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Federal Department of the
Environment, Transport, Energy and Communications DETEC

Federal Office of Civil Aviation FOCA

Appendix AeMC to CL “Management System”

Supplementary Provisions

Supplementary provisions, explanations and guidance in addition to the “CL Management System” specific for Aero Medical Centre Certificate Holders presented in a format of a sample Organisation Management Manual (AeMC-OMM)

Document Reference	56-04
Registration No.	57.02.01_03_HAP_TP2-D-02 / 56-04_APP_AeMC_ISS1REV0
Prepared by	FOCA SB EASA Implementation Project – TP2-D-02 / mue
Released by	SB AFS 2013-11-12
Distribution	Internal/External

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Log of Revision (LoR)

Date	Issue	Revision (REV)	Changes
12.11.2013	1	0	First Issue

List of Effective Chapters (LoC)

0.0	REV0 / 12.11.2013	4.9	REV0 / 12.11.2013
1.1	REV0 / 12.11.2013 / APP	4.10	REV0 / 12.11.2013
1.2	REV0 / 12.11.2013 / APP	5.0	REV0 / 12.11.2013
1.3	REV0 / 12.11.2013	5.1	REV0 / 12.11.2013
1.4	REV0 / 12.11.2013	5.1.2	REV0 / 12.11.2013
1.5	REV0 / 12.11.2013	5.1.3	REV0 / 12.11.2013
1.6	REV0 / 12.11.2013	5.1.4	REV0 / 12.11.2013
1.7	REV0 / 12.11.2013 / APP	5.1.5	REV0 / 12.11.2013
1.8	REV0 / 12.11.2013 / APP	5.2	REV0 / 12.11.2013
1.9	REV0 / 12.11.2013	5.3	REV0 / 12.11.2013
2.1	REV0 / 12.11.2013	6.0	REV0 / 12.11.2013
2.2	REV0 / 12.11.2013	6.1	REV0 / 12.11.2013
2.3	REV0 / 12.11.2013	6.3	REV0 / 12.11.2013
2.4	REV0 / 12.11.2013 / APP	6.3	REV0 / 12.11.2013
2.5	REV0 / 12.11.2013	7.0	REV0 / 12.11.2013
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3.1	REV0 / 12.11.2013 / APP	8.0	REV0 / 12.11.2013
3.2	REV0 / 12.11.2013	8.1	REV0 / 12.11.2013
3.3	REV0 / 12.11.2013 / APP	8.2	REV0 / 12.11.2013
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4.1	REV0 / 12.11.2013 / APP	9.0	REV0 / 12.11.2013
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4.3	REV0 / 12.11.2013	9.2	REV0 / 12.11.2013
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4.5	REV0 / 12.11.2013	9.4	REV0 / 12.11.2013
4.6	REV0 / 12.11.2013	9.5	REV0 / 12.11.2013
4.7	REV0 / 12.11.2013	10.0	REV0 / 12.11.2013
4.8	REV0 / 12.11.2013	10.1	REV0 / 12.11.2013

Aero Medical Centre		Federal Office of Civil Aviation Approval		
Name:		Name:		stamp
Function:	Head of Aero Medical Centre	Function:	Head of Aero Medical Section, Medical Assessor	
Date:	DD.MM.YYYY	Date:	DD.MM.YYYY	
Signature:		Signature:		

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List of Abbreviations

The following abbreviations are within this appendix:

Abbreviation	Definition
ACM	Accountable Manager
AeMC	Aero Medical Centres
AeMC-OMM	Aero Medical Centre Organisation's Management Manual
Alt Moc	Alternative Means of Compliance
AMC	Acceptable Means of Compliance
AME	Authorised Medical Examiner
AMS	Aero Medical Section
APP	Element requiring prior Approval
ATCO	Air Traffic Controller
CC	Cabin Crew
CL	Certification Leaflet
CM	Compliance Management
CMM	Compliance Monitoring Manager
CV	Curriculum Vitae
DD.MM.YYYY	Date format - Day-Month-Year
e.g.	exemplī grātiā, for example
EASA	European Aviation Safety Agency
EC	European Commission
ECG	Electrocardiography
EDP	Electronic Data Processing
EEC	European Economic Community
EMP	Emergency Management Plan
EMPIC	European Medical Pilot Certificate EMPIC-EAP European Aviation Processing System
EU	European Union
FOCA	Federal Office of Civil Aviation
GEN	General
GM	Guidance Material
HAeMC	Head of Aero Medical Centre
ICAO	International Civil Aviation Organisation
IEC	International Electrotechnical Commission
ISO	International Standards Organisation
IT	Information Technology
LAPL	Light Aircraft Pilot Licence
LFG	Luftfahrtgesetz
LoC	List of Effective Chapters
LoR	Log of Revision
MED	Medical
MS	Management System
No.	Number
OMM	Organisation's Management Manual
ORA	Organisation Requirements Air Crew
P x S = R	Risk-**P**robability x Risk-**S**everity = **R**isk-Score
REV	Revision
SM	Safety Manager
SM	Safety Management
SRT	Safety Related Task
STS	Swiss Testing Services - Schweizerische Prüfstellendienst
UVEK	Eidgenössisches Department für Umwelt, Verkehr, Energie und Kommunikation
VAPF	Verordnung für das Personal der Flugsicherungsdienste
VFD	Verordnung über den fliegerärztlichen Dienst
x-Check	Cross Check

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0 Introduction

0.0 REV0 / 12.11.2013

This Aero Medical Centre Organisation Management Manual (AeMC-OMM) for *Name* takes into account all aspects of the organisation, such as philosophies, policies, processes, guidelines and responsibilities and includes Safety- and Compliance Management.

It has been developed with considerations to ANNEX VII to the Regulation on Air Crew, Part ORA and Annex IV Part MED and relevant Acceptable Means of Compliance (AMC) and Guidance Material (GM).

1 The Aero Medical Centre Organisation

1.1. Safety Policy and Vision

1.1 REV0 / 12.11.2013 / APP

Safety Policy	• We are committed to ensure medical examination and assessment according to the "state of the art" medical knowledge and practise, as well as to follow the applicable standards and regulation; • The safety standard of aviation medicine should be the concern of all employees at any level within the organisation; • We strive to achieve the highest safety standards of aviation medicine; • We provide appropriate resources and enforce safety as one of the primary responsibilities of all employees; and • We support a non-blame culture for reports of occurrences which would not have been otherwise detected.
Vision	• We provide the complete frame of aero medical examinations which include the initial assessments of professional aviation personnel; • We strive for highest standards in aviation medicine; and • Focus on professional, honest and friendly relationship with customers and ensure medical confidentiality at all times.

Name	*Signature*
Accountable Manager	Signature

1.2. Scope of Activity – AeMC Certificate *Number*

1.2 REV0 / 12.11.2013 / APP

The scope of the Aero Medical Centre is to issue medical certificates including initial class 1 (and class 3) and medical certificates pertaining to an aircrew or ATCO Licence:

Air Navigation System Personnel	Medical Certificate Class 3 Medical Certificate Class SRT	Initial Revalidation Renewal
Flight Crew	Medical Certificate Class 1 Medical Certificate Class 2 Medical Certificate Class LAPL	
Cabin Crew	Cabin Crew Medical Report	
…		

1.3. Statement of Complexity

1.3 REV0 / 12.11.2013

The Aero Medical Centre *Name* is to be considered as a non-complex organisation.

1.4. Relevant Standards and Requirements

1.4 REV0 / 12.11.2013

The AeMC ensures the compliance with the following legal requirements (including their amendments):

- **Basic regulation** (EC) No 216/2008 of 20/02/2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency;
- Commission Regulation (EU) No 1178/2011 of 03/11/2011 laying down technical requirements and administrative procedures related to civil aviation **aircrew**;
- Commission Regulation (EU) No 290/2012 30/03/2012 (amending Regulation (EU) No 1178/2011) laying down technical requirements and administrative procedures related to civil aviation **aircrew**; and
- Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on **occurrence reporting** in civil aviation.
- Bundesgesetz vom 21.12.1948 über die **Luftfahrt** (LFG) 748.0;
- Verordnung des UVEK über den **fliegerärztlichen Dienst** der Zivilluftfahrt (VFD) 748.222.5; und
- Verordnung des UVEK vom 30.11.1995 über die Ausweise für das Personal der **Flugsicherungsdienste** (VAPF) 748.222.3
- *…?*

1.5. Compliance Statement

1.5 REV0 / 12.11.2013

The undersigned declares, that

- our organisation's documentation (Management System) has been established and will be maintained in full compliance with the provisions of the legal requirements as stated in Chapter 1.4 "Relevant Standards and Requirements" and that it complies with the terms and conditions of the Aero Medical Centre Certificate(s) and Approval(s);
- I am responsible for the content of the Management System and confirm, that besides the requirements stated in Chapter 1.4 "Relevant Standards and Requirements" all relevant national rules and regulations as well as ICAO standards and procedures are reflected in the different chapters;
- I am familiar with and understand the content and meaning of the Management System and will perform all duties in full accordance with it;
- the detailed knowledge of the relevant content is mandatory to all personnel concerned and we commit to make sure that they comply with the instructions given in the Management System and;
- I am aware of the fact, that FOCA does not approve/accept the organisation's documentation as such, but only specific elements thereof, as indicated in the list of elements requiring prior approval, chapter 2.5.1 The responsibility for the completeness and the correctness of the organisation's documentation remains therefore solely with the organisation.

