EUROPEAN ORGANISATION
FOR THE SAFETY OF AIR NAVIGATION

EUROCONTROL

ESARR ADVISORY MATERIAL/GUIDANCE MATERIAL
(EAM/GUI)

EAM 3 / GUI 4

MAPPING BETWEEN ISO 9001:2000 AND ESARR 3

Edition	**:**	**1.0**
Edition Date	**:**	**18 May 2004**
Status	**:**	**Released Issue**
Distribution	**:**	**General Public**
Category	**:**	**ESARR Advisory Material**

SAFETY REGULATION COMMISSION

F.2 DOCUMENT CHARACTERISTICS

TITLE		
EAM 3 / GUI 4 **Mapping between ISO 9001:2000 and ESARR 3**		
Document Identifier :	**Reference :**	EAM 3 / GUI 4
eam3gui4_e10_ri_no_signatures	**Edition Number :**	1.0
	Edition Date :	18-05-2004

Abstract :

This document includes a detailed comparison between the provisions of ISO 9001:2000 and the safety regulatory requirements established in ESARR 3. It also provides ATM safety regulators with harmonised guidance to deal with situations where ISO-based approaches are proposed by ATM service providers as possible means of compliance to meet ESARR 3 requirements.

Keywords :

ISO	ISO 9001:2000	ISO 10011
ESARR 3	Mapping of Requirements	Quality
Quality Management System	Means of Compliance	Safety Management System

Contact Person(s) :	**Tel :**	**Unit :**
Juan Vazquez Sanz	+32 2 729 46 81	DG/SRU

DOCUMENT STATUS AND TYPE					
Status :		**Distribution :**		**Category :**	
Working Draft	☐	General Public	☑	Safety Regulatory Requirement	☐
Draft Issue	☐	Restricted EUROCONTROL	☐	Requirement Application Document	☐
Proposed Issue	☐	Restricted SRC	☐	ESARR Advisory Material	☑
Released Issue	☑	Restricted SRU	☐	Comment / Response Document	☐
				Policy Document	☐
				Document	☐

SOFTCOPIES OF SRC DELIVERABLES CAN BE DOWNLOADED FROM :
www.eurocontrol.int/src

F.3 DOCUMENT APPROVAL

The following table identifies all management authorities who have approved this document.

AUTHORITY	NAME AND SIGNATURE*	DATE
Quality Control (SRU)	***signed by Daniel Hartin*** (Daniel HARTIN)	18-May-04
Head Safety Regulation Unit (SRU)	***signed by Peter Stastny*** (Peter STASTNY)	18-May-04
Chairman Safety Regulation Commission (SRC)	***signed by Martin Radusch*** (Martin RADUSCH)	18-May-04

* In order to reduce the size of files, all documents placed on the SRC Website do not contain signatures. However, please note that all management authorities have signed the master copies held by the SRU. Requests for copies of master documents should be e-mailed to: sru@eurocontrol.int.

F.4 DOCUMENT CHANGE RECORD

The following table records the complete history of this document.

EDITION NUMBER	EDITION DATE	REASON FOR CHANGE	PAGES AFFECTED
0.01	25-Oct-03	Creation of document by SRU. Working draft submitted to RTF for review and comment.	All
0.1	21-Jan-04	Draft produced after RTF consultation. Submitted to SRC for review and comment	Section 2 (insertion in 5th para)
1.0	18-May-04	Final released issue produced after SRC consultation. Modifications included to address comments received.	Appendices A and C (various insertions) Section 4.10 (references to ISO updated)

F.5 CONTENTS

F.6 EXECUTIVE SUMMARY

The EUROCONTROL Safety Regulatory Requirement 3 (ESARR 3) 'Use of Safety Management Systems by ATM Service Providers', requires the implementation and operation of a safety management system (SMS) as an integral part of the management of ATM services. ESARR 3 also identifies the mandatory elements of any SMS implemented in the provision of ATM services within the EUROCONTROL Member States.

The ISO 9000 family of standards has been developed by the International Organisation for Standardisation (ISO) to assist organisations to implement and operate quality management systems (QMS). ISO 9001:2000 specifies requirements for QMS where an organisation needs to demonstrate its ability to provide products or services that fulfil applicable requirements.

Although the SMS approach involves various aspects not specifically addressed in the most common quality management standards, it has been recognised that quality management standards, notably ISO 9001:2000, can be used to support a successful implementation of ESARR 3. In fact, the use of integrated management systems encompassing safety and quality has been considered in some countries as a possible approach to address the implementation of ESARR 3 in an efficient manner.

As a result, there is a need to compare ESARR 3 and ISO 9001:2000 and provide ATM safety regulators with guidance to deal with situations where ISO-based approaches are proposed by ATM service providers as possible means of compliance to meet ESARR 3 provisions.

This document includes a detailed comparison between the provisions of ISO 9001:2000 and the safety regulatory requirements established in ESARR 3. It also provides ATM safety regulators with harmonised guidance that can be brought into play wherever there is a need for developing national regulatory material on the use of ISO 9001:2000 by ATM service providers to implement SMS.

Appendix C presents the detailed comparison between ISO 9001:2000 and ESARR 3 Section 5. The comparison is shown in form of table. Two additional tables have been produced to summarise the findings and map ISO 9001:2000 and ESARR 3 in a briefer manner.

Generally speaking, the findings of the mapping show that ISO 9001:2000 may provide useful tools to support the implementation of most ESARR 3 requirements. However, some specific conditions have been identified in relation to various ISO provisions.

