

Safety Management Systems: Guidance for Aeromedical Centres (AeMC)

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Chapter 1

Introduction

Why do I need a Safety Management System?

- 1.1 In recent years our understanding of how accidents and incidents happen has improved. More emphasis is now placed on the causal factors involved and the organisational factors that contribute to errors being made. Organisational factors include how an organisation operates, how it sets out its procedures, how it trains its staff and what level of importance it gives to safety issues identified within the organisation.
- 1.2 A Safety Management System (SMS) allows you to take a proactive approach to safety by identifying some of these causal factors and taking action before an event happens. SMS helps you to have a greater understanding of the hazards and risks affecting the safety of your AeMC. These hazards and risks could have a severe impact on your AeMC in terms of financial cost and reputation. An SMS is an effective way to take your AeMC beyond compliance with the regulations.
- 1.3 The European Aviation Safety Agency (EASA) mandates Aeromedical Centres (AeMC) that fall within its scope to have an SMS in place that is appropriate for a non-complex organization. The International Civil Aviation Organization (ICAO) also requires organisations to have an SMS.

What is an SMS?

- 1.4 An SMS is an organised approach to managing safety. It sets out the organisation's structure, identifies the accountabilities and responsibilities of key staff members and documents the policies and procedures to manage safety effectively. An effective SMS allows the hazards and risks that could affect your AeMC to be identified, assessed and prioritised so that appropriate mitigation measures can be put in place to reduce the risks to as low as reasonably practicable (ALARP).

- 1.5 A risk may be described as ALARP if you have taken all reasonable action to mitigate the risk and the cost (in terms of time, effort and money) of taking further action would be 'grossly disproportionate' to any further reduction in the level of risk. Reducing a risk to ALARP does not mean that the risk has been eliminated as some level of risk still remains; however, the organisation has accepted the remaining level of risk.
- 1.6 There is a lot of advice and guidance on SMS already available. Whilst you may find it useful to review this material, AeMCs are encouraged to use this document in conjunction with the EASA Basic Regulations, Part MED and Part ORA. You should also refer to the ICAO documents Annex 1, Annex 19 and Document 9859 Safety Management Manual for guidance on SMS.
- 1.7 Implementing an SMS may initially appear to be a daunting task; however, it is likely that some of the key elements that make up an SMS are already in place, but perhaps not formalised or clearly documented. The structure and content of an SMS should be essentially the same for any organisation but the level of detail should reflect the size, complexity and level of risk faced by your AeMC. It is important to realise that there is no 'one size fits all' in terms of SMS development and implementation; what is important is to develop an SMS that works for your AeMC and is effective.

What are the key elements of an SMS?

- 1.8 This guidance material describes the key elements of an SMS. We have also included key points that will help you implement your SMS. The key elements are:
- Safety Policy and Objectives
 - Management commitment and responsibility
 - Safety accountabilities
 - Appointment of key staff members
 - Emergency response planning

- SMS documentation
- Safety Risk Management
 - Hazard identification
 - Risk assessment and mitigation
- Safety Assurance
 - Safety performance monitoring and measurement
 - Management of change
 - Continuous improvement
- Safety Promotion
 - Training and education
 - Safety communication

1.9 An effective SMS requires all these elements to be in place. To what degree these elements are in place will depend on the size and complexity of your AeMC, and also the maturity of your SMS. This guidance material is generic and intended for all AeMCs and therefore how you implement these key components will depend on your particular circumstances.

1.10 An effective SMS also requires a 'Just Culture' to be in place. A just culture encourages and supports people to provide essential safety-related information in a non-threatening environment, but is clear about where the line is drawn between acceptable and unacceptable behaviour.

