Safety Management Systems: Guidance for Aeromedical Centres (AeMC)

CAP 1457

Contents

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.

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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

can be taken. An example of a suitable template for an internal Safety Reporting Form can be found in Appendix D to this guidance material.

3.8   The reporting system should use the information provided to enhance safety rather than to apportion any blame if genuine errors or mistakes have been made. To encourage reporting without fear of repercussion, it is important that staff members feel that there is an open and just culture within your AeMC. It is also important that adequate feedback is given to the person reporting an incident.

3.9   **Key Point** – It is important to remember that hazard identification is not a static, one-off process; it needs to be performed whenever you plan an organisational change, your AeMC is undergoing rapid expansion or contraction, you introduce new equipment or procedures, changes to key staff members are taking place or whenever you think there is a possibility that a new risk may be created.

3.10   **Key Point** – To encourage staff to report potential hazards, your AeMC should have a safety reporting system that is just, confidential, simple and convenient to use. In a just safety reporting system, employees should not be punished for unpremeditated or inadvertent errors or lapses. Instead the reasons for the errors or lapses should be investigated so that safety lessons can be learnt.

Hazard identification

3.11   A hazard identification process is the formal means of collecting, recording, analysing, acting on and generating feedback about hazards that affect the safety of the operational activities of your AeMC. In a mature SMS hazard identification is an ongoing process.

3.12   There are many ways of identifying hazards and depending on the size of your AeMC, the following methods may be useful:

- Brainstorming, where your Safety Committee or small groups meet to identify possible hazards;

- Data from previous accidents, incidents and associated significant event analysis;

- Mandatory/voluntary incident reporting schemes (internal and external);

- Internally or externally conducted safety assessments/audits;

- Safety information from external sources, e.g. similar organisations, media, air accident investigation groups, national aviation authorities etc.;

- Generic hazard checklists.

Risk assessment and mitigation

3.13   The purpose of the risk assessment process is to allow your AeMC to assess the level of risk associated with the identified hazards in terms of the potential harm. Risks should be assessed in terms of severity and likelihood. Once you have assessed the risk in terms of severity and likelihood, a simple risk assessment matrix can be used to determine the overall level of risk. Depending on the level of risk, appropriate mitigation measures can be taken to either eliminate the risk or reduce the risk to a lower level or as low as reasonably practicable, so that it is acceptable to your AeMC. Mitigation measures should be implemented to reduce the likelihood of the risk occurring or reduce the severity of the outcome if it does.

3.14   The assessment process also allows the risks to be ranked in order of risk potential so that priorities can then be established and resources can be targeted more effectively at the higher-level risks. Figure 2 shows a simple risk management process and an example of how the process could work is shown in Appendix B to this guidance material.

3.15   **Key Point** – It is important to include people with the relevant expertise and experience in the risk assessment process to ensure the robustness of the process. All risk assessments are reliant on the quality of the information used to make the assessment, and the knowledge of the people conducting the assessment.