Name	*Signature*
Accountable Manager	Signature

1.6. Location, Facilities and Infrastructure

1.6 REV0 / 12.11.2013

Address	*Rue de la Medicine* *…*	☎	*0041 123 45 67*
		🖷	*0041 123 45 68*
		💻	*aeromedical-management@aemc.com*
Facilities	*Office, medical technical facilities, laboratory, waiting room and rooms for examination are integrated in …*		
Infrastructure	*Refer to XXX*		

1.7. Exemption and Derogation

1.7 REV0 / 12.11.2013 / APP

A flexibility provision is an exemption or derogation from (EC) 216/2008 (Basic Regulation) and its Implementing Rules. If the organisation needs an exemption or derogation with or without limited duration the following provisions apply:

- The equivalent level of safety must be provided;
- The organisation must not implement an exemption or a derogation without having received the formal approval;
- FOCA may prescribe conditions under which the organisation may process the work during the exemption or derogation;
- Formal approval by FOCA will only be granted to the organisation after EASA has approved the exemption or derogation to FOCA;
- Formal approval will be granted on specific documentation issued by FOCA and effective only after the organisation has received respective documentation; and
- The submission to FOCA has to include:
    1. A written application;
    2. A full description of the exemption/derogation,
    3. The proposed revision/amendment or temporary amendment of the manual system reflecting the exemption or derogation; and
    4. A documented assessment including risk-assessment, demonstrating that Regulation (EC) No 216/2008 and its Implementing Rules are met.

1.7.1 List of Approved Exemptions and Derogations

The organisation is the holder of the following approved exemptions/derogations:

Legal Reference	Short Description	Date of Approval	Reference
Blank	*Blank*	*Blank*	*Blank*

1.8. Alternative Means of Compliance

1.8 REV0 / 12.11.2013 / APP

Instead of Acceptable Means of Compliance (AMC), Alternative Means of Compliance (Alt MOC) may be established to ensure compliance with the Implementing Rules, provided the same level of safety is ensured. If the organisation intends to use Alternative Means of Compliance the following provisions apply:

- The equivalent level of safety as the one established by the Acceptable Means of Compliance (AMC) adopted by the Agency must be reached;
- The organisation must not implement Alternative Means of Compliance without having received the formal approval;
- FOCA may stipulate conditions under which the organisation may process the work during the implementation of an Alternative Means of Compliance;
- Formal approval will be granted on specific documentation issued by FOCA and effective only after the organisation has received respective documentation; and
- The submission to FOCA must include:
  1. A written application;
  2. A full description of the Alternative Means of Compliance;
  3. The proposed revision/amendment of the manual system reflecting the application of the Alternative Means of Compliance; and
  4. A documented assessment, demonstrating that Regulation (EC) No 216/2008 and its Implementing Rules are met. In order to demonstrate that the Implementing Rules are met, the assessment shall include a documented risk-assessment. The result of this risk-assessment should demonstrate that an equivalent level of safety as the one established by the Acceptable Means of Compliance (AMC) adopted by the Agency is reached.

1.8.1 List of approved Alternative Means of Compliance

The organisation uses the following approved Alternative Means of Compliances:

Legal Reference	Short Description	Date of Approval	Reference
Blank	*Blank*	*Blank*	*Blank*

1.9. Access and Power of Authorities

1.9 REV0 / 12.11.2013

For the purpose of determining compliance with the relevant requirements of Regulation (EC) No. 216/2008 and its Implementing Rules, the organisation grants access to any facility, document, records, data, procedures or any other material relevant to its activity subject to certification, whether it is contracted or not, to any person authorised by the Federal Office of Civil Aviation (FOCA).

2 Organisation Documentation, System of Amendment and Revision

2.1. Overview

2.1 REV0 / 12.11.2013

AeMC-OMM	Aero Medical Centre Organisation's Management Manual	The Aero Medical Centre Organisation's Management Manual includes the Safety Management and the Compliance Management, and documents all superior aspects of the organisation such as philosophies, policies, processes, guidelines and responsibilities.
…	…	…

2.2. Common Language

2.2 REV0 / 12.11.2013

Management System related documentation and manuals are issued in English. In addition, any Non-Aero Medical Centre Certificate or EASA related documents, manuals, working tools and forms may be issued in or translated into another language if and when required. The first choice of language for all verbal communication is *German / French / Italian / English.* An alternative choice of language may be used provided all parties are in agreement.

2.3. System and Form of Distribution

2.3 REV0 / 12.11.2013

The Head of Aero Medical Centre, or delegated person, provides the distribution of the organisation documentation and ensures electronic access, where applicable:

Document User Personal / Function / Location	**Form**		**Personal Copy**	**Access only**
	EDP	Text – Paper		
Federal Office of Civil Aviation, Head of AMS	X	X	X	
Accountable Manager		X	X	
Head of Aero Medical Centre	X	X	X	
Compliance Monitoring Manager	X	X	X	
Safety Manager	X	X	X	
Aero Medical Examiner		X	X	X
Auditor / Inspector				X
Office / Medical Technical Facilities				X
Secretariat		X	X	
Subcontractor				X
…				

2.4. System of Amendment and Revision

2.4 REV0 / 12.11.2013 / APP

2.4.1 Responsibility Matrix

Document	Owner	Content	Format	Content Owner			
				ACM	HAeMC	CMM	SM
Management System	ACM	Complete Organisation Documentation	EDP/Text-Paper	X			
AeMC-OMM	HAeMC	Safety Management	Text -Paper				X
		Safety Policy and Vision	Text-Paper	X			
		Compliance Monitoring	EDP/Text-paper			X	
		Occurrence Reporting	EDP/Text-paper		X		
		Medical issues and decisions	EDP/Text-paper		X		
…							

2.4.2 Revision / Amendment Process

Step	Remarks	Tool	Responsibility
Monitoring and Change Identification	• Collection of suggestions and discrepancies • Findings, corrective and preventive actions • Changes in relevant standards and Requirements • Change Management	• Rules and regulations • Audit- / Inspection Schedule, Checklist and Report • Analysis / Report Form	Document Owner
Change Initialisation	• Identify/define type of change: revision or new issue?		Document Owner
Elements requiring prior approval	• Identify elements requiring prior approval • Verify administrative requirements • Ensure Compliance Check prior to FOCA submission	• List of Elements requiring prior Approval, Chapter 2.5.1	Document Owner
Establish draft of revision/amendment	• Edit and establish change • Mark any changes to previous version by a vertical line on the border of the page • Eliminate change indicators from the previous revision of that page	• AeMC-OMM	Document Owner
Compliance check	• Verify compliance, compatibility and completeness with standards, requirements and regulations, harmonisation with other documents, viability & appropriateness • Conduct assessment of risks, if required • Verify the requirement of a detailed audit	• Relevant Requirements and Standards • Risk Assessment in case of Flexibility Provisions or Alternative Means of Compliance (Alt MOC)	Compliance Monitoring Manager Document Owner

Step	Remarks	Tool	Responsibility
	• Ensure traceability of changes • Check completeness		
FOCA Submission	Prepare submission in accordance with the administrative requirements • changes requiring prior approval/acceptance only: - submit revised pages as draft at least 30 days before the date of the intended changes • in case of planned change of a nominated person: inform FOCA at least 10 days before the date of the proposed change • in case of unforeseen changes: inform FOCA at the earliest opportunity	• FOCA administrative requirements • FOCA Homepage • Proposed revision/ amendment/ manual/document • For nominated persons: - Form 4 and CV • In case of flexibility provisions/alternative means of compliance: - Application - Full description proposed revision amendment including documented assessment demonstrating compliance	HAeMC
Document Evaluation	• Apply corrective actions • Agree implementation or conditions with FOCA • Implement FOCA prescribed conditions under which the organisation may process work during the implementation • Agree effective date with FOCA	• Document Evaluation Report • Emails • Phone	Document Owner FOCA
Distribution	• If approval or acceptance by FOCA required, initiate distribution and implementation only after formal approval or approval/acceptance is received by FOCA • Add effective date • Complete list of highlights of revision • Poss. up-date list of alternative means of compliance / flexibility provisions • distribute new edition/revision/amendment (including FOCA) • instruct / inform employees	• Distribution list, Chapter 2.3 “System and Form of Distribution”	HAeMC
Up-date document / manual	enter revision/amendment correctly	Revision/Amendment	Document user

2.5. Elements/Changes requiring prior Approval

2.5 REV0 / 12.11.2013

- Any revision / amendment must be submitted to FOCA before any implementation of a change takes place;
- The amendment / revision process includes the identification of elements requiring approval. Changes requiring prior approval may only be implemented by the organisation upon receipt of formal approval by the competent authority;
- The application for the amendment of a certificate should be submitted at least 30 days before the date of the intended changes; and
- In the case of a planned change of a nominated person, the organisation should inform FOCA at least 10 days before the date of the proposed change.