The issues and conditions identified in this document should be taken into consideration wherever ISO 9001:2000 is considered as a possible means to support the implementation of ESARR 3

1. INTRODUCTION

In its initial work on the harmonisation of safety regulatory requirements, the SRC identified and focussed on those safety areas which, in their view, needed most urgent attention. On this basis, the SRC Work Programme recognised the need to establish a number of EUROCONTROL Safety Regulatory Requirements (ESARRs), one of which was ESARR 3 “Use of Safety Management Systems by ATM Service Providers”.

ESARR 3 requires ATM service providers to implement and operate a safety management system (SMS) as an integral part of the management of ATM services. ESARR 3 also identifies the mandatory elements of any SMS implemented in the provision of ATM services within the EUROCONTROL Member States.

The ISO 9000 family of standards has been developed by the International Organisation for Standardisation (ISO) to assist organisations of all types and sizes to implement and operate quality management systems (QMS). ISO 9001:2000 specifies requirements for QMS where an organisation needs to demonstrate its ability to provide products or services that fulfil applicable requirements.

The SMS approach involves various aspects not specifically addressed in the most common quality management standards. However, it has been recognised that quality management standards, notably ISO 9001:2000, can be used to support a successful implementation of specific ESARR 3 provisions.

SMS and QMS are both management tools with proactive and reactive elements embedded in performance and capability oriented processes. Their links may offer a variety of possibilities when implementing ESARR 3 in those situations where SMS and QMS are operated simultaneously. In that context, the use of integrated management systems encompassing safety and quality has been considered in some countries as a possible approach to address the implementation of ESARR 3 in an efficient manner.

Consequently, there is a need to compare ESARR 3 and ISO 9001:2000 and provide ATM safety regulators with guidance to deal with situations where ISO-based approaches are proposed by ATM service providers as possible means of compliance to meet ESARR 3 provisions.

2. PURPOSE OF DOCUMENT

This document is part of a series of guidance deliverables developed by SRC for its use by ATM safety regulators when dealing with the implementation of ESARR 3 by ATM service providers.

It includes a detailed comparison between the provisions of ISO 9001:2000 and the safety regulatory requirements established in ESARR 3 Section 5. The document also intends to support ATM safety regulators in dealing with those cases where ISO-based approaches are proposed as means of compliance to implement SMS.

It should be noted that this document does not represent a SRC recognition of ISO 9001:2000 as an acceptable means of compliance to meet ESARR 3 requirements.

As different approaches based on ISO 9001:2000 can be proposed depending upon local circumstances, specific proposals for possible means of compliance should normally be considered at national level. ATM safety regulators may therefore recognise ISO-based approaches as acceptable means of compliance to meet ESARR 3 requirements.

Any formal recognition of means of compliance should be based on an assessment demonstrating compliance with requirements. This document offers a systematic comparison that may be used as guidance where specific assessments are undertaken by ATM safety regulators. However, all QMS forming a basis for SMS needs to be specifically checked.

The document also provides ATM safety regulators with harmonised guidance that can be brought into play wherever there is a need for developing national regulatory material on the use of ISO 9001:2000 by ATM service providers to implement SMS.

3. COMPARISON CONDUCTED

3.1 Methodology

Appendix C presents the detailed comparison produced between ISO 9001:2000 and ESARR 3 Section 5. The comparison is shown in form of table. It takes each one of the provisions included in ISO 9001:2000 from Section 4 on, and identifies the ESARR 3 requirements related to the specific issue addressed in each ISO statement.

That table includes comments presenting the rationale for each correspondence established as well as conclusions on the possible use of each ISO statement to support the implementation of the ESARR 3 requirement related.

The main conclusions are shown in bold and normally identify two types of situations:

- The use of the ISO statement can support the implementation of the ESARR 3 requirement related
- Specific issues should be noted wherever the ISO provisions are considered as a possible means to support the implementation of ESARR 3.

Two additional tables have been produced to summarise those findings and map ISO 9001:2000 and ESARR 3 in a briefer manner:

- Appendix A includes a table presenting the ISO provisions that could be used to support each ESARR 3 requirement. The comments indicate those cases where specific issues (conditions identified) have been identified;
- The table on Appendix B summarises all the conditions identified for each ISO provision. Those conditions should be taken into account wherever ISO is considered as a means to support the implementation of ESARR 3.

3.2 Terminology

Some terminological aspects have to be taken into account when considering the tables of this document. Definitions used by ISO and SRC may differ[1].

In particular, it should be noted that:

- ISO uses extensively the term "product" defined as "result of a process". In other words, a product is an output of a set of interacting actions irrespective of its nature. Within the ISO approach there are four generic product categories: services, software, hardware and processed materials. The notion of "service" as a particular type of product is essential when considering the applicability of ISO 9001:2000 to ATM services.

- The term "requirement" has a broad meaning in ISO 9001:2000. It is defined as a "need or expectation that is stated, generically implied or obligatory". On the other hand the expression "safety requirement" is normally used[2] by SRC to refer to the mitigation measures identified through a risk assessment and mitigation process. That difference should be taken into account when considering the mapping of ISO provisions related to risk assessment and mitigation.

- No definition for "purchasing" is provided in ISO 9001:2000 or ISO 9000:2000 although the concept is implicitly defined in the provisions of Section 7.4 (Purchasing). The term purchasing needs to be compared with the "external services" concept that appears to be wider.

3.3. References for Interpretation

The comparison between each ISO provision and ESARR 3 requirements has been based on an assessment that considers primarily the exact text of ESARR 3 Section 5 and the set of definitions included in ESARR 3 Appendix A.

In some cases the assessment has made use of two additional sources of interpretation. Wherever that is the case, the comments included on the table of Appendix C make the issue clear. The two additional SRC references used are:

- EAM 3 / GUI 1, Guidance Material for ATM Safety Regulators, Explanatory Material on ESARR 3 Requirements, Edition 1.0. June 2001.