Figure 2: Simple risk management process

```
┌─────────────────────────────┐
│ Identify the hazard and      │
│ associated risks to aircraft,│
│ equipment, property          │
│ and people                   │
└─────────────────────────────┘
            │
            ▼
┌─────────────────────────────┐
│ Evaluate the severity of the │
│ consequences                 │
└─────────────────────────────┘
            │
            ▼
┌─────────────────────────────┐
│ Evaluate the likelihood of   │
│ the consequences             │
└─────────────────────────────┘
            │
            ▼
┌─────────────────────────────┐
│ Evaluate the risk tolerability│
└─────────────────────────────┘
        │           │
        ▼           ▼
┌──────────────┐ ┌──────────────────┐
│ Yes: Accept  │ │ No: Avoid or     │
│ the risk     │ │ mitigate the     │
│              │ │ risk to          │
│              │ │ acceptable level │
└──────────────┘ └──────────────────┘
        │           │
        └─────┬─────┘
              ▼
┌─────────────────────────────┐
│ Safety Assurance to monitor  │
│ the performance/verify action│
│ is effective                 │
└─────────────────────────────┘
```
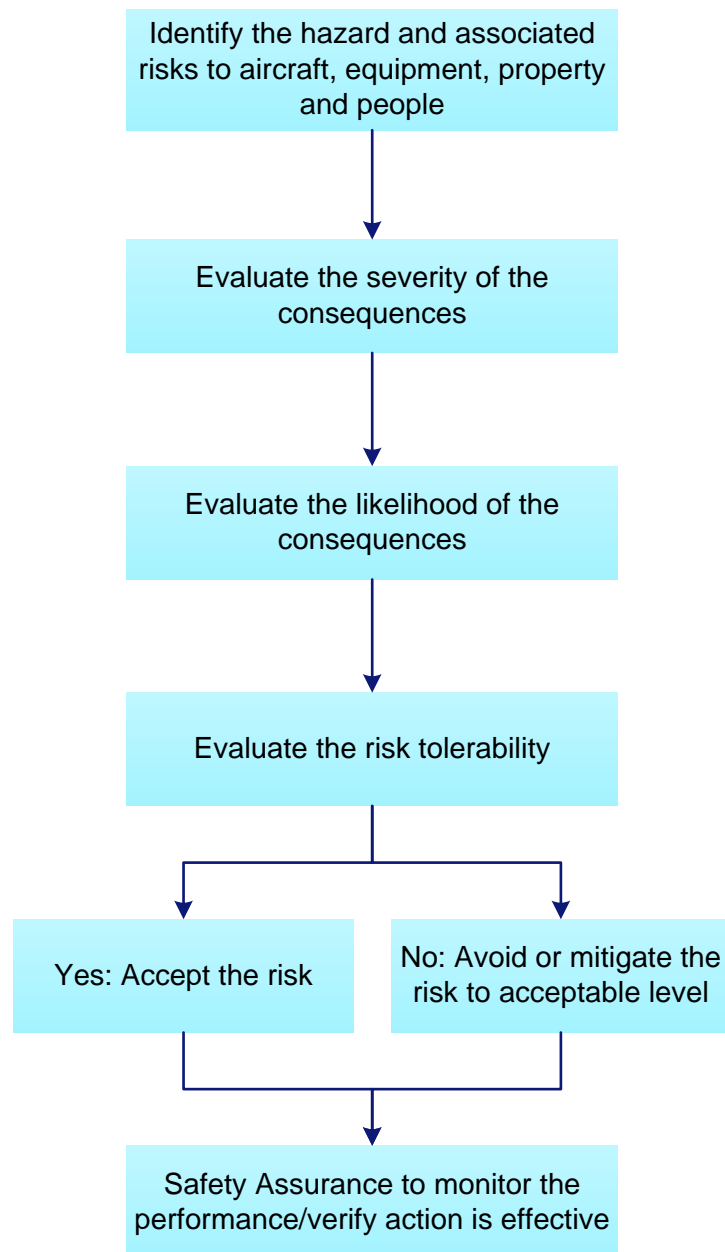
3.16   The risk assessment process starts with identifying the risk(s) associated with the hazards you have previously identified. There may be more than one risk associated with a particular hazard and a risk assessment may need to be conducted for each risk.

Risk severity

3.17   The risk will need to be assessed in terms of its severity (if it happens how bad will it be?). In order to assess the severity you should take into

account any mitigation measures that are currently in place to reduce the severity. You should assess the severity in terms of the worst possible realistic scenario but may find that by looking at the most credible outcome it is easier to grade the levels of severity.

3.18   To help assess the severity you should ask the following questions:

- Would lives be lost (employees, applicants, passengers, bystanders)?
- What is the likely extent of equipment, property or financial damage?
- What is the likelihood of environmental impact?
- What are the likely commercial implications or media interest?
- Would there be a loss of reputation?

3.19   To help define the severity Appendix B, Figure 4 gives an example of a severity table that could be used, or you may decide to define the severity in another way.

Risk likelihood

3.20   The risk will also need to be assessed in terms of its likelihood (what is the likelihood of the risk occurring?) In order to assess the likelihood you should take into account any mitigation measures that are currently in place to reduce the likelihood. Defining the likelihood is sometimes more difficult as it is not an exact science. It will rely on a logical, common sense analysis of the risk to arrive at a reasonable answer.

3.21   To help assess the likelihood you should ask the following questions:

- Is there a history of similar occurrences (either in your AeMC or in other organisations known to you) to the one under consideration, or is this an isolated occurrence?
- What other equipment or components of the same type might have similar defects?
- What other processes might be affected in the same way?

> - How many people are involved and how frequent is the activity?
> - Which (other) group of applicants might be affected?

3.22   To help define the likelihood Appendix B, Figure 5 gives an example of a likelihood table that could be used, or you may decide to define the likelihood in another way.