2.5.1 List of Elements requiring prior Approval

Paragraph	Content	Reference
ORA.GEN.120	Alternative Means of Compliance are subject to prior approval	• Chapter 1.8 “Alternative Means of Compliance”
ORA.GEN.130	Any change affecting the scope of the Aero Medical Centre certificate or the terms of approval	• Aero Medical Centre Certificate and Attachment
ORA.GEN.130	Procedure for the handling of changes not requiring prior approval	• Chapter 2.4 “System of Amendment and Revision”
ORA.GEN.200	Lines of Responsibilities	• Chapter 3.1 “Organisational Structure”
ORA.GEN.200	Accountability	• Chapter 3.4 “Duties, Responsibilities and Accountabilities”
ORA.GEN.200	Safety Policy	• Chapter 1.1 “Safety Policy and Vision”
ORA.GEN.210	Change of the following nominated person: • Accountable Manager • Head of Aero Medical Centre • Compliance Monitoring Manager • Safety Manager	• Chapter 3.3 “Management Personnel – Names and Contacts” • Respective Form 4

2.6. Control of External / Foreign Documents

2.6 REV0 / 12.11.2013

External documents are established and amended by third parties (e.g. law, international standards, health departments' bulletins, relevant medical studies documents and publications, etc.). They have an impact on the organisation's activities. The amendment process shall ensure that new issues and revisions of foreign documents are identified.

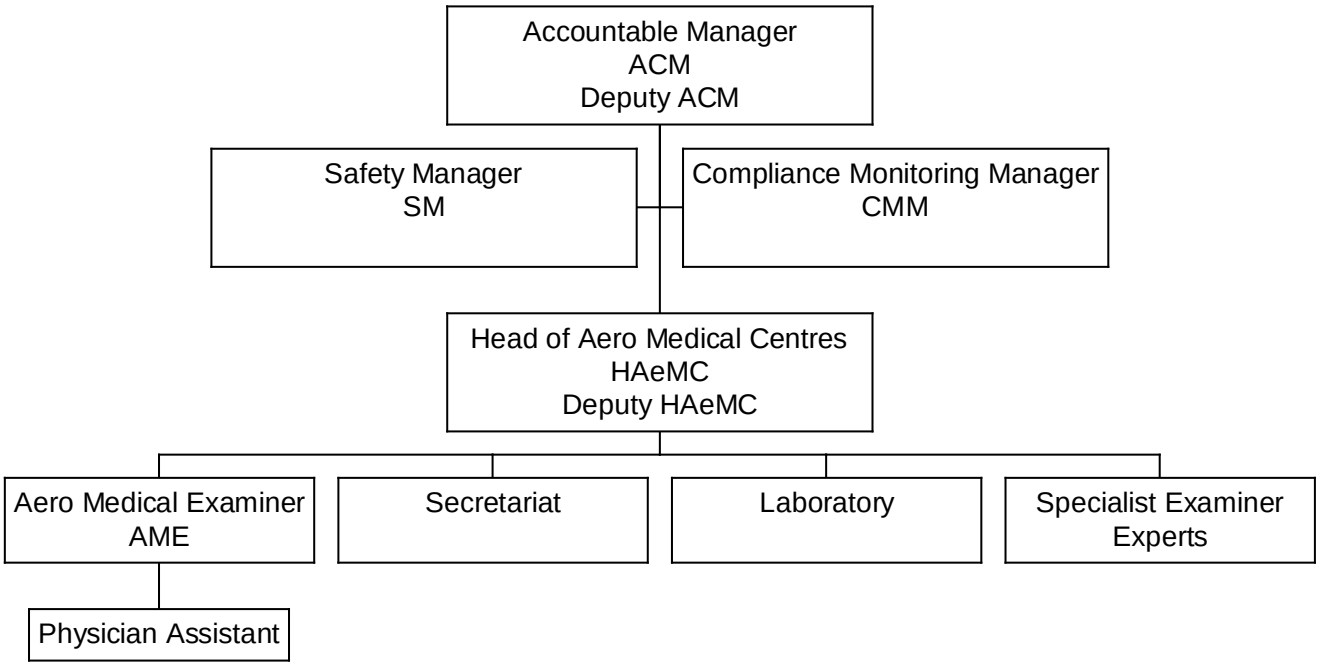
Step		**Remarks**
1	Identification	Identify new issues and changes in external documents
2	Analysis	Verify the impact on the organisation processes
3	Amendment	Trigger the amendment of the organisation processes and documentation
4	Archive	Ensure that old versions of documents are stored to ensure traceability

Reference	**Subject**	**Responsible**
Basic Regulation (EC) No 216/2008	Common rules in the field of civil aviation and establishing a European Aviation Safety Agency	ACM
Commission Regulation (EU) No 1178/2011	Technical requirements and administrative procedures related to civil aviation aircrew including Acceptable Means of Compliance (AMC) and Guidance Material (GM)	HAeMC
Commission Regulation (EU) No 290/2012 (amending regulation 1178/2011)	Technical requirements and administrative procedures related to civil aviation aircrew including Acceptable Means of Compliance (AMC) and Guidance Material (GM)	HAeMC
Directive 2003/42/EC	Occurrence reporting in civil aviation	CMM
Federal Office of Civil Aviation Aero Medical Section Periodic Bulletin	Work instructions, Terms of Reference	HAeMC
...		

3 Organisational Structure, Duties, Responsibilities and Accountabilities

3.1. Organisational Structure

3.1 REV0 / 12.11.2013 / APP



Insert your graphical presentation of the structure of the Aero Medical Centre's organisation The organisation's subordination and reporting lines shall clearly show the relationship between divisions, departments and functions defined and shall represent the organisation as a whole. To ease revision processes do not include the name of the nominated function.

3.2. Clinical Attachment to hospital or liaisons with medical Institutes

3.2 REV0 / 12.11.2013

The AeMC is attached to *Name.*

The AeMC liaises with the following designated hospital or medical institute:

- *Name*

3.3. Management Personnel – Name and Contacts

3.3 REV0 / 12.11.2013 / APP

Function	**Name of Function Holder** **Name of Deputy**	**Contact details**
Accountable Manager		
Head of Aero Medical Centre		
Compliance Monitoring Manager (CMM)		
Safety Manager		
….		

3.4. Duties, Responsibilities and Accountabilities

3.4 REV0 / 12.11.2013 / APP

3.4.1 Accountable Manager (ACM)

The accountability, responsibilities and duties of the Accountable Manager are:

- His duty to endorse the safety policy;
- His responsibility of establishing and maintaining an effective Management System;
- His authority to ensure that all activities can be financed and carried out in accordance with the applicable requirements;
- His authority to designate the Compliance Monitoring Manager;
- His duty to grant direct access to nominated persons and the Compliance Monitoring Manager;
- His duty to ensure that sufficient resources are allocated, taking into account the size of the organisation and the nature and complexity of its activities.
- His accountability in relation to Safety Policy, ensuring that the management personnel (senior management):
  - continually promote the Safety Policy to all personnel and demonstrate their commitment to it;
  - provide necessary human and financial resources for its implementation; and
  - establish safety objectives and performance standards
  - to endorse the Safety Policy.

3.4.2 Head of Aero Medical Centre (HAeMC)

The accountability, responsibilities and duties of the Head of Aero Medical Centre are:

- Responsibility for coordinating the assessment of examination results and signing reports, certificates, and initial class 1 medical certificates;
- Assurance that all subordinates meet the qualification requirements for their respective activities, management and planning of continuous education/ currentness and career development of the subordinates.
- Allocation of responsibilities and duties and issuing instructions to individuals, sufficient for implementation of the safety policy and ensuring best standard of aviation medicine;
- Monitoring of safety standards and “state of the art” in aviation medicine, including the adherence of employees to these standards, also by means of inspections;
- Evaluation of relevant records in order to avoid the occurrence of undesirable trends;
- Recording and analysis of any deviations from organisation specific standards and ensuring correction, corrective action and preventive action within the organisational unit;
- Promoting of corporate culture of safety and quality, philosophy, policies and overall standard of performance, risk awareness and associated behaviour;
- Assurance of a comprehensive document and record management/ storage/ archive and liaising with FOCA regarding administration and coordination;

3.4.3 Aero Medical Examiner (AME)

The accountability, responsibilities and duties of the Aero Medical Examiner are:

- Performing medical assessments according to relevant standards and regulation;
- Responsibility for the establishment and maintenance of medical assessment files, including related forms, records, documents and entries of data as required by the Aero Medical IT applications (EMPIC);
- Promoting corporate culture for safety standards of aviation medicine and medical knowledge and practice;
- Providing feedback and reporting of occurrences and hazards in accordance with the feedback and reporting system.

3.4.4 Safety Manager (SM)

- The safety manager should act as the focal point and be responsible for the development, administration and maintenance of an effective safety management system.
- The functions of the safety manager are:
  - To facilitate hazard identification, risk analysis and management;
  - To monitor the implementation of actions taken to mitigate risks and to evaluate their results/effectiveness;
  - To ensure maintenance of safety management documentation;
  - To ensure that a safety management training is available and that it meets acceptable standards;
  - To provide advice on safety matters;
  - To ensure initiation and follow-up of internal occurrence investigations; and
  - to actively promote corporate culture for safety.

3.4.5 Compliance Monitoring Manager (CMM)

The responsibilities, duties and competences of the Compliance Monitoring Manager are:

- Ensuring that the activities of the organisation are monitored for compliance with the applicable regulatory requirements and standards, as well as any additional requirements as established by the organisation;
- Ensuring that these activities are being carried out properly under the supervision of the relevant head of the respective functional area;
- Responsibility to ensure that the compliance monitoring programme is properly implemented, maintained, continually reviewed and improved;
- Performing of audits and inspections provided he possesses the related competence in the area of audits/inspections to be conducted. He may appoint one or more auditors by choosing personnel having the related competences either from within or outside the organisation, assuring their independence.
- Ensuring accessibility to all parts of the organisation, and if necessary, any contracted organisation.