- ESARR 4, Risk Assessment and Mitigation in ATM, Edition 1.0, April 2001.

Nevertheless, the scope of this document is confined to considering the links between ISO 9001:2000 and ESARR 3. Compliance with ESARR 4 might imply additional aspects not necessarily addressed in this exercise. Wherever that possibility was clearly identified, the issue has been indicated explicitly on the tables.

[1] *Definitions applicable to ISO 9001:2000 are contained in ISO 9000:2000, Quality Management Systems – Fundamentals and Vocabulary.*

[2] *As utilised in ESARR 4.*

4. SUMMARY OF COMPARISON – ESARR 3 WITH ISO 9001:2000

This section only summarises some of the main aspects identified. The tables of the appendices collect all the findings in a more comprehensive manner:

4.1 General Aspects

- Generally speaking, the findings of the mapping show that ISO 9001:2000 may provide useful tools to support the implementation of most ESARR 3 requirements.

- On balance, most of the differences identified appear to be caused by the fact that the SMS concept focuses on a very specific aspect –safety-, and is primarily applicable to safety-related industries, while QMS present a more generic approach applicable to any industry. In addition, ESARR 3 is clearly tailored to a service-oriented industry, the provision of ATM services, while ISO 9001:2000 gives a more generic approach applicable to any organisation producing any type of product (services, software, hardware or materials).

- Those differences in approach have resulted in different levels of detail to address interconnected issues. In some cases ISO is much more detailed and provides useful means to support the implementation of ESARR 3 without raising specific issues. However, in other situations ESARR 3 gives the interpretation needed for generic concepts, such as the term “appropriate” which is widely used throughout ISO 9000:2001.

4.2 Systematic Safety Management

- Several ISO 9001:2000 provisions can be useful to define possible means of compliance to implement the generic ESARR 3 principles[3] requiring a “formalised approach” to “systematic” safety management. A case in point is the determination of processes that ISO 9001:2000 requires in Section 4.1 (General Requirements). A **process approach** based on ISO[4] seems a proper means to implement the ESARR 3 requirement for a “systematic” and “formalised” approach.

(Space Left Intentionally Blank)

[3] ESARR 3, 5.1.1 a, requires the ATM service provider to have in place a SMS which “ensures a formalised, explicit and pro-active approach to systematic safety management in meeting its safety responsibilities within the provision of ATM services.”

[4] Within ISO, the systematic identification and management of the processes employed within an organisation and particularly the interactions between such processes is referred to as the “process approach”

4.3 Safety Policy and Safety Objectives

- ISO requires defining quality objectives, but does not provide detailed guidance as to what is acceptable as an objective[5]. However, ESARR 3, 5.1.4, identifies an overall safety objective for all ATM service providers. Wherever the use of ISO is considered to support ESARR 3, any objective defined should be consistent with the **minimum common safety objective** defined for all ATM service providers.

- ISO requires top management to ensure that the quality policy is "appropriate" to the purpose of the organisation. However, ISO does not provide guidance as to what constitutes, or is acceptable as, a policy statement. ESARR 3, Section 5.1, contains four high level principles[6] that should normally[7] be addressed by means of safety policy statements. The safety policy **should normally include**, as a minimum, statements to cover ESARR 3, 5.1.1, 5.1.2, 5.1.3 and 5.1.4.

- ISO requires the quality manual to include the scope of the QMS, including details of and justification for any exclusion. No other ISO requirements exist as regards the minimum QMS scope. However, ESARR 3, 5.1.1 b, requires a specific scope. SMS **should cover, necessarily,** not only all the ATM services provided but also the supporting services[8] which are under the managerial control of the organisation.

4.4. Top Management Commitment

- ISO is much more specific and requires specific evidences to demonstrate top management commitment. In particular, ISO requires top management to ensure the availability of resources. The use of that approach **may support practically** the implementation of the generic statements included in ESARR 3, 5.2.2 d, regarding the "general role" to be played by the highest level of the service provider organisation.

- **Management reviews** are not required explicitly in ESARR 3, although SMS management reviews are identified in EAM 3/GUI 1 as one of the usual elements of the implementation of ESARR 5.4.2 b (Safety Improvement). EAM 3/GUI 1 underlines that SMS management reviews **should involve top management** as a means to ensure the continuous improvement of safety. ISO provides a detailed framework for management reviews, consistent with EAM 3/GUI 1. The ISO provisions may support the definition of **possible means of compliance** to meet ESARR 5.4.2 b) in conjunction with 5.2.2 d).

---

[5] Apart from requiring those objectives needed to meet requirements for product

[6] 5.1.1 Safety Management, 5.1.2 Safety Responsibility, 5.1.3 Safety Priority, 5.1.4 Safety Objective of the ATM Service

[7] As pointed out in EAM 3/GUI 1.

[8] ESARR 3 defines supporting services as the "systems, services and arrangements, including Communication, Navigation and Surveillance services, which support the provision of an ATM service."

4.5 Safety Responsibilities

- ISO requires top management to ensure that responsibilities and authorities are defined and communicated within the organisation. No other details are given. On the other hand, ESARR 3 is more specific and emphasises three key aspects:

  a) The notion of individuality in the safety responsibility concept

  b) The link between responsibility and own actions

  c) The safety responsibility of managers is related to the safety performance of their organisations.

  Wherever the use of ISO is considered to support ESARR 3, it should be ensured that safety responsibilities are **defined for individuals** and related to their **own actions**, and that the responsibilities of managers are related to the performance of the part of the organisation they manage.