Risk tolerability

3.23   When the severity and likelihood have been defined, a Risk Tolerability Matrix can then be used to assess how tolerable the risk is. An example of a Risk Tolerability Matrix can be found in Appendix B, Figure 6.

3.24   Using a risk tolerability matrix the risk can then be classified as either acceptable, to be reviewed or unacceptable, allowing a suitable risk mitigation strategy to be developed if required.

3.25   **Unacceptable**: If the risk is unacceptable, the operation or activity should stop immediately or not take place. Major mitigation will be necessary to reduce the severity if the risk actually occurs or reduce the likelihood of the risk occurring. Normally it is the likelihood of the occurrence that can be reduced rather than the severity.

3.26   **Review**: If the risk falls into the review category, the severity or likelihood of occurrence is of concern; measures to mitigate the risk to as low as reasonably practicable (ALARP) should be sought. Where the risk is still in the review category after this action has been taken, it may be that the cost of actions required to reduce the risk further are too prohibitive. The risk may be accepted, provided that the risk is understood and has the endorsement of the Accountable Manager.

3.27   **Acceptable**: If the risk is acceptable, the consequence is either so unlikely or not severe enough to be of concern; the risk is acceptable. However, consideration should still be given to reducing the risk further.

Risk mitigation

3.28   If the level of risk falls into the unacceptable or review categories, mitigation measures will be required to reduce the risk to a level as low as reasonably practicable (ALARP).

3.29   Mitigation measures are actions or changes, such as changes to operating procedures, equipment or infrastructure, to reduce either/both the severity and/or the likelihood.

3.30   Generally risk mitigation strategies fall into three categories:

- **Avoidance**: The operation or activity is cancelled or avoided because the safety risk exceeds the benefits of continuing the activity, thereby eliminating the risk entirely.

- **Reduction**: The frequency of the operation or activity is reduced or action is taken to reduce the magnitude of the consequences of the risk.

- **Segregation**: Action is taken to isolate the effects of the consequences of the risk or build in redundancy to protect against them.

Hazard log

3.31   Any identified safety hazards, risk assessments and subsequent follow-up actions need to be clearly documented. An acceptable way to do this is by creating a hazard log or risk register. The log or register should include each identified hazard, the associated risk(s), results of the risk assessment taking into account any current mitigation measures in place, further risk mitigation measures if required and a reassessment of the risk once the mitigation measures have been implemented, to assess whether they have achieved the desired outcome. The hazard log is a working document and should be reviewed regularly, especially during any Safety Committee meetings. The hazard log forms part of your AeMC's SMS documentation. Examples of a suitable hazard log and risk assessment can be found in Appendix B to this guidance material.

Chapter 4

Safety assurance

Introduction to safety assurance

4.1   Safety assurance monitors the safety performance of your AeMC and the effectiveness of your SMS. This will ensure that your hazard identification, risk assessment and mitigation process is being followed effectively and that appropriate mitigation measures are being implemented and working as intended.

4.2   **Key Point** – The safety assurance element gives confidence that for all identified hazards the mitigation measures applied are implemented and achieve their intended objectives.

Safety performance monitoring and measurement

4.3   For your AeMC to manage safety performance you need to measure it in some way and for that you need safety data. The first step is to identify what safety performance indicators (SPI) will be used. An SPI is a measure of how safe your AeMC is. What SPIs you use will depend on your particular AeMC and the level of data you collect but some generic examples are given in Appendix E.

4.4   **Key Point** – Performance indicators do not always need to be based on events; consider frequency and attendance of safety meetings and safety reporting levels. This can progress with sufficient data to a review of the safety reports, which can include categorisation of safety reports into business area of reporter, types of events and types of equipment or applicants.

Sources of safety data

4.5   Sources of safety data that can be used as SPIs include the number of:

- Hazard and incident reports;
- Warranty claims and customer complaints;
- Mandatory reports required by national law;
- Customer/contractor surveys;
- Safety survey or safety audit findings.

4.6　　Safety performance targets may be difficult to define and it will be more important to investigate individual events and look for trends in the limited data available. A review of events/incidents/accidents elsewhere, such as air accident investigation reports and reports from other similar organisations, may also prove useful.

The management of change

4.7　　The operation of your AeMC is dynamic and changes will frequently occur. A simple process should be introduced to help identify potential hazards and to assess the safety impact of any significant changes made. Changes include the introduction of new equipment, changes to facilities or scope of work, new contracted services, new procedures or changes to key staff members. Are your existing procedures and documentation adequate or do they need to be amended? Have staff members received adequate training and are your AeMC's user groups aware of any changes?