4 Safety Management

4.1. Safety Policy

4.1 REV0 / 12.11.2013 / APP

Refer to Chapter 1.1 “Safety Policy and Vision”

4.2. Hazard Identification and Risk Management

4.2 REV0 / 12.11.2013

The hazard identification process is the formal means of collecting, evaluating and recording hazards, evaluate the associated risk and define related mitigation measures.

Definition of hazard and risk:

Hazard: Condition or object with the potential of causing injuries to personnel, damage to equipment or structures, loss of material, or reduction of ability to perform a stipulated function.

Risk: The assessment, expressed in terms of predicted probability and severity, of the consequence(s) of a hazard, taking as reference the worst foreseeable situation.

Starting with the Hazard Identification Process and the associated tables, the hazard identification and the associated Risk Assessment can be performed.

4.3. Hazard Identification Process

4.3 REV0 / 12.11.2013

Step	Tool	Responsibility
Indentify hazard		All personnel
Inform Safety Manager	Hazard reporting Form Verbally during weekly Briefing	All personnel
Evaluate associated risk	Table for probability, severity, tolerability Matrix and Risk Assessment Checklist	SM
Define mitigation action	Risk Assessment Checklist	SM
Filing		SM
Inform HAeMC	Written report	SM
Set duties on task list	Task list	HAeMC
Controlling	Internal Audit	CMM

4.4. Hazard Reporting Form

4.4 REV0 / 12.11.2013

- Refer to feedback and reporting system Chapter 6.3 “Reporting Form”

4.5. Probability Table

4.5 REV0 / 12.11.2013

Probability Classification	Definition Qualitative	Definition Quantitative	Value
Frequent	Likely to occur many times (has occurred frequently)	Probability of occurrence ≥ once per day	5
Occasional	Likely to occur sometime (has occurred infrequently)	Probability of occurrence ≥ once per week	4
Remote	Unlikely but possible to occur (has occurred rarely)	Probability of occurrence ≥ once per 6 months	3
Improbable	Very unlikely to occur (not known to have occurred)	Probability of occurrence ≥ once a year	2
Extremely improbable	Almost inconceivable that the event will occur	Probability of occurrence < once in three years	1

4.6. Severity Classification Table

4.6 REV0 / 12.11.2013

Severity Classification	Level of injury	Safety Barriers	Value
Catastrophic	Sudden incapacitation combined with the possibility of an aircraft accident	No safety barriers remaining	5
Hazardous	Sudden incapacitation on duty	Non or very few safety barriers remaining	4
Major	Subtle incapacitation	Non or very few safety barriers remaining	3
Minor	Subtle incapacitation	Several safety barriers remaining and compensate for a possible accident	2
No Significant Safety Effect	Minor medical symptoms	Existing safety barriers come into play to avoid the event turning into a minor incident	1

4.7. Tolerability Matrix

4.7 REV0 / 12.11.2013

Risk Score	Acceptability	Action
01-06	Acceptable Region	No Action/nominate existing barriers
07-14	Tolerable Region	Might require additional risk mitigation.
15-25	Intolerable Region	Unacceptable under existing circumstances. Reduce risk to acceptable or tolerable Region.

4.8. Risk-Assessment Checklist

4.8 REV0 / 12.11.2013

Hazard Description	Existing Barriers	Risk Assessment PxS=R			Mitigation Action	Risk post mitigation		
		P	S	R		P	S	R
Mix-up of personal data	• x-check with birthday and/or licence number	3	1	3	• none	3	1	3
Failure to obtain complete medical history		4	2	8	• Regular teaching of AME's of consequences	3	2	6
Mix-up of laboratory results (most critical case)		3	5	15	• Internal Audits • clear identification of blood samples	2	5	10
Erroneous interpretation of ECG findings	• compare with previous ECG • ECG with interpretation capability	2	3	6	• none	2	3	6
Erroneous application of applicable medical standards		4	2	8	• Regular refresher training of AME's • Regular internal teaching and analysing of contentious cases	3	2	6
Malfunctioning of technical equipment: • ECG device • audiometer, • visual testing system • blood analysing apparatus	• Periodic check and or calibration of devices • Periodic external laboratory quality control	2	2	4	• none	2	2	4
Wrong entries in IT-System (EMPIC) Mix-up of personal data	• Use of EMPIC screening system • Surveillance through AMS	3	2	6	• none	3	2	6
Inconsistencies if part of the examination (e.g. foreign laboratory examination) is performed outside the AeMC	• Delegate external examination only if absolutely necessary • Results of external examination must be signed and transmitted by external physician	1	2	2	• none	1	2	2
Wrong storage of documents leading to a mix-up of personal data	• Internal Audits/Inspections • x-check with birthday and/or licence number	3	1	3	• none	3	1	3

Hazard Description	Existing Barriers	Risk Assessment PxS=R			Mitigation Action	Risk post mitigation		
		P	S	R		P	S	R
Damaging technical equipment leading to erroneous results	• Correct packaging • Information to all involved personnel	2	2	4	• none	2	2	4
Wrong application due to missing introduction leading to erroneous application of applicable medical standards		4	2	8	• Procedure for Introduction of new personnel	2	3	6
Non adequate temperature for technical equipment/and or medical examples leading to erroneous results	• Information about temperature requirement • Verification of actual temperature	2	2	4	• none	2	2	4

4.9. Change Management

4.9 REV0 / 12.11.2013

Change Management is a process to manage safety risk related to a change. The related hazards are listed in table "hazards related to changes" and rated in the "Risk Assessment Checklist"

Changes that could have a negative impact on safety could come from:

- implementation of new, or modification of processes / procedures;
- contracting new providers;
- implementation of new or modification of tools;
- evaluation of new external offices

any kind of projects with safety relevance.

4.9.1 Change Management Process

Task	Note	Responsible
Identify scope of change		Responsible Manager (Project Manager)
Perform initial impact assessment (refer to table "hazards related to change)	Work-instructions Infrastructure Equipment Personnel	Project Manager with Safety Manager
Perform Safety Risk Analyses	Identify Hazards (refer to risk assessment check-list) add new hazards to the Risk-Assessment Checklist	Project Manger with Safety Manager
Define mitigation actions	Preventive barriers	Domain Manager/SM
Identify key personnel	Key personnel who assists the implementation of the change	Project Manager
Define implementation plan	Timelines	Project Manager
Assess related financial costs	Budgeting	Project Manger
Controlling	Check that everything is functioning	Safety Manager

4.9.2 Hazards related to changes

Area	Sub-Area	Hazard
Change of Location	Transport	Damaging technical equipment leading to erroneous results.
	Temperature	Non adequate temperature for technical equipment/and or medical examples leading to erroneous results
Implementation or modification of new tools, processes and procedures	Procedures	Wrong application leading to erroneous application of applicable medical standards
	Introduction	Wrong application due to missing introduction leading to erroneous application of applicable medical standards
	Service-contract	Malfunctioning of equipment due

Area	Sub-Area	Hazard
		to lack of service leading to erroneous results
Contracting of new providers and/or external offices	Quality	Erroneous application of applicable medical standards
		Malfunctioning of technical equipment: • ECG device • audiometer, • visual testing system • blood analysing apparatus
	Procedures	Mix-up of laboratory results (most critical case)
Change of personnel	Qualification	Erroneous application of applicable medical standards
		Mix-up of laboratory results (most critical case)
		Wrong entries in IT-System (EMPIC)
		Wrong storage of documents
		Mix-up of personal data
	Introduction	Wrong application due to missing introduction leading to erroneous application of applicable medical standards

- For the assessment of the hazards refer to the Risk-Assessment Checklist.

4.10. Safety Promotion

4.10 REV0 / 12.11.2013

The Safety Promotion is a process aimed to promoting a culture of safety by ensuring that, all personnel in an organisation are aware that, at their level and in their day-to-day activity, they are key players in safety and that everyone, therefore, contributes to an effective safety management.

Managers are an important driving force of effective safety management. It is the responsibility of each manager to demonstrate his/her commitment to safety, to promote safety in everyday activities and to lead by example.

Regular briefings and distribution of specific literature ensure that all personnel are aware of:

- Safety management related activities;
- The conveyance of safety critical information and the reporting of hazards;
- The importance of procedures.

4.10.1 List of Safety Communication Tools

Tool	Information	Frequency/Year	Responsibility
Briefing	Information of daily activities, safety and related procedures	52	HAeMC
Medical Literature	New developments in medicine	12	HAeMC

5 Compliance Management

5.0 REV0 / 12.11.2013

The Compliance Management ensures the conformity of the organisation with all relevant requirements and standards, including those of the Safety Management. The verification of the compliance is mainly conducted through the audit- and inspection processes.