4.6. Safety Managerial Function

- ESARR 3 requires the safety manager to be independent of line management, while ISO only requires the appointment of a member of the management as quality manager[9], irrespective of other responsibilities. Wherever the use of ISO is considered as a means to support ESARR 3, it should therefore be ensured that the safety managerial function is **independent of line management** (except perhaps in the case of some small organisations).

- On the other hand, it should be noted that:

  a) ISO explicitly requires the quality manager **to be part of the management team**. ESARR 3 does not include such explicit specification in regard to the safety manager. However, that notion is stressed in EAM 3/GUI 1 as a key aspect that stems from the requirement of SMS being an integral part of the overall management function (ESARR 3, 5.1).

  b) In ISO, the term **"authority"**[10] reinforces significantly the role of the quality manager. Within the context of ESARR 3, its use may provide a positive input to the definition of proper terms of reference for the safety management function.

  Consequently, it should be noted that using the ISO expressions 'member of the management' and 'authority' within the terms of reference of the safety manager could be helpful to support the implementation of ESARR 3, 5.2.2.

---

[9] *Management representative is the exact expression used in ISO 9000:2001*

[10] *ISO 9000:2001, Section 5.5.2 states that "top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:*

a) ensuring that processes needed for the QMS are established, implemented and maintained,
b) reporting to top management on the performance of the QMS and any need for improvement
c) ensuring the promotion of awareness of customer requirements throughout the organisation.

4.7 SMS Documentation

- ISO establishes a detailed framework for the control of documents. ESARR 3 only states that the SMS has to be documented "systematically". Therefore, most of the ISO provisions on documentation, control of documents, quality manual and records can support the implementation of ESARR 3, 5.2.5 by **offering possible means of compliance** to document the SMS in a systematic manner.

- ISO 9001:2000 only requires those records explicitly identified throughout its provisions. ESARR 3, 5.3.3, requires maintaining safety records throughout the SMS operation, that is to say, in relation to all the arrangements required in the 17 requirements of ESARR 3. In addition, ESARR 3, 5.3.4 underlines explicitly the need for producing specific records for the results of risk assessment and mitigation. Therefore wherever the use of ISO is considered, it should be ensured that **records are produced for all the ESARR 3 arrangements**, and very particularly for the results of risk assessment and mitigation processes.

4.8. Internal Communication

- ISO requires top management to ensure that "appropriate" communication processes are established within the organisation and that communication takes place regarding the effectiveness of the QMS. No further details are provided about the minimum processes needed. However, ESARR 3 defines at least two specific processes in this regard:

  a) Dissemination of lessons learnt (ESARR 3, 5.4.1), and

  b) The establishment of mechanisms to ensure that all staff are actively encourage to communicate (ESARR 3, 5.4.2 a)

  Wherever the use of ISO is considered as a means to support ESARR 3, it should be ensured that **specific internal communication actions** are implemented to cover explicitly the requirements of ESARR 3, 5.4.1 and 5.4.2. a).

4.9. Safety Occurrences

- Useful provisions have been found in ISO 9001:2000 to support the implementation of ESARR 3, 5.2.7, Safety Occurrences. In particular, Section 8.5.2 (corrective action) states that the organisation shall take action to eliminate the cause of non-conformities in order to prevent recurrence. That generic principle may certainly provide a framework to deal with safety occurrences. However, ESARR 3 is much more specific and requires the **immediate investigation of safety occurrences**. That notion does not appear in ISO. Therefore, wherever the use of ISO is considered as a means to support ESARR 3, it should be ensured that safety occurrences are **immediately** investigated.

4.10 Internal Auditing

- EAM 3 / GUI 1 explicitly recognises that internal auditing based on ISO 9001:2000 can be used for designing safety survey processes. EAM 3 / GUI 1 also points out that, in dealing with the implementation of safety surveys, service providers should normally establish processes in a manner which:

  a) Ensures independence of the area being surveyed; and

  b) Ensures systematic planning, assessment of all factors affecting safety, identification of corrective actions, recording of results, initiation and follow up of corrective actions.

  Those aspects are in line with the ISO approach. Therefore the use of internal ISO audits can support the implementation of ESARR 3 Section 5.3.1 by providing **possible means of compliance** to meet the requirement

- ISO 9001:2000 refers to other **complementary guidance** material on auditing techniques. The use of ISO 19011:2002 provides further detailed guidelines which could be used to support the definition of means of compliance to meet ESARR 3, Section 5.3.1.

4.11 Risk Assessment and Mitigation

- ESARR 3 necessarily implies the adoption of a risk-based approach and the use of risk management techniques. SMS cannot be conceived without these features. However, ISO 9001:2000 can be implemented without adopting such approach. Quality management is conceivable without risk management.

- In spite of those differences, various ISO provisions could effectively support the risk assessment and mitigation process required in ESARR 3. More particularly, this applies to most of the provisions included in Section 7 (Product Realisation). However, a common condition has been identified in regard to the possible use of most of the provisions of ISO 9001:2000 Section 7 to support the implementation of ESARR 3, 5.2.4 (Risk Assessment and Mitigation). Generally speaking, there is a need to ensure that **risk assessment and mitigation is addressed explicitly and differentially** throughout the product realisation processes outlined by ISO[11].

[11] *Let us consider, for example, the use of ISO 9001:2000 Section 7.1 (Planning of Product Realisation). ISO requires the organisation to determine, as "appropriate", the processes needed to produce the product. Wherever those provisions are used to implement ESARR 3, the requirements contained in ESARR 3, 5.2.4 (Risk Assessment and Mitigation) give an interpretation of the term "appropriate". Explicit risk assessment and mitigation processes are needed to deal with the changes to the ATM system associated to the realisation of that product.*

To take another example: ISO 9001:2000 Section 7.2.1 (Determination of Requirements Related to the Product) requires the organisation to determine the various types of requirements in relation to the product. That includes "any additional requirements determined by the organisation". The requirements of ESARR 3, 5.2.4 c) may give an interpretation for that expression. Normally, mitigation measures (safety requirements in ESARR 4) should be identified explicitly in the light of the results of risk assessment and mitigation processes conducted by the organisation as part of the realisation of the product.