4.8　　Taking into account the ALARP principles, the aim of the change management process should be to determine that risks associated with the intended change will not have an impact on the AeMC's future or current activities.

4.9　　**Key Point** – The change management process should follow the same structured approach as the normal risk assessment process used by the AeMC.

Incident management

4.10   Incidents will inevitably occur and these can provide a valuable learning
            opportunity for your AeMC. In an effective SMS a process should be in
            place to learn from any incident and implement any changes that may be
            required. Therefore, your AeMC should establish a process to ensure that
            each incident/accident is investigated. The level of investigation should
            reflect the significance of the event. The investigation should include what
            happened, when, where, how and who was involved. It should also try to
            understand why. It is important to establish the facts and avoid
            speculation.

4.11   **Key Point** – You should try to be objective: it's about finding out why it
            happened to prevent it reoccurring rather than finding someone to blame.

4.12   **Key Point** – Your Safety Committee should review the findings from all
            incidents and recommend improvements if required. Safety lessons
            should be shared both within your AeMC and those relevant organisations
            that you interface with.

Continuous improvement of the SMS

4.13   Your SMS should be an integral part of your AeMC. It should be dynamic
            rather than static and it should aim to continually improve the safety
            performance of your AeMC.

Safety assurance and compliance monitoring of the SMS

4.14   As part of your SMS there will be a need to establish a compliance
            monitoring function (for certain organisations this would be part of a
            Quality Management System). The compliance monitoring function is
            ideally an independent assessment to assure that the SMS is effective
            and working.

4.15   This requires monitoring of the following:

- A review of how your AeMC complies with the published requirements for an SMS;
- Verification that the mitigations and controls that have been put into place to control identified hazards are robust and effective;
- An assessment of the effectiveness of the procedures and processes in your SMS Manual as described, and how they are implemented and practised.

4.16   There should be a closed loop process to ensure identified problems are corrected. Audits should also include assessments of other organisations that interface with your AeMC and could affect safety.

4.17   **Key Point** – In a small AeMC where everyone may be involved in the SMS it will be challenging to establish an independent review or audit. In such cases independent external auditors could be sought or arrangements made with other external organisations.

4.18   **Key Point** – As the compliance monitoring system helps to monitor the safety performance of the AeMC it is important that the Accountable Manager is involved and monitors the system and what it reveals.

4.19   **Key Point** – As an approved AeMC there may be specific requirements that dictate what is acceptable as a compliance monitoring system and this guidance should be read in context with those specific requirements.

Chapter 5

Safety promotion

Safety training and education

5.1   Everyone within your AeMC has a responsibility for aviation safety. It is important that all staff members are competent to carry out their safety roles and responsibilities. This is achieved through training and ongoing assessment of individuals. This training should include the AeMC's SMS, safety policy, reporting procedures, safety responsibilities and how individuals can contribute at all levels. Safety training should include periodic refresher training.

5.2   **Key Point** – A record of all staff members' training should be held.

5.3   **Key Point** – Effective safety promotion should result in all staff being actively encouraged to identify and report hazards.

5.4   **Key Point** – All staff should be aware of the safety hazards and risks associated with their duties.

5.5   **Key Point** – Lessons arising from investigations should be disseminated effectively.

Safety communication

5.6   It is important that all staff members, either employed or volunteers, are fully aware of the SMS and any safety matters affecting your AeMC. Relevant safety information should also be distributed to other users and contractors working for your AeMC.

5.7   Effective communication ensures that all staff members are fully aware of the SMS including safety-critical information related to analysed hazards and assessed risks. All staff members should understand why particular actions are taken and why safety procedures are introduced or changed.

5.8   Regular staff meetings where information, actions and procedures are
           discussed may be used for the purpose of communication on safety
           matters.

5.9   **Key Point** – This can easily be achieved through meetings, safety
           bulletins, information sheets or newsletters clearly displayed in prominent
           positions or distributed via post, e-mail and on your AeMC's website.
           Efforts should be made to share best practice and relevant safety-related
           information with other similar organisations.

Chapter 6

Processes specific to an AeMC

What you must cover in your SMS

6.1   Up until this point this document has looked at the parts of an SMS that are generic to non-complex organisations. There are activities and process that are particular to AeMCs that should also be covered in your AMS and these include:

- Medical certification in compliance with Part MED;
- Ensuring medical confidentiality;
- Medical research.