5.1. Compliance Monitoring Programme

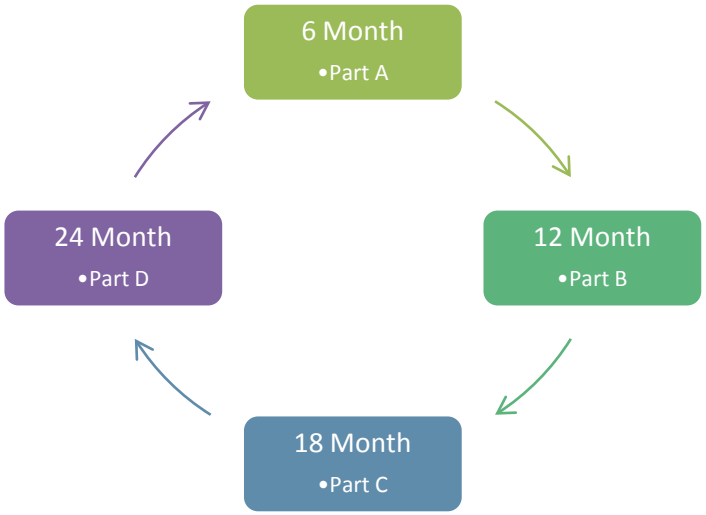
5.1 REV0 / 12.11.2013

The Compliance Monitoring Programme of the organisation comprises:

Audit and inspection procedures including related documents	Refer to Chapter 5.2 “Audit and Inspections
Scope and area of audit and inspection, including related checklist	Audit- / Inspection Schedule, Checklist and Report
The schedule for the programme	Refer to Chapter 5.1.1 “Programme Schedule”
Follow-up and corrective action procedures	Refer to Chapter 5.3 “Findings, Corrective- and Preventive Actions”
Feedback to the Accountable Manager	Refer to Chapter 5.2 “Audit and Inspections
Record and archiving system	Refer to Chapter 9 “Record Keeping”
Compliance Monitoring Training	Refer to Chapter 8 Management System Training”

5.1.1 Programme Schedule

To ensure that all aspects of the organisation are reviewed periodically, the scope and area of the compliance monitoring programme is divided in 4 parts and scheduled in a specified 24 month cycle:



Part	Scope	Schedule
A	Scope of approved activities	*March*
B	Aero medical standards and issues including training standards	*September*
C	Manuals, documents and records	*January*
D	Management system procedures including safety- and compliance management	*May*

5.1.2 Audit- / Inspection Schedule, Checklist and Report Part A

5.1.2 REV0 / 12.11.2013

A = Audit / I = Inspection / ☺ = o.k."oll correct" – all correct / 2 = Level 2 Finding / 1 = Level 1 Finding / Sign = Signature / CMM = Compliance Monitoring Manager / C = Checked / Ref: = Reference

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Are there any changes to the conditions under which the aero medical centre certificate has been granted?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
Ref: ORA.GEN.130, MED.D.025						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	☺

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Are the requirements for the issuance of AME certificate still met?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
Ref: ORA.GEN.130, MED.D.025						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	☺

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Is there a change of the aero medical centre practice location, facility and infrastructure?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
Ref: ORA.GEN.215, ORA.AeMC.215						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	☺

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
What is the latest revision of the Aero Medical Centre's Management Manual? Does the revision status correspond to the actual terms of approval and scope of activity issued by FOCA?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
ORA.GEN.200 / 130, MED.D.025						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	☺

5.1.3 Audit- / Inspection Schedule, Checklist and Report Part B

5.1.3 REV0 / 12.11.2013

A = Audit / I = Inspection / ☺ = o.k."oll correct" – all correct / 2 = Level 2 Finding / 1=Level 1 Finding / Sign = Signature / CMM = Compliance Monitoring Manager / C = Checked / Ref: = Reference

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:
Are the AME's and technical staff qualified and holders of the relevant diploma and governmental permissions?					Name:					Follow-up A I C
					Sign:					CMM Sign:
Ref: ORA.AeMC.210, MED.D.005						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed 👍

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:
Do the AME's and technical staff undertake continued education and follow the 3 years refresher training cycle? Did the AME's performing Class 1 examination undertake an advanced course in aviation medicine or equivalent?					Name:					Follow-up A I C
					Sign:					CMM Sign:
Ref: ORA.GEN.200, MED.D.015/030						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed 👍

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:
Do the AME's perform at least 10 aero medical examinations every 12 months?					Name:					Follow-up A I C
					Sign:					CMM Sign:
Ref: MED.D.030						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed 👍

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:
Is it ensured that all AME's are performing their duties based on the latest applicable aviation medicine requirements? Are updated versions of the relevant documents and IT applications available?					Name:					Follow-up A I C
					Sign:					CMM Sign:

Ref: ORA.GEN.210						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed
A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:
Have all aero medical centre employees undertaken the Basic Management System Training? Do all aero medical centre employees perform the continuous Management System every 12 month?					Name: Sign:					Follow-up A I C CMM Sign:
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:
Do the training organisations used for training in aviation medicine hold an approved course syllabus? Does the person in charge of providing the training have adequate knowledge and expertise?					Name: Sign:					Follow-up A I C CMM Sign:
Ref: ORA.GEN.200 / MED.D.020						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:
Is it ensured, that the applications for a medical certificate are complete and reviewed? • Proof of identity; • Signed declaration/application form; • For revalidation and renewal: the previous medical certificate.					Name: Sign:					Follow-up A I C CMM Sign:
Ref: MED.A.035						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:
Were corrective and preventive actions defined following an occurrence? Were the actions implemented as stated on the reporting form?					Name: Sign:					Follow-up A I C CMM Sign:
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Are application forms for medical certificate completely filled-out and signed by the respective applicant? Is a respective applicant file established, complete and stored according to the record keeping system?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	☝

5.1.4 Audit- / Inspection Schedule, Checklist and Report Part C

5.1.4 REV0 / 12.11.2013

A = Audit / I = Inspection / ☺ = o.k."oll correct" – all correct / 2 = Level 2 Finding / 1 = Level 1 Finding / Sign = Signature / CMM = Compliance Monitoring Manager / C=Checked / Ref: = Reference

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Is it ensured that all relevant personnel have easy access to the portions of the Aero Medical Centre's Management System Manual that are relevant for their duties?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
ORA.AeMC.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	👍

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Is there a comprehensive revision/ amendment procedure for the Aero Medical Centre's Management Manual? Does the procedure consider both kind of changes – changes needing prior approval and changes not needing prior approval by FOCA?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
ORA.GEN.200, ORA.AeMC.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	👍

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Is a list available with all medical records and is the retention period defined with a minimum of 10 years?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
Ref: ORA.AeMC.220						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	👍

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Are security and confidentiality adequate to prevent unauthorised access to records/ test samples and does a procedure to report unauthorised access exist?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
Ref: ORA.GEN.220, MED.A.015						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	👍

5.1.5 Audit- / Inspection Schedule, Checklist and Report Part D

5.1.5 REV0 / 12.11.2013

A = Audit / I =I nspection / ☺ = o.k."oll correct" – all correct / 2 = Level 2 Finding / 1 = Level 1 Finding / Sign = Signature / CMM = Compliance Monitoring Manager / C = Checked / Ref: = Reference

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Is there a description of the overall philosophies and principles of the organisation with regard to safety, referred to as the safety policy?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	👍

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Are the lines of responsibility and accountability including direct safety accountability throughout the organisation defined?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	👍

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Is/are a Safety Manager and Compliance Monitoring Manager appointed and qualified?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	👍

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:	
Is a function to monitor compliance with the relevant requirements established?					Name:					Follow-up	A I C
					Sign:					CMM Sign:	
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed	👍

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:			
Are safety hazards, their evaluation and mitigation actions addressed and their effectiveness addressed?					Name:					Follow-up	A	I	C
					Sign:					CMM Sign:			
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed			

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:			
Do the documented hazards correspond to the nature and complexity of the activities of the organisation?					Name:					Follow-up	A	I	C
					Sign:					CMM Sign:			
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed			

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:			
Are internal findings issued and corrective, preventive actions applied? Are third party (FOCA, EASA etc.) findings / measurements issued and are corrective, preventive action defined and applied?					Name:					Follow-up	A	I	C
					Sign:					CMM Sign:			
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed			

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:			
Are there any internal reports available? • Occurrence • Voluntary • Anonymous • Hazard					Name:					Follow-up	A	I	C
					Sign:					CMM Sign:			
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed			

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:			
Is a feedback system of findings to the accountable manager established to ensure effective implementation of corrective actions as necessary?					Name:					Follow-up	A	I	C
					Sign:					CMM Sign:			
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed			

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:			
Are there any notifications or reports related to occurrences, feedback or hazard? Are the respective corrective, preventive actions defined and applied?					Name:					Follow-up	A	I	C
					Sign:					CMM Sign:			
Ref: ORA.GEN.200						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed			

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:			
Is an equipment inventory established and current/valid? Have equipment calibration, service and/or preventive maintenance schedules been established and are they followed and documented?					Name:					Follow-up	A	I	C
					Sign:					CMM Sign:			
Ref: ORA.AeMC.215						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed			

A	I	☺	2	1	Date:	Finding, recommendation, comments, suggestion:		Root-cause, corrective-/preventive action:		Verification Date:			
Are ophthalmologists involved in initial Class 1 examinations and are they appointed as FOCA experts or supervised by FOCA experts?					Name:					Follow-up	A	I	C
					Sign:					CMM Sign:			
Ref: ORA.GEN.205						Responsible:	Due Date:	Closing Date:	Sign:	Report Closed			

<table>
<tr><td>A</td><td>I</td><td>☺</td><td>2</td><td>1</td><td>Date:</td><td colspan="2" rowspan="2">Finding, recommendation, comments, suggestion:</td><td colspan="2" rowspan="2">Root-cause, corrective-/preventive action:</td><td colspan="4">Verification Date:</td></tr>
<tr><td colspan="5" rowspan="3">Are contractors / vendors / external laboratories utilised?
Are external laboratories accredited according to:
• ISO 15189
• ISO / IEC 17025
• STS 292
• Qualab recommendations</td><td>Name:</td><td colspan="4">Follow-up</td><td>A</td><td>I</td><td>C</td></tr>
<tr><td>Sign:</td><td colspan="2" rowspan="2">CMM Sign:</td><td colspan="4" rowspan="2"></td></tr>
<tr><td colspan="5">Ref: ORA.GEN.205</td><td colspan="2">Responsible:</td><td>Due Date:</td><td>Closing Date:</td><td>Sign:</td><td colspan="3">Report Closed</td><td>👍</td></tr>
</table>

5.2. Audit and Inspections

5.2 REV0 / 12.11.2013

- 'Audit' means a systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which requirements are complied to.
- 'Inspection' means an independent documented conformity evaluation by observation and judgement, accompanied, as appropriate by measurement and testing, in order to verify compliance with applicable requirements.

