulation (EU) 2015/340 Training Course as required
- Basic Safety Management System Course
- Accountable Manager / Nominated Persons Course
- Briefing on Part-IS

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A.2 Head of AeMC

The organisation shall be responsible to nominate an aero-medical examiner (AME) nominated as head of the AeMC that meet the below requirements:

Requirements:

- Shall hold an EASA Aero-Medical Examiner (AME) certificate with privileges to issue class 1 medical certificates
- Shall maintain and be able to demonstrate their aero-medical competency
- Shall maintain current with the applicable Implementing Rules and Acceptable Means of Compliance, as well as the national procedures established by the AMS section for the implementation of the relevant requirements under Part-MED and Part-ATCO.MED.
- Has held Class 1 privileges for at least 5 years
- Has performed at least 200 aero-medical examinations for a class 1 medical certificate
- Has the competencies to maintain oversight on AMEs within the AeMC ensuring they comply with applicable regulations and regulatory notices.

Assessment:

- Assess the nominee's knowledge of the content of the relevant parts of the AeMC manual
- Assess the nominee's experience in aviation medicine
- Ensures that the nominee meets the requirements as established in AMC 1 ORA.AeMC.210

Guidance on Training Requirements for the Position

- Commission Regulation (EU) 1178/2011
- Commission Regulation (EU) 2015/340 Training Course as required
- Basic Safety Management System Course
- Basic and/or Advanced Auditing Techniques Course

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A.3 Compliance Monitoring Manager (CMM) Nominated Person

Requirements:

The organisation shall be responsible to nominate a person or group of persons with the responsibility of ensuring that the organisation remains in compliance with the applicable requirements.

- The Compliance Monitoring Manager shall be responsible for ensuring that the compliance monitoring programme is properly implemented, maintained and continually reviewed and improved
- The Compliance Monitoring Manager shall have direct access to the Accountable Manager
- The Compliance Monitoring Manager shall have access to all parts of the AeMC and, as necessary, the contracted organisations

Assessment:

- Assess the nominee's qualifications and experience
- Assess the nominee's knowledge of the principles of the Compliance Monitoring system in the organisation.
- Assess the nominee's knowledge of EU regulations governing AeMCs
- Assess the nominee's knowledge of the elements of the Safety Management System, the principles of the Compliance Monitoring System of the organisation
- Assess the nominee's knowledge of the role the position he is being nominated for has in Safety Management and Compliance Monitoring
- Assess the nominee's knowledge in Audit Planning and from where this requirement is derived from the regulation
- Assess the nominee's administrative skills with regards to findings and their safety impact on operations
- Assess the nominee's knowledge about regulation requirements that deals with Mandatory Occurrence Reporting.
- Assess the nominee's knowledge of a Compliance Monitoring Programme.
- Assess the nominee's hours of employment in relation to the scope of the AeMC
- Assess the nominee's general attitude towards the regulations and TMCAD

Guidance on Training Requirements for the Position

- Commission Regulation (EU) 1178/2011
- Commission Regulation (EU) 2015/340 Training Course as required
- Basic and/or Advanced Safety Management System Course
- Instruction Techniques
- Basic and/or Advanced Auditing Techniques Course
- Root Cause Analysis Course

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A.4 Safety Manager (SM) Nominated Person

Requirements:

The organisation shall identify a person who fulfils the role of Safety Manager and who is responsible for coordinating the safety management system of the organisation.

- The safety manager is responsible for coordinating the safety management system.

Assessment:

- Assess the nominee's qualifications and experience
- Assess the nominee's knowledge of the elements of the Safety Management System, the principles of the Compliance Monitoring System of the organisation
- Assess the nominee's knowledge of EU regulations governing AeMCs
- Assess the nominee's knowledge of the role the position s/he is being nominated for has in Safety Management and Compliance Monitoring
- Assess the nominee's knowledge of AeMC manuals.
- Assess the nominee's knowledge of ICAO Annexes dictating the requirements of Safety Management System
- Assess the nominee's knowledge of the EU regulation that governs Safety Management System
- Assess the nominee's knowledge on the components of Safety Management System, purpose of the Safety Review Board, the HIRA process of the organisation, the SSP
- Assess the nominee's knowledge on the regulation that applies in case of occurrences
- Assess the nominee's knowledge on the levels of risk severity and probability applicable in the organisation, identification of hazards and mitigation of associated risks
- Assess the nominee's hours of employment in relation to the scope of the AeMC
- Assess the nominee's general attitude towards the regulations and TMCAD

Guidance on Training Requirements for the Position

- Commission Regulation (EU) 1178/2011
- Commission Regulation (EU) 2015/340 Training Course as required
- Basic and/or Advanced Safety Management System Course
- Investigation Techniques

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A.5 Common Responsible Person (CRP)

The accountable manager or the common responsible person, shall have corporate authority to establish and maintain the organisational structures, policies, processes and procedures necessary to implement point IS.I.OR.200.

Requirements:

- The CRP should be given the appropriate delegation that is necessary to implement the provisions of IS.I.OR.200, including the authority and the financial means to mobilise and control the resources across the organisations, or parts of the organisation involved.
- The common responsible person has direct access to the accountable manager;
- The CRP is expected to have information security competencies.

Assessment:

- Assess the nominee's knowledge of the elements of the Information security management manual
- Assess the nominee's knowledge of EU regulations governing ATOs
- Assess the nominee's knowledge of his responsibilities as CRP
- Assess the nominee's management experience and capabilities
- Assess the nominee's knowledge of Regulation Part-FCL
- Assess the nominee's general attitude towards the regulations and TMCAD

Guidance on Training Requirements for the Position

- Briefing on EU Regulation No. 1178/2011
- Briefing on Commission Regulation (EU) 2015/340 Training Course as required
- Appropriate knowledge in Information security management systems (ISMS) (e.g., ISO/IEC 27001 frameworks or similar)
- Appropriate knowledge in Cybersecurity threats and risk management

AERO MEDICAL SECTION