Medical certification in compliance with Part MED

6.2   You should consider the hazards and risks that arise within the processes that are used at your AeMC in for the assessment for and issuing of medical certificates in compliance with Part MED.

6.3   In particular you might consider:

- How you manage cases in compliance with any guidance produced by your competent authority to help you understand the EASA implementing rules.
- Your process for consultation with or referral to your competent authority or the authority of the state of licence issue of your applicant.
- The way you ensure that previous medical certificates are checked and any new certificates issued contain the correct details for the applicants and any appropriate limitations.
- How resting ECGs are further assessed so that any showing features that may be clinically significant are not interpreted as normal without proper consideration.

6.4   You may already be undertaking audits of the output from medical examinations for the purpose of detecting errors and this could be included in the mitigation measures on your risk assessment.

6.5   ICAO Annex 1 recommends that findings arising from medical assessments be reviewed to identify areas of increased risk for aeromedical certification and in flight incapacitation. This could become part of your SMS activity in collaboration with your competent authority.

Ensuring medical confidentiality

6.6   An AeMC is required to establish a system of record keeping that allows adequate storage and reliable traceability of all activities. In addition an AeMC shall maintain records with details of medical examinations and assessments performed for the issue, revalidation or renewal of medical certificates for a minimum of 10 years after the last examination date.

6.7   All medical records should be kept in a way that protects them from damage, alteration or theft and ensures medical confidentiality is respected at all times. Protection will vary according to whether the records are stored as paper copies or using electronic media. In both cases security against unauthorized access will be required e.g. limiting entry into the areas where paper records are stored or robust IT security for electronic records.

Medical research

6.8   If aero-medical research is conducted at or by your AeMC then your SMS should include the processes to conduct that research and publish the results, taking account of any associated hazards and risks so that the work is conducted in a safe and ethical fashion.

Chapter 7

Implementing an effective SMS

Gap analysis

7.1 This document describes the basic component parts that make up an SMS for an AeMC. Most organisations will already have some of these components in place. It is also not expected that your SMS will be fully functioning overnight; it will take time and effort to integrate these SMS components into your AeMC for them to be fully effective.

7.2 It is recommended that you assess your AeMC to identify what components are in place and what components need to be implemented or strengthened. A Gap Analysis is a useful method to achieve this. To help you assess each component within your AeMC, a set of assessment questions for an AeMC is provided in Appendix F.

Implementation plan

7.3 From your gap analysis an implementation plan can then be developed to implement the remaining relevant components over time in a logical and structured way. Although your plan should have an implementation timeline you should be realistic, as you will find certain components more difficult to implement than others.

7.4 Remember:

- A mature SMS will take time to fully implement;
- It is important that all staff members should have the opportunity to contribute to the development of the SMS;
- If in doubt contact your competent authority for advice.

Appendix A

Example safety policy

Safety is a prime consideration at all times within [*name of your organisation*].

As the Accountable Manager it is my responsibility to ensure the safety of all our operations and services.

I will ensure that adequate resources and training are provided to manage safety effectively. We encourage all our staff and stakeholders to report safety events or potential hazards however insignificant they may consider them at the time.

We have an open reporting culture that encourages free and frank reporting through a just culture.

We strive to achieve:

- An accident free environment
- An effective safety management system and continuous improvement
- Full compliance with the statutory national and international regulations that apply to us

These objectives are for the benefit of the company, its employees and its customers. To this end we have a shared responsibility to achieve these aims.

Safety is everyone's responsibility. Signed by Accountable Manager.

Signed ....

Appendix B

Example hazard log and risk assessment

Date: ....

Owner: ....

Contact: ....

Participants: ....

Reported by: ....

Contact: ....

Date reported: ....

Follow up review date: ....

Figure 3: Example hazard log and risk assessment

Identified hazard	Associated risk / consequences	Existing mitigation measures in place	Current level of risk	Further mitigation measures	Revised level of risk	Action by and when
Exercise electrocardiography using a treadmill	Slips, trips and falls on the treadmill	Handle bars on side of treadmill Ensuring no objects located directly behind treadmill Annual maintenance checks on equipment	Severity 3 Likelihood 3 Review		Severity 3 Likelihood 3 Review	
	Provoke a significant arrhythmia or cardiac	Clearly documented process for undertaking testing which all	Severity 4 Likelihood 2 Review	Ensure all AeMC staff have undertaken Immediate Life Support (ILS) training and maintain competency	Severity 3 Likelihood 2 Review	Safety Manager July 2014

| | ischaemia during the test | staff are familiar with

Assessment by cardiologist prior to undertaking test | | Have available all equipment necessary for ILS including external defibrillator

Undertake simulation exercises twice per year | | |

Example hazard identification and risk assessment process for an AeMC

Identifying a hazard

High Flyers Medical Group is an Aeromedical Centre (AeMC) that undertakes further assessment of applicants with resting ECG anomalies and suspected or known coronary disease. The hazard identified is exercise electrocardiography (ECG) using a treadmill.