- The scope of this document is confined to considering the links between ISO 9001:2000 and ESARR 3. Therefore it should be noted that compliance with ESARR 4 might imply additional aspects[12] not necessarily addressed in this exercise.

4.12 External Services[13]

- The ISO approach proposed in Section 7.4 (Purchasing) appears effective as a means to deal with those situations in which external suppliers can be selected. However, the use of external services in ATM may involve situations[14] where there are no options and external inputs need to be used as the only possible ones.

- As explained in EAM 3 / GUI 1 (ESARR 3 Guidance Material), even in those situations any external input (product, service, information, etc) can be managed through a risk assessment and mitigation approach. A process can identify the hazards associated with the input and ensure that their risk is mitigated to a tolerable level. Appropriate mitigation measures could include techniques such as monitoring, redundancy, operational or contingency procedures, etc, etc

- The use of the ISO provisions on purchasing (Section 7.4) can support the implementation of ESARR 3, 5.2.6, provided that complementary arrangements are put in place to deal with **those situations in which external suppliers can not be selected.** Those additional arrangements should normally be based on a risk-based approach.

(Space Left Intentionally Blank)

[12] For example, when considering ISO 9001:2000 Sections 7.3.4, 7.3.5, 7.3.6, (Design and Development Review, Verification and Validation) it should be noted that, although ESARR 3 is not specific about equivalent activities within risk assessment and mitigation, ESARR 4 contains detailed requirements on equivalent actions.

[13] External services are defined in ESARR 3 as "all material and non-material supplies and services, which are delivered by any organisation not covered by the ATM service-provider's safety management system."

[14] The ESARR 3 definition of "External Services" is wide and may include several categories of external inputs. Some possible examples: services provided by external organisations (e.g. CNS, MET, AIS, telecom, power supply, fire-fighting, etc), procurement of equipment, operational inputs from adjacent sectors, radar data from other organisations, etc, etc.

5. SIGNIFICANT ISSUES REGARDING INTER-RELATIONSHIP BETWEEN SMS AND QMS

5.1 Verification of Compliance with ESARR 3

The findings of the comparison confirm that ISO 9001:2000 can be used to support the implementation of ESARR 3 in the provision of ATM services.

ATM safety regulators could therefore recognise the use of ISO 9001:2000 as an acceptable means of compliance to meet specific ESARR 3 requirements, provided that the approach proposed demonstrates that it meets all the specific requirements under consideration.

ESARR 3 Section 5 includes 17 requirements. Full compliance with ESARR 3 is only achieved when those 17 requirements are met. Consequently, wherever the use of an ISO-based approach is proposed as a means to meet, totally or partially, those requirements, the practical steps to verify compliance with ESARR 3 would normally involve:

- The identification of the specific ESARR 3 requirements that the approach proposed intends to cover;
- The identification of the specific ISO 9001:2000 provisions intended to meet those ESARR 3 requirements; and
- An assessment that could consider, without excluding any additional input, the issues raised in this document, and notably the "conditions identified" in the table included in Appendix B.

5.2 Explicitness of the SMS

ESARR 3, 5.1.1.a, requires[15] the implementation of a SMS which ensures an explicit approach to safety management. In that regard, EAM 3/GUI 1 points out that an intuitive or ad hoc approach is not enough. Safety issues must be dealt with and managed explicitly.

SMS is specifically intended to deal with safety. Safety is its recognised and explicit subject. On the other hand, QMS aims to achieve customer satisfaction by meeting its requirements: this involves the identification of customer requirements, their satisfactory implementation by the prevention and correction of non-conformities, and measurement of achieved quality. Although safety is normally considered as an essential attribute of quality, QMS have a wider scope that might obscure the effective recognition of safety as prime objective.

[15] ESARR 3, 5.1.1 a) states that the ATM service provider shall have in place a SMS which "ensures a formalised, explicit and pro-active approach to systematic safety management in meeting its safety responsibilities within the provision of ATM services".

Throughout the mapping, it has been useful to compare equivalent statements by replacing the term ”quality”, normally used by ISO, with the term “safety”. In other cases generic actions mentioned in ISO have been compared with ESARR 3 by assuming a scope specifically focused on safety (e.g. monitoring vs. safety monitoring). Therefore the comparison and its results made the assumption that the actions proposed by ISO would be used to deal with safety in a differentiated manner. The need to deal with safety explicitly and specifically is indeed one of the main principles embedded in ESARR 3 and that fact has been reflected in the issues identified in the comparison.

From the comparison, it stems that, wherever ISO 9001:2000 provisions are used to support the implementation of ESARR 3, a way to provide appropriate explicitness is to ensure that safety is addressed as a specific and **differentiated subject in the ISO-based processes** and arrangements used to implement ESARR 3.

5.3 Integration of SMS and QMS

ESARR 3 does not require any specific level of integration or separation between both management systems (SMS and QMS) when they are simultaneously operated within the same organisation.

Therefore ATM safety regulators may recognise any proposed level of integration between SMS and QMS as an acceptable means of compliance, provided that:

- The approach proposed meets the requirements contained in ESARR 3 and,
- In particular, safety is addressed as a specific subject in the processes and arrangements proposed[16].

Different approaches and arrangements could be acceptable to combine or differentiate the two functions and a mixed Safety and Quality Management System is conceivable although a clear separation between QMS and SMS might ensure a more transparent SMS explicitness when implementing ESARR 3 Section 5.1.1.