Chapter 2

Safety policy and objectives

Management commitment and responsibility

- 2.1 For your SMS to be effective it will require the allocation of both time and resources. It requires the senior management to show commitment and take responsibility for your AeMC's SMS. Without this the SMS will not function effectively.
- 2.2 The management's commitment to safety should be expressed in a written safety policy. The policy should set a clear, high-level direction for your AeMC to follow in order to manage safety effectively and should be endorsed by the Accountable Manager.
- 2.3 The safety policy should be read and understood by all staff members and be reflected in actions as opposed to impressive words just cut and pasted into a document. The Accountable Manager should actively demonstrate his or her commitment to the policy. This will help contribute to the creation of a just culture within your AeMC, which is essential to the success of your SMS. With a just culture all staff members should be responsible for safety, and consider the safety implications of everything they do.
- 2.4 **Key Point** – Your safety policy should be individual, reflecting your AeMC. As a minimum it should:
- Outline your AeMC's fundamental approach to safety;
 - Show a senior management commitment to safety;
 - Show a commitment to provide adequate resources to manage safety effectively and to reduce risks to an acceptable level;
 - Encourage all staff members to actively participate in and fulfil all aspects of the SMS;
 - Encourage a just safety culture within the organisation.

- 2.5 An example of a safety policy showing the level of detail required can be found in Appendix A to this guidance material.

Safety accountabilities

- 2.6 Your AeMC's management structure should be clearly defined. For small organisations this structure may be fairly simple and consist of the person in charge (Accountable Manager) and other key staff members who have a role in how the organisation is managed on a day- to-day basis. The accountabilities and responsibilities of the Accountable Manager and key staff members should be clearly understood.
- 2.7 The Accountable Manager should normally be the person ultimately accountable for safety and who is involved in the day-to-day management of the organisation. It is essential that the Accountable Manager has the authority and budgetary control to make safety-related decisions and take any appropriate actions to maintain safety.
- 2.8 **Key Point** – The responsibility for safety issues can be delegated as appropriate; however, the Accountable Manager remains ultimately accountable for safety within the organisation at all times.
- 2.9 **Key Point** – AeMCs should complete an organisational chart showing the key positions with their responsibilities and the lines of accountability within the organisation.

Appointment of key staff members

- 2.10 An AeMC is required to have an aero-medical examiner (AME) nominated as head of the AeMC. This doctor should have privileges to issue Class 1 medical certificates and sufficient experience in aviation medicine. The head of the AeMC is responsible for co-ordinating the assessment of examination results and signing reports, certificates, and initial Class 1 certificates. The AeMC must also have on staff an adequate number of fully qualified AMEs and other technical staff and experts. An individual

should be identified who is the focal point for the SMS. This person could be the head of the AeMC if they are also the Accountable Manager or delegated to a member of staff as a part-time role as appropriate.

- 2.11 **Key Point** – A person in your AeMC should have the role of managing the SMS and report directly to the Accountable Manager.
- 2.12 Depending on the size of your AeMC, the SMS focal point may need to be supported by a Safety Committee. For a small AeMC a Safety Committee could consist of a few key members of staff and appropriate people from other organisations or groups that interface with your AeMC.
- 2.13 **Key Point** – It is important that the relevant people, both within your AeMC and those that interface with it, meet to discuss safety- related issues on a regular basis.

Emergency response planning

- 2.14 An Emergency Response Plan (ERP) should be established that describes the actions to be taken by staff in an emergency.
- 2.15 As a minimum the ERP should describe procedures for:
- An orderly transition from normal to emergency operations;
 - Designation of emergency authority (who will take charge out of hours or at the weekend?);
 - Assignment of emergency responsibilities (what happens when that person is away or on leave?);
 - Coordination of efforts to resolve the emergency (who is going to call the emergency services?);
 - Safe continuation of operations or return to normal operations as soon as practicable.
- 2.16 The ERP should identify the responsibilities, roles and actions for staff members involved in dealing with emergencies within your AeMC and consider any outside agencies or third party contractors affected. For

some AeMCs there may be regulatory requirements already set for the ERP or contingency planning.