Associated risk

The Safety Committee of High Flyers Medical Group comprises the Head of the AeMC (Accountable Manager), another AME who is employed by the centre and the Practice Manager, who also has the role of Safety Manager and reports to the Accountable Manager. The Safety Committee considered a number of different hazards within the AeMC and amongst the actions required to address these it was determined that there should be a suitably documented risk assessment for exercise ECGs (Figure 1). The Safety Committee determined that the most significant adverse consequences of undertaking exercise electrocardiography are slips and trips on the treadmill and provoking a significant arrhythmia or cardiac ischaemia during the test.

Existing mitigation

The mitigation measures in place to prevent slips and trips include hand rails on the side of the treadmill for the applicant to hold onto whilst walking and ensuring that there are no objects located directly behind treadmill should the applicant fall off the back. In addition to general cleaning tasks undertaken by clinic staff, there is an annual maintenance check on the equipment performed by an external contractor to lower the risk of the treadmill stopping suddenly. The mitigation measures in place to reduce the risks related to provoking a significant arrhythmia or cardiac ischaemia during the test include a documented process for pre-assessment and undertaking testing which all staff are made familiar with at induction and which is reviewed on an annual basis or if an issue arises. Prior to testing, all applicants are assessed by a cardiology specialist to minimise the risk of provoking an untoward event.

Determining the current level of risk

The next stage was to determine the level of risk associated with falling or a cardiac event. How severe would it be if it happened and what was the likelihood of it happening?

Severity

Using the table in Figure 4 the severity was determined. The Safety Committee considered that slips, trips and falls might result in a significant head injury scored severity as value 3. They considered that the test itself could cause serious injury by provoking an adverse cardiac event and so scored severity as value 4.

Figure 4: Severity of consequence classifications

Aviation definition	Meaning	Value
Catastrophic	Results in an accident, death or equipment destroyed	5
Hazardous	Serious injury or major equipment damage	4
Major	Serious incident or injury	3
Minor	Results in a minor incident	2
Negligible	Nuisance of little consequence	1

Determining the likelihood

Using the table in Figure 5 the likelihood of a slip, trip or fall or significant cardiac event was determined. Determining the likelihood should be based on any current mitigation measures in place and the effectiveness of those measures related to the risk identified. With pre-assessment by a cardiologist and then continual monitoring through the process and with a review of published literature it was determined that the likelihood of a significant cardiac event would be very rare and so risk likelihood was scored as "improbable". It was more likely that an applicant would trip and fall. This had rarely occurred and so the risk of occurrence was judged to be "remote".

Figure 5: Likelihood of occurrence classifications

Qualitative definition	Meaning	Value
Frequent	Likely to occur many times (has occurred frequently)	5
Occasional	Likely to occur sometimes (has occurred infrequently)	4
Remote	Unlikely to occur but possible (has occurred rarely)	3
Improbable	Very unlikely to occur (not known to have occurred)	2
Extremely improbable	Almost inconceivable that the event will occur	1

NOTE: The definitions used in figure 5 are an example only. You may find it more useful to define quantitative definitions, such as, number of events in a given time period or events per number of applicants assessed.

Determining the risk tolerability

Using the risk assessment matrix in Figure 6, if the risk is determined to be Catastrophic (5) and Remote (3) the risk would be classified in the Unacceptable category.

Figure 6: Risk tolerability matrix

Risk likelihood	Risk severity				
	Catastrophic 5	Hazardous 4	Major 3	Minor 2	Negligible 1
Frequent 5	Unacceptable	Unacceptable	Unacceptable	Review	Review
Occasional 4	Unacceptable	Unacceptable	Review	Review	Review
Remote 3	Unacceptable	Review	Review	Review	Acceptable
Improbable 2	Review	Review	Review	Acceptable	Acceptable
Extremely improbable 1	Review	Acceptable	Acceptable	Acceptable	Acceptable

Unacceptable: The risk is unacceptable and major mitigation measures are required to reduce the level of risk to as low as reasonable practicable.