Without presenting an exhaustive list, three basic levels of integration may be suggested:

- Complete separation and establishment of two different systems, QMS and SMS;
- Intermediate approaches in which common subjects would be partially implemented in a shared manner;
- Full integration to propose either SMS to be implemented within QMS or quality management elements to be added to SMS.

Any proposed approach, associated with a particular level of integration, should demonstrate that ESARR 3 requirements are met before being recognised as an acceptable means of compliance.

[16] *As a possible way to ensure appropriate explicitness as required in ESARR 3, 5.1.1 a).*

5.4 ISO Certification

Organisations operating QMS may obtain accreditation of compliance with ISO 9001:2000. Accreditation is normally documented by a certificate issued by a certification body which itself needs to be accredited by a national accreditation body signatory to the European Co-operation for Accreditation (EA) Multilateral Agreement (MLA) for Certification for Quality Systems.

Such accreditation does not imply necessarily compliance with ESARR 3 in those cases where the QMS is used to support the implementation of ESARR 3.

However, when verifying compliance with ESARR 3 safety regulators could make use of accreditation processes comprising ISO 9001:2000 and augmented for ATM service providers by means of ESARR 3. Without excluding any additional input, the issues raised in this document, and notably the “conditions identified” in the table included in Appendix B, could be considered to design such processes.

5.5 Small Organisations

ISO 9001:2000 is applicable to all types of organisations irrespective of their size. No specific provisions exist in ISO 9001:2000 with regard to small organisations.

ESARR 3 includes some specific provisions as regards small organisations. According to ESARR 3, 5.2.2 c) and d), the independence of line management normally required for the safety manager could not be needed under certain conditions in the case of some small organisations[17].

It should be noted that ISO 9001:2000 does not require independence of line management for the quality manager.

(Space Left Intentioanlly Blank)

[17] *EAM 3/GUI 2, Safety Regulatory Aspects of the Implementation of ESARR 3 in Small Organisations, Edition 1.0, provides specific guidance on this matter.*

APPENDIX A – Summary of Mapping

Table of ISO 9001:2000 provisions that can support the implementation of specific ESARR 3 requirements

ESARR 3 requirements	ISO 9001:2000 provisions whose use can support the implementation of ESARR 3 requirements	COMMENTS
5.1. General Requirement		
5.1.1. Safety Management	4.1 General Requirement	-
	5.1 Management Commitment	-
	5.4.2 QMS Planning	*Related to bullet a) in ESARR 3*
	6.1 Provision of resources	*Related to bullet 5.1 as a whole*
5.1.2. Safety Responsibility	5.5.1 Responsibility, authority and communication	**CONDITIONS IDENTIFIED**
5.1.3. Safety Priority	-	-
5.1.4. Safety Objective ATM Service	5.4.1 Quality Objectives	**CONDITIONS IDENTIFIED**
5.2. Requirements for Safety Achievement		
5.2.1. Competency	6.2 Human Resources	-
5.2.2. Safety. Management Responsibility	5.1 Management Commitment	*Related to bullet d) in ESARR 3*
	5.5.2 Management Representative	**CONDITIONS IDENTIFIED**
	5.6 Management Review	*Related to bullet d) in ESARR 3*
	6.1 Provision of Resources	*Related to bullet d) in ESARR 3*
5.2.3 Quantitative Safety Levels	5.4.1 Quality Objectives	**CONDITIONS IDENTIFIED**
5.2.4. Risk Assessment and Mitigation	7.1 Planning of Product Realisation	**CONDITIONS IDENTIFIED**
	7.2.1 Determination of Requirements related to the product	**CONDITIONS IDENTIFIED**
	7.2.2 Review of Requirements related to the product	**CONDITIONS IDENTIFIED**
	7.3.1 Design and Development	**CONDITIONS IDENTIFIED**
	7.3.2 Design and Development Inputs	**CONDITIONS IDENTIFIED**
	7.3.3 Design and Development Outputs	**CONDITIONS IDENTIFIED**
	7.3.4 Design and Development Review	*Full compliance with ESARR 4 might involve additional conditions*
	7.3.5 Design and Development Verification	
	7.3.6 Design and Development Validation	
	7.3.7 Control of Design & Development Changes	**CONDITIONS IDENTIFIED**
	7.5.1 and 7.5.2 Control and Validation of Processes for Production and Service Provision	**CONDITIONS IDENTIFIED**
	8.3 Control of Non-Conforming Product	-
5.2.5. SMS Documentation	4.2.2 Quality Manual	-
	4.2.3 Control of Documents	-
	4.2.4 Control of Records	-
5.2.6. External Services	4.1 General Requirement (last paragraph)	**CONDITIONS IDENTIFIED**
	7.4 Purchasing	**CONDITIONS IDENTIFIED**