- 2.17 **Key Point** – The ERP should be available and understood by all key staff members and practiced on a regular basis to ensure that everyone is aware of their responsibilities and required actions and is competent to carry out appropriate actions in an emergency.
- 2.18 **Key Point** – The ERP should be available and understood by all key staff members and practiced on a regular basis to ensure that everyone is aware of their responsibilities and required actions and is competent to carry out appropriate actions in an emergency.
- 2.19 **Key Point** – It is important to coordinate your ERP with other organisations that you interface with, including the emergency services that may attend an emergency and third party organisations that are contracted to your AeMC.

SMS documentation and control

- 2.20 All aspects of your SMS should be clearly documented in order to keep an accurate record of why decisions were made, why actions were taken and why any changes were implemented. Your documentation should be controlled and in a suitable format so that it can be clearly understood by staff members in your AeMC, any third party organisations that are contracted to work with you, and your competent authority. Templates and examples are provided in the appendices to this guidance material that may be useful. Clear documentation will also allow your SMS to be easily audited or assessed.
- 2.21 As a minimum, SMS documentation should include:
- The safety policy and objectives of the SMS;
 - The accountabilities and responsibilities of the Accountable Manager and key staff members;
 - Any safety-related processes, procedures or checklists;

- The results and subsequent actions from any safety audits or assessments;
- The results of any risk assessments and mitigation measures in place;
- A hazard log (an example of a hazard log/risk assessment can be found in Appendix B to this guidance material);
- The specific items listed in Chapter 6.

2.22 You may find it useful to create a separate SMS manual for your AeMC or it may be easier to document your SMS within existing manuals. An example of a contents page for an SMS manual can be found in Appendix C to this guidance material. Other documents may be held either as hard copies or electronically. However you keep a record of your SMS, the system should be reliable and secure, for example information technology systems should be backed up and protected from damage and enable easy access and retrieval of this information.

Chapter 3

Safety risk management

Introduction to safety risk management

- 3.1 The safety risk management process starts with identifying the hazards affecting the safety of your AeMC and then assessing the risks associated with the hazards in terms of likelihood (what is the likelihood of the risk happening?) and severity (if the risk occurs how bad will it be?). Once the level of risk is identified, appropriate remedial action or mitigation measures can be implemented to reduce the level of risk to as low as reasonably practicable. The implemented mitigation measures should then be monitored to ensure that they have had the desired effect.

Figure 1: Simple safety risk management process



- 3.2 A Hazard is simply defined as a condition, event or circumstance that has the potential to cause harm to people or damage to aircraft, equipment or structures.

- 3.3 A Risk is defined as the potential outcome from the hazard and is usually defined in terms of the likelihood of the harm occurring and the severity if it does.
- For example:
A needle used to take a blood sample is a hazard to both applicants and medical staff. An additional hazard is the blood of an applicant with a transmissible disease (such as HIV or Hepatitis B). The associated risks with these hazards include the possibility that a needle contaminated with blood from such an applicant pierces the skin of the AeMC's medical staff and inoculates that member of staff.
- 3.4 In general a hazard exists in the present whereas the risk associated with it is a potential outcome in the future.

Reporting systems

- 3.5 Hazards can only be controlled if their existence is known. Through a confidential safety reporting system, underlying situations or conditions that have the potential to endanger the safety of aircraft operations can be identified. Safety reporting can be reactive (from an event that has happened) or proactive (from a potentially unsafe situation being identified) or predictive (trying to predict what might happen in the future).
- 3.6 Internal voluntary reporting of less significant incidents, which may not necessarily be required to be reported under any mandatory reporting scheme but are very useful to your AeMC, should be actively encouraged. Greater levels of reporting, even what may be classified as minor issues, will allow you to monitor the safety performance of your AeMC and to identify developing safety trends.
- 3.7 All staff members within your AeMC and staff members of other organisations that interface with you need to actively participate in the safety reporting system. All stakeholders and users need to be clear about how to report, what to report and who to report to. Information from the reports can then be used to identify safety risks so that appropriate action