Review: The level of risk is of concern and mitigation measures are required to reduce the level of risk to as low as reasonably practicable. Where further risk reduction/mitigation is not practical or viable, the risk may be accepted, provided that the risk is understood and has the endorsement of the Accountable Manager.

Acceptable: Risk is considered acceptable but should be reviewed if it reoccurs.

Further mitigation measures

Further review of the risk determined that the Safety Manager should ensure that all staff are capable of managing an adverse cardiac event should it occur and that this could be improved by ensuring all staff had received Intermediate Life Support training and that they keep their knowledge and skills current through refresher training. Suitable equipment to manage incidents was also moved to within easy reach of the treadmill and unannounced simulations were planned to occur periodically to assess how events would be managed.

Revised level of risk

The Safety Committee felt that this reduced the severity of any injury that could occur during the exercise ECG process, although it kept the overall Risk Tolerability at the "Review" level.

Appendix C

Example of SMS manual contents page

1. **Table of contents**

2. **List of effective pages**

3. **Distribution list**

4. **Safety policy and objectives** – should include the safety policy signed by the Accountable Manager

5. **Safety organisation** – should detail management structure of the AeMC

   a. **Scope of SMS and contracted activities** – should detail what the SMS covers and how it interfaces with other safety-related parties

   b. **Safety accountabilities and responsibilities** – should detail the key safety staff members, the members of the safety committee and the safety accountabilities and responsibilities of all key staff members

   c. **Documentation of SMS** – should describe the way the SMS is documented and recorded

6. **Hazard identification and risk management process** – should include the safety reporting and hazard identification process and how hazards and their risks are assessed and then managed and controlled

7. **Safety assurance** – should include how the SMS and its outputs are audited, it should also include the safety performance monitoring and measurement process

8. **Change management** – should detail how the AeMC uses the SMS system to manage change

9. **Emergency Response Plan** – should detail how the AeMC would deal with an emergency situation and provide a quick reference guide for key staff members

Appendix D

Example safety reporting form

Part A: To be completed by the person identifying the event or hazard

Date of event: ....   Local time: ....

Location: ....

Name of reporter: ....

Section / Organisation: ....

Please fully describe the event or identified hazard:

Include your suggestions on how to prevent similar occurrences.

```



```

In your opinion, what is the likelihood of such an event or similar happening or happening again?

Extremely improbable   Frequent

    1   **2**   **3**   **4**   **5**

What do you consider could be the worst possible consequence if this event did happen or happened again?

Negligible   Catastrophic

    1   **2**   **3**   **4**   **5**

Part B: To be completed by the Safety Officer/Safety Manager

The report has been dis-identified and entered into the company database.

Report reference: ....

Name: .... Date: ....

Signature: ....

Part C: To be completed by the Safety Committee

Rate the likelihood of the event occurring or reoccurring:

Extremely improbable   Frequent

1   **2**   **3**   **4**   **5**

Rate the worst-case consequences:

Negligible   Catastrophic

1   **2**   **3**   **4**   **5**

What action or actions are required to ELIMINATE, MITIGATE or CONTROL the hazard to an acceptable level of safety?

```
┌─────────────────────────────────────────────────────────────┐
│                                                             │
│                                                             │
│                                                             │
│                                                             │
│                                                             │
└─────────────────────────────────────────────────────────────┘
```

Resources required: ....

Responsibility for action: ....

Agreed and accepted by: Safety Officer / Safety Manager   Date: ....

Responsible Manager   Date: ....

Accountable Manager   Date: ....

Appropriate Feedback given to staff by Safety Officer/Safety Manager

Signed: ....   Date: ....

Follow up action required: When: ....

                                    Who: ....

Hazard log updated: When: ....

Appropriate Feedback given to staff by Safety Officer/Safety Manager

Appendix E

Example of AeMC safety objectives and safety performance indicators

Performance indicator	Objectives	Performance											
		1	2	3	4	5	6	7	8	9	10	11	12
		Qtr. 1			Qtr. 2			Qtr. 3			Qtr. 4		
Number of major risk clinical incidents	1 or fewer												
Number of cases where medical certificate issued in error	1												
Number of resting ECGs misread as acceptable	2 or fewer												
Number of internal audits	4												
Number of audit findings per audit	2 or fewer												
Number of safety committee meetings	6												
Safety committee attendance of key personnel	Minimum												
Number of hazard / safety reports	20 or more												
Number of safety newsletters issued	2												
Number of formal risk assessments	5 or more												
Number of safety surveys	1												
Number of mandatory reports required by national law	1 or fewer												

NOTE: The suggested objectives are an example only. Organisations should set objectives that are relevant to their particular type of operation.