ESARR 3 requirements	ISO 9001:2000 provisions whose use can support the implementation of ESARR 3 requirements	COMMENTS
5.2.7. Safety Occurrences	8.3 Control of Non-Conforming Product (last paragraph)	**CONDITIONS IDENTIFIED**
	8.5.2 Corrective Action	**CONDITIONS IDENTIFIED**
5.3. Requirements for Safety Assurance		
5.3.1. Safety Surveys	8.2.2 Internal Audit	*ISO-19011 can also support the implementation of ESARR 3, 5.3.1*
	8.2.3 Monitoring and Measurement of Processes	-
	8.2.4 Monitoring and Measurement of Product	-
	8.4 Analysis of Data	-
	8.5.2 Corrective Action	-
	8.5.3 Preventive Action	-
5.3.2. Safety Monitoring	8.2.4 Monitoring and Measurement of Product	-
	5.4.2 Analysis of Data	-
	8.3 Control of Non-Conforming Product	-
	8.5.2 Corrective Action	-
	8.5.3 Preventive Action	-
5.3.3. Safety Records	4.2.4 Control of Records	-
	7.5.3 Identification and Traceability	-
5.3.4. Risk Assessment & Mitigation Documentation	4.2.4 Control of Records	-
	7.3.7 Control of Design & Development Changes	**CONDITIONS IDENTIFIED**
	7.5.3 Identification and Traceability	-
5.4. Requirements for Safety Promotion		
5.4.1. Lesson Dissemination	5.5.3 Internal Communication	**CONDITIONS IDENTIFIED**
5.4.2. Safety Improvement	5.1 Management Commitment	*Related to bullet b) in ESARR 3*
	5.4.2 QMS Planning	-
	5.5.3 Internal Communication	**CONDITIONS IDENTIFIED**
	5.6 Management Review	*Related to bullet b) in ESARR 3*
	8.4 Analysis of Data	*Related to bullet b) in ESARR 3*
	8.5.1 Continual Improvement	*Related to bullet b) in ESARR 3*

(Space Left Intentionally Blank)

APPENDIX B – Summary of Mapping

Table of conditions to note wherever ISO 9001:2000 provisions are considered to implement specific ESARR 3 requirements

ISO 9001:2000 provisions whose use to implement ESARR 3 should be subject to certain conditions	CONDITIONS IDENTIFIED	ESARR 3 related requirements
4. Quality Management System		
4.1. General Requirement (last paragraph)	The paragraph can support the implementation of ESARR 3, 5.2.6 (External Services) but only as regards a very particular type of externally provided services	5.2.6
4.2.1. General (Documentation) (bullet a)	Any safety objective defined by ATM service providers must be consistent with the minimum common objective defined for all ATM providers in ESARR 3, 5.1.4.	5.1.4
	The Safety Policy should normally include policy statements to address ESARR 3, 5.1.1, 5.1.2, 5.1.3 and 5.1.4	5.1, 5.1.1 c)
4.2.1. General (Documentation) (bullet e)	Records have to be produced and maintained for all the actions (processes) intended to meet ESARR 3, and in particular for the results of risk assessment and mitigation	5.3.3, 5.3.4
4.2.2. Quality Manual (bullet a)	The scope of the SMS must be the one specified in ESARR 3	5.1.1 b)
5. Management Responsibility		
5.3. Quality Policy	Any safety objective defined by ATM service providers must be consistent with the minimum common objective defined for all ATM providers in ESARR 3, 5.1.4.	5.1, 5.1.1 c)
	The Safety Policy should normally include policy statements to address ESARR 3, 5.1.1, 5.1.2, 5.1.3 and 5.1.4	
5.4.1. Quality Objectives	Any safety objective defined by ATM service providers must be consistent with the minimum common objective defined for all ATM providers in ESARR 3, 5.1.4.	5.1.4, 5.2.3
5.5.1. Responsibility and Authority	ISO is more generic than ESARR 3. Safety responsibilities must be defined for individuals in relation to their own actions, and responsibilities of managers must be related to the safety performance of the part of the organisation they manage	5.1.2
5.5.2. Management Representative	The safety managerial function should be independent of line management (except perhaps in the case of some small organisations)	5.2.2 a), b)
5.5.3. Internal Communication	ISO is more generic than ESARR 3. There are very specific internal communication actions required in ESARR 3 (lessons dissemination, feedback from staff in safety improvement)	5.4.1, 5.4.2 a)
7. Product Realisation		
7.1. Planning of Product Realisation	Planning of processes should include, explicitly, those processes needed for risk assessment and mitigation in accordance with ESARR 3	5.2.4
7.2.1. Determination of Requirements Related to the Product	The requirements determined should include, explicitly, the safety requirements (mitigation measures) derived from risk assessment and mitigation processes	5.2.4
7.2.2. Review of Requirements Related to the Product		
7.3.1. Design and Development Planning	Design and development planning should include, explicitly, the planning of risk assessment and mitigation as regards any associated changes to the ATM system.	5.2.4

ISO 9001:2000 provisions whose use to implement ESARR 3 should be subject to certain conditions	CONDITIONS IDENTIFIED	ESARR 3 related requirements
7.3.2. Design and Development Inputs	Design and development inputs should identify, explicitly, the inputs needed to conduct risk assessment and mitigation with regard to any associated changes to the ATM system	5.2.4
7.3.3. Design and Development Outputs	Design and development outputs should identify, explicitly, the outputs from risk assessment and mitigation undertaken in regard to any associated changes to the ATM system (notably the safety requirements, also known as mitigation measures)	5.2.4
7.3.7. Control of Design and Development Changes	The control of design and development should include specific documentation to present the results and conclusions of risk assessment and mitigation related to associated changes to the ATM system.	5.2.4, 5.3.4
7.4. Purchasing	Complementary arrangements are needed to deal with those situations in which external suppliers cannot be selected. Those additional arrangements should normally be based on a risk-based approach	5.2.6
7.5.1. Control of production and service provision	These provisions can support the implementation of ESARR 3, 5.2.4, with regard to ATM operational procedures. However, the control and validation of processes for service provision should explicitly include appropriate risk assessment and mitigation activities.	5.2.4
7.5.2. Validation of processes for production and service provisions		
8. Measurement, Analysis and Improvement		
8.3. Control of Non-Conforming Product (last paragraph)	Wherever these ISO statements are considered as possible means to implement ESARR 3, Section 5.2..7 (Safety Occurrences), the actions mentioned in ISO should necessarily include an immediate investigation of occurrences and the implementation of corrective actions resulting from such investigation	5.2.7
8.5.2. Corrective Action		

Additionally, wherever ISO 9001:2000 provisions are used to support the implementation of ESARR 3, safety should normally be addressed as a specific and differentiated subject in the ISO-based processes and arrangements used to implement ESARR 3.