Step	Remarks	Tool	Responsibility
Planning	Audit: Establish audit/inspection agenda according to programme schedule every year Consider former : • Audit- / Inspection Schedule, Checklist and Report • changes in the organisation • changes in regulatory requirement • changes in activities • Findings and recommendations • trends Follow-up audits when necessary All aspects at least once within 24 months Assign Auditor(s): consider independence & qualification	Compliance Monitoring Programme Schedule, Chapter 5.1 "Compliance Monitoring Programme"	CMM
	Inspection: Spot-Check planning Review the inspection plan and performed inspections	Compliance Monitoring Programme Schedule, Chapter 5.1 "Compliance Monitoring Programme" Audit-/Inspection Schedule, Checklist and Report	CMM
Preparation	Study relevant documentation, manuals and procedures Consider Feedback & Reporting system, former audit/inspection reports, former actions and changes Consider FOCA / EASA Standardisation Audits-/ and Inspections including Recommendations	Organisations Documentation List of pending items Audit-/Inspection Schedule, Checklist and Report	Auditor Inspector
Execution	Audit: Apply different techniques: • Interviews • witnessing of activities • Examination of evidences, records and review of documents	Audit-/Inspection Schedule, Checklist and Report	Auditor Inspector
	Inspection: Observe, Monitor, Witness the activity Analyse the completion, results, product; Compare with defined philosophies,	Audit-/Inspection Schedule, Checklist and Report	Auditor Inspector

Step	Remarks	Tool	Responsibility
	policies, procedures; Interview.		
Reporting	Establish Report Store Report Give over to CMM	Audit-/Inspection Schedule, Checklist and Report	Auditor Inspector
Feedback to the ACM	Provide the ACM with the Report, data, circumstances and results	Audit-/Inspection Schedule, Checklist and Report	CMM
⇨ Continue with the Corrective- and Preventive Action Process			

5.2.1 Auditors and Inspectors

- Inspections and audits should be carried out by personnel not responsible for the function, procedures or products being audited;
- The Compliance Monitoring Manager may perform all audits and inspections himself/herself or appoint one or more auditors by choosing personnel having the related competence either from within or outside the organisation;
- If external personnel are used to perform compliance audits or inspections:
  - any such audits or inspections are performed under the responsibility of the Compliance Monitoring Manager; and
  - the organisation remains responsible to ensure that the external personnel have relevant knowledge, background and experience as appropriate to the activities being audited or inspected; including knowledge and experience in compliance monitoring.
  - The organisation retains the ultimate responsibility for the effectiveness of the compliance monitoring function in particular for the effective implementation and follow-up of all corrective actions.

5.2.1.1 Qualification

Auditors and inspectors should have and demonstrate relevant knowledge, background and experience as appropriate to the activities being audited or inspected; including knowledge and experience in compliance monitoring;

5.2.1.2 Authority, Duties and Responsibilities

The authority, duties and responsibilities of an auditor are:

- conducting audits and inspections in accordance with the defined processes;
- evaluating safety management issues and procedures;
- evaluating the compliance of the organisation in accordance with the Compliance Monitoring Programme;
- supporting the establishment of audit and/or inspection checklist;
- establishing the audit and/or inspection report, as applicable;
- reporting of findings/deficiencies/concerns identified directly to the CMM/SM or as applicable, in accordance with the audit/inspection processes and providing recommendations for improving the organisation's operations, in terms of both efficient and effective performance;
- refusing an audit / inspection if:
  - not trained and qualified as auditor;
  - not in the position to demonstrate relevant knowledge, background and experience as appropriate to the activities being audited or inspected; and

- responsible for the function, procedure or product being audited (audit only).

5.2.1.3 List of Auditors and Inspectors

- Auditors and Inspectors are listed by name on the Audit- / Inspection Schedule, Checklist and Report.

5.3. Findings-, Corrective- and Preventive Actions

5.3 REV0 / 12.11.2013

- Correction is the action to eliminate a detected non-compliance.
- Corrective action is the action to eliminate or mitigate the root cause(s) and prevent reoccurrence of an existing detected non-compliance or other undesirable condition or situation. Proper determination of the root cause is crucial for defining effective corrective actions to prevent reoccurrence.
- Preventive action is the action to eliminate the cause of a potential non-compliance or other undesirable potential situation.

5.3.1 Classification of Findings

Level		Corresponds	Description
1	unacceptable	red zone	Safety standard of aviation medicine affected No further medical examination activity until closure of finding
2	tolerable	yellow zone	Safety standard of aviation medicine might be affected Finding to be closed within the due date, maximum 2 month

5.3.2 Corrective- and Preventive Action Process

Step	Remarks	Tool	Responsibility
Analysis	Analysis of action/measurement required Perform Risk Assessment Identification of the root cause and human factors Definition of mitigation/preventive action Establish corrective action plan	FOCA Document-/ Audit-/ or Inspection Report; Third parties safety-/ measures information (e.g. EASA); Audit- / Inspection Schedule, Checklist and Report Occurrence Report Risk Assessment Checklist	CMM with the management function of the area concerned
Initiation of actions and measures	Initiate corrective action and preventive action (Who does what, when and due date): • correction to eliminate problem • corrective action to eliminate root cause • preventive action to eliminate potential root cause • define measurement criteria to evaluate effectiveness	List of pending items Audit- / Inspection Schedule, Checklist and Report	Responsible management function of the area concerned
Monitoring of Effectiveness	Verify implementation of measures and the effectiveness	Follow-up audit or inspection	CMM
Feedback to the ACM	Inform the ACM with data, facts and results	Audit- / Inspection Schedule, Checklist and Report	CMM

6 Feedback and Reporting System

6.0 REV0 / 12.11.2013

The reporting scheme is an essential part of the overall monitoring function with the aim to improve aviation safety. And additionally, increase product quality, efficiency, job satisfaction and adding value. The overall purpose of a reporting scheme is to use reported information to improve the level of safety performance of the aero medical centre and not to attribute blame. It is complementary to the normal day-to-day procedures and 'control' systems and is not intended to duplicate or supersede any of them. The procedures are there to ensure that knowledge of relevant occurrences is disseminated, so that other persons and organisations may learn from them.

All persons involved in civil aviation are to report any occurrence endangering or potentially endangering safety.

6.1. Reportable occurrences

6.1 REV0 / 12.11.2013

Area	Subject	Type of Notification	FOCA
General	Any suggestions to improve medical examination practices, processes and procedures	verbally	No
	Any suggestions for improvements related to the aero medical centres administration and documents	verbally	No
	Any occurrence affecting the safety standards of aviation medicine	Report form	Yes
Equipment	Damage or malfunctioning of technical equipment: • ECG Device • Audiometer • Visual Testing system • Blood analysis apparatus • etc.	verbally	NO
	Lack of calibration and/or service / preventive maintenance	Report form	NO
Process	Erroneous application of applicable medical standards Failure in security and confidentiality, unauthorised access to records, test samples and medicine reports Inadequate or wrong labelling Mix-up of laboratory results Mix-up of personal data Wrong entries in IT-systems or documents Incorrect use of EMPIC screening system	Report form	Yes
Facility	Inadequate storage of technical equipment Incorrect packaging Inadequate sanitation or cleaning Dangerous goods occurrence/accident	Report form	No

6.2. Follow-up process for handling occurrence reports

6.3 REV0 / 12.11.2013

Step	Remarks	Tool	Responsibility
Report	Verify type of notification: • verbally; or • complete “Reporting/Analysis Form” Describe circumstance, issues, situation, occurrence suggestion Within 24h assign report to: • HAeMC	Daily briefing; or Reporting/Analysis Form	Author / Sender
Initial Analysis	Evaluate the severity and the necessity of immediate corrective(mitigation)/preventive action Open issue on the Pending Item list Verify the requirement to report to FOCA	Verbal Information/Data Reporting/Analysis Form Risk Assessment Checklist Pending Item List	HAeMC / SM
Notification	Notify FOCA at the latest within 72 hours	Report by the most practicable communication means	HAeMC
Mitigation	Define corrective action and preventive measures	Risk Assessment Checklist	HAeMC / SM
Notification	If applicable notify FOCA regarding corrective/mitigation action and preventive measures	Communication means	HAeMC / SM
Feedback	Provide the sender with a feedback	Reporting/Analysis Form; or verbally	HAeMC / SM
Information	Notification of internal and external parties involved and/or interested	Reporting schemes of external parties and/or means as adequate to the case including investigation documentation or parts thereof	HAeMC / SM
Implementation	Implement corrective/mitigation action and preventive measures		HAeMC
Monitor	Monitor the effectiveness		CMM