Appendix F

Assessment questions to support a gap analysis

To be completed and signed for by the Safety Manager or Accountable Manager.

Organisation: ....

Approval reference: ....   Signature: ....

Position: ....   Print name: ....

Date: ....   SMS manual revision: ....

		Compliance Y/ N / Partial	Comments / Reference to compliance
Management commitment and responsibility	Is there a written safety policy endorsed by the Accountable Manager?		
	Does Senior Management continuously promote and demonstrate its commitment to the safety policy?		
	Has the safety policy been communicated effectively throughout the AeMC?		
	Does the safety policy cover the points in this guidance material?		
Safety accountabilities	Are the safety accountabilities and responsibilities of the Accountable Manager and other key staff members clearly defined and published for all staff and contractors to see?		
	Does the Accountable Manager have full responsibility for the SMS and authority to make decisions regarding the budget?		
	Has the management structure of the AeMC been defined?		
	Are all staff members aware of their safety roles and responsibilities?		
Appointment of key safety staff members	Has a focal point/Safety Manager for the SMS been appointed?		
	Is there a direct reporting line between the SMS focal point/ Safety Manager and the Accountable Manager?		
	Does the SMS focal point/ Safety Manager have the appropriate SMS knowledge and understanding?		
	Does the AeMC have a Safety Committee or equivalent?		
	Does the Safety Committee or equivalent monitor the safety performance and the effectiveness of the SMS?		

	Does the Safety Committee or equivalent meet at least annually and are the meetings minuted?		
Emergency response planning	Has an emergency response plan (ERP) been developed and is it kept up to date?		
	Are the roles, responsibilities and actions of key staff members defined in the ERP?		
	Does the ERP include all the considerations in this guidance material if appropriate?		
	Is the ERP regularly reviewed and tested?		
Safety documentation	Does the safety management manual or safety documentation in existing manuals contain all the elements as detailed in this guidance material?		
	Is it regularly reviewed?		
	Is there a system for the recording and storage of SMS documentation and records i.e. hazard logs, risk assessments, safety reports from staff/contractors and safety cases?		
Hazard identification	Is there a confidential safety reporting system?		
	Are safety reports assigned an 'owner' and reviewed by the Safety Committee or equivalent?		
	Is there feedback to the reporter?		
	Is there a written procedure describing how hazards are identified?		
	Have the major hazards associated with the AeMC been identified?		
Risk assessment and mitigation	Is there a risk assessment process in place?		
	Is the risk tolerability matrix appropriate and can it be applied consistently?		
	Is there a process for deciding any necessary risk mitigation?		

	Are risk mitigations and controls being verified/audited to confirm the effectiveness?		
	Are risks being managed to a reasonable level?		
	Are the hazards and risks recorded on a hazard log or risk register?		
Safety performance monitoring	Have safety performance indicators been defined?		
	Are the safety performance indicators reviewed regularly to identify any trends?		
Management of change	Is there a process to proactively identify hazards and to mitigate risks when significant changes in the AeMC occur?		
Incident management	Are safety investigations carried out after incidents or accidents to establish root cause?		
	Are the hazards identified from safety investigations addressed and communicated to the rest of the AeMC?		
AeMC Specific areas	Have the elements of an SMS described in Chapters 6 and 7 been applied your processes for ensuring medical certification is conducted in compliance with Part MED		
	Have the elements of an SMS described in Chapters 6 and 7 been applied your processes for ensuring medical confidentiality		
	Have the elements of an SMS described in Chapters 6 and 7 been applied your processes for medical research		
Continuous improvement	Is continuous improvement in the safety performance being achieved?		
Safety auditing	Are safety audits and surveys carried out?		
Safety training	Is there an independent quality system or third party agency that audits the SMS?		
	Have all staff been appropriately trained in respect of the SMS and their safety roles and responsibilities?		

Communication	Does safety related information get communicated to all staff members as appropriate?		
	Does relevant safety information reach external users/customers etc?		
SMS implementation	Has a gap analysis been carried out?		
	Is there an SMS implementation plan?		
	Does the implementation plan reflect the gap analysis?		
	Is the implementation plan on target?		