6.3. Reporting Form

6.3 REV0 / 12.11.2013

<table>
<tr><th colspan="5">Reporting/Analysing Form</th></tr>
<tr><td rowspan="5">AUTHOR/SENDER or SM</td><td colspan="4">☐ Occurrence ☐ Anonymous ☐ Voluntary ☐ Hazard</td></tr>
<tr><td colspan="4">Description of the event or hazard:</td></tr>
<tr><td colspan="4">Reason why the event happened (route cause):</td></tr>
<tr><td colspan="4">Action taken to manage the event (corrective action) or possible action to mitigate hazard:</td></tr>
<tr><td colspan="4">Suggestions to prevent this event in the future (preventive action)</td></tr>
<tr><td></td><td>Date:</td><td>Name:</td><td colspan="2">Signature:</td></tr>
<tr><td rowspan="3">SM</td><td colspan="4">Classification based on Tolerability Matrix</td></tr>
<tr><td>☐ Acceptable Region</td><td>☐ Tolerable Region</td><td colspan="2">☐ Intolerable Region</td></tr>
<tr><td>Date:</td><td>Name:</td><td colspan="2">Signature:</td></tr>
<tr><td rowspan="4">Head AeMC</td><td colspan="4">Corrective/Preventive Action</td></tr>
<tr><td>Action</td><td>Responsible</td><td colspan="2">Due date</td></tr>
<tr><td></td><td></td><td colspan="2"></td></tr>
<tr><td>Date:</td><td>Name:</td><td colspan="2">Signature:</td></tr>
<tr><td rowspan="2">CMM</td><td colspan="4">Verification</td></tr>
<tr><td>Verification Date:</td><td>Follow-up:
☐ Inspection
☐ Audit</td><td>Status:
☐ closed
☐ open</td><td>Signature:</td></tr>
</table>

7 Emergency Management Plan

7.0 REV0 / 12.11.2013

The Aero Medical Emergency Management Plan (EMP) details the overall strategy to respond, recover short-term, and mitigate from all emergencies or events that jeopardise the safety of the centre's customers, medical examiner, technical staff and visitors and threaten to damage Aero Medical Centre's assets and property. Knowing the impracticality of developing and maintaining plans for every possible emergency the following subchapters provides general guidelines only.

In the event of an emergency, the following priorities have been set:

1. Rescue of people and assistance for injured persons;
2. Safety of customers, visitors, medical examiner, technical staff and all others present;
3. Mitigation of damage including the safeguarding of persons and the protection of relevant data and records;
4. Communication and notification of internal and external parties involved; and
5. Recovery and restoration of the Aero Medical Centres operations.

7.1. Applicable Emergency Management Plan

7.1 REV0 / 12.11.2013

Recognising that the Aero Medical Centres utilises the facilities of *Name*, the respective emergency plan applies.

- Refer to *Name of Emergency Management Plan*

8 Management System Training

8.0 REV0 / 12.11.2013

Training on aspects of the management system and associated procedures are provided as relevant to and required by the function and position within the Aero Medical Centre organisation. The training comprises:

- Basic Management System Training for all employees;
- Advanced Management System Training for management personnel, auditors and inspectors; and
- Continuous training for all employees.

8.1. Management System Basic Training

8.1 REV0 / 12.11.2013

The basic training is provided to all employees when joining the Aero Medical Centre. It is based on the AeMC management system documentation.

The basic training consists of:

Training Subject	Level of Training	Standard of Performance	Instructor
The Aero Medical Centre and its Scope of Activity	overview instruction including facility walk trough	Knows the organisation, its facility and infrastructure, understands and names clinical attachment to hospital or liaisons with medical Institutes Names the scope of activity	HAeMC
Organisation's Strategic Planning and Safety Policy	in-depth collaborative instruction	Understands the safety standard of aviation medicine including objectives and is able to actively apply the elements thereof; Names the organisation's vision and strategy	ACM
Organisation's Documentation and System of Revision and Amendment	in-depth instruction, self-study of content	Names the Aero Medical Centre's documentation including manual system and knows the relevant documents, manuals and/or parts as required by his function	HAeMC
Organisational Structure, Duties, Responsibilities and Accountabilities	in-depth collaborative instruction, self-study	Is able to find the defined organisational structures, management personnel including contacts, understands the role and function of the management personnel; Understands and knows the duties and responsibility as defined for his function and is proficient to perform the respective duty	HAeMC
Safety Management	overview instruction, explanation	Understands and is able to explain the basic principles of the safety management Understands and knows the own role within the safety management	SM
Compliance Management	overview instruction, explanation	Understands and is able to explain the basic principles of the compliance management Understands and knows the own role within the compliance management	CMM
Occurrence Reporting	in-depth collaborative instruction, case studies	Understands the different types of reporting and is able to report according to the defined reporting procedures Understands and knows the own role within the occurrence reporting system	HAeMC
Emergency Management Plan	overview instruction, self-study	Is able to find the EMP relevant documentation, names the priority and is able to act accordingly	HAeMC

8.2. Management System Advanced Training

8.2 REV0 / 12.11.2013

The advanced management system training shall ensure that the management personnel are able and skilled to establish, implement and maintain an effective management system. Additionally, all management functions, auditors and inspectors involved, shall have detailed and comprehensive knowledge of the Aero Medical Centres' structure, vision, safety standard of aviation medicine, scope of activity and procedures. Consequently, the content of the basic management system training shall be the prerequisite for advanced management system training.

Advanced Management System Training, as required by Management Function:

Training Subject	**Provider**	Accountable Manager	Head of Aero Medical Centres	Safety Manager	Compliance Monitoring Manager	Auditor	Inspector	**Standard of Performance**
Advanced Management System Training	*Internal*	*X*	*X*	*X*	*X*	*X*	*X*	*Gets expertise and comprehensive knowledge of the organisation's management system and associated procedures. Is competent to maintain an effective management system within the organisation. Is skilled to actively promote safety standard of aviation medicine, to analyse and evaluate data for the purpose to identify trends and systematic weaknesses within the organisation and to maintain continuous improvement*
Safety Management Training	*External*			*X*				*Is qualified and skilled to implement and maintain an effective Safety Management*
Compliance Monitoring Management	*External*				*X*			*Is qualified and skilled to implement and maintain an effective Compliance Monitoring Management*
Audit and Inspection Techniques	*External*					*X*	*X*	*Is qualified and skilled to conduct, evaluate and document audits and inspections. Is competent to initiate measures and to monitor its effectiveness*
Relevant Standards and Requirements	*External*		*X*	*X*	*X*			*Gets expertise and comprehensive knowledge of the relevant standards and requirements. Names the structure, content and is able to find relevant paragraphs. Is skilled to interpret legal paragraphs to ensure legal compliance*

Based on the organisation's management system, the advanced management system training consists of:

Training Subject		**Standard of Performance**	**Instructor**
The Organisation and Scope of Activity	• Safety standard of aviation medicine and vision of the organisation • Scope of Activity • Statement of Complexity • Relevant Standards and Requirements • Compliance Statement • Exemption and Derogation • Alternative Means of Compliance • Locations, Facilities and Infrastructure • Power of Authority	The participant shall practically show the ability to create the safety standard of aviation medicine and the organisation's vision as well the scope of activities. Additionally, the participant shall be able to define and/or fully understand the details concerning statement of clinical attachment to hospital or liaison with medical institutes, complexity, relevant standards requirements, compliance statements, exemption and derogation, alternative means of compliance, locations, facilities and infrastructure, and the power of the Authority.	ACM
Organisation Documentation, System of Amendment and Revision	• Overview of the Organisation Documentation • System and Form of Distribution • System of Amendment and Revision • Changes/Elements requiring prior Approval • Changes/Elements not requiring prior Approval • Control of External/Foreign Documents	The participant shall fully understand the requirement for the Aero Medical Centre's organisation documentation and its structures (including overview), distribution forms, and the control of external/foreign documents. Additionally, the system of amendment shall be explained together with the documentation "change management", also identifying items to be or not to be approved prior to the document's publication. The participant shall be able to support and/or lead the organisation's documentation needs and respective processes and document definitions, including changes.	HAeMC
Organisational Structure, Duties, Responsibilities and Accountabilities	• Organisational Structure • Management Personnel – Name and Contacts • Duties, Responsibilities and Accountabilities • Accountable Manager • Safety Manager • Compliance Monitoring Manager	The participant shall know the required/applied organisational structure of the company in detail and shall be able to explain/define duties, responsibilities and accountabilities for the different management functions/posts.	HAeMC
Safety Management	• Hazard Identification and Risk Management • Hazard Identification Process	The participant shall fully support and enable the safety standard of aviation medicine and shall be able to define respective changes and policies to	SM

Training Subject		Standard of Performance	Instructor
	• Reporting/Analysing Form (Hazard Reporting Form) • Severity classification • Tolerability Matrix • Risk Assessment Checklist • Change Management • Safety standard of aviation medicine promotion	international standards. The participant shall furthermore practice hazard identification and risk management, shall understand the data retrieved from and shall enable or lead the processes for change management.	
Compliance Management	• Compliance Monitoring Programme • Audit and Inspections • Audit- / Inspection Schedule, Checklist and Report • Auditors and Inspectors • Findings, Corrective- and Preventive Actions • Classification of Findings	The participant shall actively lead the compliance monitoring programme/processes and shall fully understand respective audit/inspection systems, checklists, finding classifications and resulting corrective and preventive actions. The participant shall be able to systematically communicate with auditors and inspectors, and, if within the activity scope, shall be able to lead these persons and to enable their important role within the company.	CMM
Feedback and Reporting System	• Reporting- and Feedback System • Occurrence Reporting	The participant is able to establish a reporting and feedback system including occurrence reporting and explains data storage and evaluation, including the ways/consequences/influences to the management.	HAeMC
Emergency Management Plan	• Relevant documentation • Objectives and Scope	The participant fully understands the requirements, objectives and scope of an emergency management plan and knows the relevant content of the applicable documentation.	HAeMC
Management System Training	• Basic Training • Advanced Training • Continuous Training	The participant explains the concepts for basic and advanced management system training, is able to define objectives of a general or actuality based kind, or, according to the managerial role, practices both types of such training.	HAeMC
Record Keeping	• Record Keeping and Archiving	The participant designs a system for record keeping and archiving, respecting all requirements (i.e. storage periods, etc.) and is able to run it smoothly.	HAeMC
Contracting	• Contracting	The participant fully understands the concept of contracting and the processes required.	HAeMC

8.3. Management System Continuous Training

8.3 REV0 / 12.11.2013

The purpose of continuous management system training is:

- to exchange data, information, knowledge and skills based on the organisation's practical experience, expertise;
- to ensure that knowledge of occurrences and their root causes are communicated;
- for continuous learning, improving skills and changing behaviour;
- to facilitate changes in Aero Medical Centre's management, practices and procedures.

The HAeMC ensures that any elements of systematic analysis of factual data and results of:

- Hazard identification and Risk Management;
- Audit and Inspections, especially findings, corrective and preventive actions;
- Reporting and Feedback System;
- Changes in relevant standards and requirements; and
- Studies of medical literature

are addressed adequately and promptly throughout the year during the Medical Centre's daily or weekly briefing.

9 Record Keeping

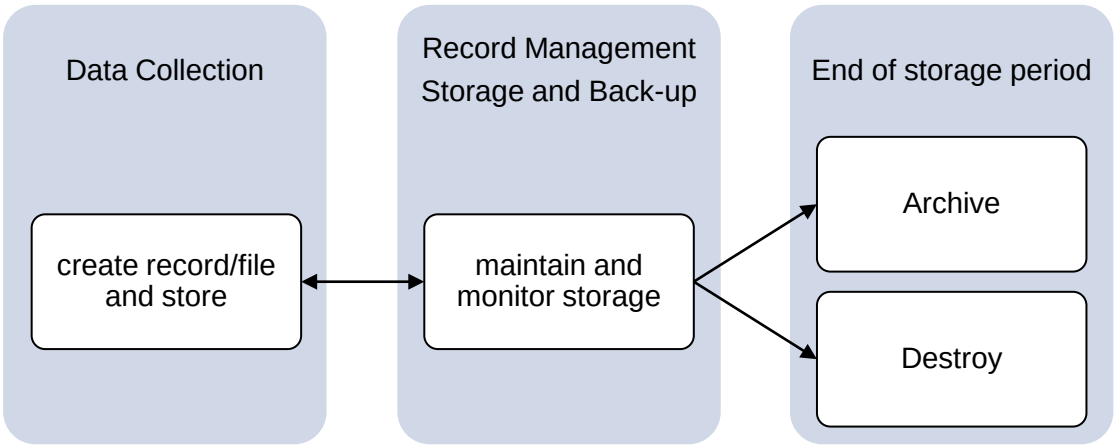
9.0 REV0 / 12.11.2013

The Aero Medical Centre's system of record keeping allows the storage and reliable traceability of all its activities and related data. The record keeping system ensures:

- that medical confidentially is respected at all times;
- the maintenance of records containing details of medical examinations and assessments performed for the issue, revalidation or renewal of medical certificates and their results, for a minimum period of 10 years after the last examination date; and
- that the records are always accessible and traceable throughout the required retention period and ensure protection from damage, alteration and theft.

9.1. Document Management Lifecycle

9.1 REV0 / 12.11.2013



9.2. Medical Examination and Assessment related Records

9.2 REV0 / 12.11.2013

Document	Responsibility	Type of Storage	Place of Storage	Storage period	Follow-up
Medical File	AME	File Folder	Office XY	10 years	Scan and destroy paper dossier

9.3. Management System related Records

9.3 REV0 / 12.11.2013

Document	Responsibility	Type of Storage	Place of Storage	Storage Period	Follow-up
Reporting and analysing form	SM	EDP	P://…/Reporting	5 years	Archive
Audit-/ Inspection Schedule, Checklist and Reports	CMM	Paper	File-folder Office CMM	5 years	Scan & destroy paper-dossier
Risk Assessment Checklist	SM	EDP	File-folder Office SM	5 years	Scan & destroy paper-dossier
Revisions of the AeMC-MM	ACM	Paper	File-folder Office ACM	5 years	Scan & destroy paper-dossier

9.4. AeMC Personnel related Records

9.4 REV0 / 12.11.2013

Document	Responsibility	Type of Storage	Place of Storage	Storage period	Follow-up
Aero Medical Centres introduction programme	HAeMC	File Folder	Office XY	until last day of employment	destroy
AME's training, qualifications, diploma and governmental permissions	HAeMC	File Folder	Office XY	3 years after last day of employment	Scan & destroy paper-dossier
AME's experience and activity log	FOCA EMPIC-M data and statistic				
Technical staff training, qualification, diploma and permission	HAeMC	File Folder	Office XY	3 years after last day of employment	destroy
Attendance records of Management System and Safety Management related training	HAeMC	File Folder	Office XY	until last day of employment	destroy

9.5. IT Backup-System

9.5 REV0 / 12.11.2013

The Aero Medical-Centre's IT application EMPIC-M is provided and updated by FOCA. The maintenance including the backup is ensured by the Federal Office of Information Technology, Systems and Telecommunication (BIT- Bundesamt für Informatik).

10 Delegation to Third Parties

10.0 REV0 / 12.11.2013

Third party activities are within the Aero Medical Centre's scope of approval when they are performed by another hospital or medical institute working under the Aero Medical terms of approval. The ultimate responsibility for the contracted service provided remains with the Aero Medical Centre.

Product / Service	**Third Party**	**Agreement**
Facility and Infrastructure	Medical Institute Address	contract
Referral for specialist examinations	Refer to FOCA List of Experts	mutual oral agreement for the respective case
Medical Equipment	Refer to Equipment Inventory	service contract
....		

When contracting, with the exception of referrals for specialist examinations, the following process applies:

Step	**Remarks**	**Tool**	**Responsibility**
Definition of requirements and needs	• define the product, service, activity or task to be contracted • specify the criteria for safety standards of aviation medicine and quality • establish budget and cap on costs	Office applications	HAeMC
Offer	• Request firm offer including evidences of certificates, diplomas, government permissions, authorisations and approvals as applicable	Offer documentation	HAeMC
Release	• Release and approval of offer, conditions, budget and cap on costs	Office applications	ACM
Evaluation	• Verify that the contractor holds the required certificates, diplomas, government permissions, authorisations and approvals as applicable • Verify the adequacy of the facilities and equipment as well as the availability of resources	Offer documentation / personal visit of facilities	HAeMC
Safety Impact	• Decide whether risk assessment is necessary	Risk assessment checklist	SM
Compliance Check	• Decide whether a detailed audit is required • Establish audit checklist especially for the contractor case concerned	Audit-/ inspection schedule, checklist and report	CMM
Decision and Closing	• Decide upon suitability, adequacy and acceptability	Audit-/ inspection schedule, checklist and report	ACM
Compile Contract	• Issue of contract	Contract	Contractor
Contract review	• Evaluate contract, verify that the contracted activity, product or service is clearly defined • Verify costs	Contract	HAeMC
Sign contract	• Signing of contracts	Contract	ACM

10.1. Continuous Monitoring

10.1 REV0 / 12.11.2013

When delegating tasks to third parties, the organisation ensures that necessary qualifications exist, are upheld and resources and competences are affirmed.

Service/Product/Activity	Monitoring	Frequency	Responsibility
Continuous education and Training	• Ensuring the validity of necessary certificates, authorisations and syllabus approvals	According to the individual education and training needs	HAeMC
	• Analysis of trainee's feedback	Each training	HAeMC
Referral for specialist examinations	• Ensuring that the specialist is qualified and holds the relevant diploma and governmental permissions • Appointed as FOCA experts or supervised by FOCA experts as applicable • FOCA List of Experts	Each referral	AME
Medical Equipment	• Equipment/Calibration/Service	Preventative maintenance schedule	HAeMC
…			

End of Appendix AeMC to CL “Management System”