(Space Left Intentionally Blank)

APPENDIX C – Detailed Comparison between ISO 9001:2000 and ESARR 3

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
4.1. General Requirements		
The organisation shall establish, document and maintain a quality management system and continually improve its effectiveness in accordance with the requirements if this International Standard. The organisation shall:	***5.1. General Requirement*** – An ATM service provider shall, as an integral part of the management of the ATM service have in place a safety management system which: *(also related to 5.4.2 Safety Improvement)*	The intent of these statements is equivalent. To note that ESARR 3 emphasises the need to implement SMS as a part of the overall management function.
a) identify the processes needed for the QMS and their application throughout the organisation b) determine the sequence and interaction of these processes c) determine criteria and methods needed to ensure that both the operation and control of theses processes are effective d) ensure availability of resources and information necessary to support the operation and monitoring of theses processes e) monitor, measure and analyse these processes, and	***5.1.1 Safety Management*** *(have in place a SMS which)* a) ensures a formalised, explicit and pro-active approach to systematic safety management in meeting its safety responsibilities within the provisions of ATM services b) operates in respect to all ATM and supporting services which are under its managerial control	ESARR 3 requires a formalised and explicit approach to systematic safety management. However, ESARR 3 does not include explicitly the bullets developed in ISO. In particular, ESARR 3 does not include explicit requirements on the identification of processes and their subsequent management as an explicit requirement. A process approach, as proposed in ISO, seems a proper means to implement the ESARR 3 requirement for a "systematic" and "formalised" approach. **The use of these ISO provisions can support the implementation of ESARR 3, 5.1.1.**
f) implement actions necessary to achieve planned results and continual improvement of these processes.	***5.4.2. Safety Improvement*** *(within the operation of the SMS, the ATM service-provider)* … b**)** shall ensure that changes are made to improve safety where they appear needed.	The intent of these statements is equivalent
These processes shall be managed by the organisation in accordance with the requirements of this International Standard	-	N/A
Where an organisation chooses to outsource any process that affects product conformity with requirements, the organisation shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.	***5.2.6 External Services*** *(within the operation of the SMS, the ATM service provider)* shall ensure adequate and satisfactory justification of the safety of the externally provided services, having regard to their safety significance within the provision of the ATM service. *(External Services are defined in ESARR 3, Appendix A)*	The ISO statement covers a particular situation included in the External Services concept. It should be noted that ESARR 3 defines External Services in a very broad manner ("all material and non-material supplies and services which are delivered by any organisation not covered by the ATM service provider's SMS") **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.6 (but only with regard to a particular type of external services).**

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
4.2. Documentation		
4.2.1. General The quality management system shall include:		
a) documented statements of a quality policy and quality objectives	***5.1.1. Safety Management*** *(have in place a SMS which)* … c) includes, as its foundation, a statement of safety policy defining the fundamental approach to managing safety ***5.1.4. Safety Objective of the ATM service*** *(have in place a SMS which)* ensures that while providing an ATM service, the principal safety objective is to minimise the ATM contribution to the risk of an aircraft accident as far as reasonably practicable *(Also 5.1.2. (Safety Responsibility) and 5.1.3. (Safety Priority) include high level statements of policy nature)*	Both documents consider the need for policy and objectives. ESARR 3 contains some high level statements that should normally be addressed in the Safety Policy (e.g. Safety Priority) as pointed out in EAM3/GUI1 (ESARR 3 Guidance Material). On the other hand ISO is very generic on the contents of the quality policy. ISO Section 5.3 (see below) requires the policy to be "appropriate" for the purpose of the organisation. ESARR 3 also identifies a minimum safety objective for all service providers, while ISO only requires defining appropriate objectives (see 5.4.1 below). **Whenever the use of ISO is considered, it should be noted that <u>any objective defined by ATM service providers must be consistent with the minimum common objective</u> defined for all ATM providers in ESARR 3, Section 5.1.4.** **Wherever the use of ISO is considered, it should be noted that the Safety Policy should <u>normally include statements</u> to address ESARR 3 Sections 5.1.1, 5.1.2, 5.1.3 and 5.1.4.**
b) a quality manual c) documented procedures required by this International Standard d) documents needed by the organisation to ensure the effective planning, operation and control of its processes	***5.2.5. SMS Documentation*** (*within the operation of the SMS, the service provider)* shall ensure that the SMS is systematically documented in a manner, which provides a clear linkage to the organisation's safety policy;	ESARR 3 is less prescriptive. The SMS must be systematically documented but no particular format is required. On the other hand ESARR 3 insists on the need to ensure a clear link between Safety Policy and SMS. **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.5.**

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
e) records required by this International Standard	***5.3.3. Safety Records*** *(within the operation of the SMS, the ATM service provider)* shall ensure that safety records are maintained throughout the SMS operation as a basis for providing safety assurance to all associated with, responsible for or dependent upon the services provided, and to the safety regulatory authority; ***5.3.4. Risk Assessment and Mitigation Documentation*** *(within the operation of the SMS, the ATM service provider)* shall ensure that the results and conclusions of the risk assessment and mitigation process of a new or changed safety significant system are specifically documented, and that this documentation is maintained throughout the life of the system.	Throughout its text, ISO identify several records to be maintained and in those cases a reference to section 4.2.4 (control of records) is done. ESARR 3 only mentions a particular type of safety record: the risk assessment and mitigation documentation. Nevertheless, ESARR 3 requires records "throughout the SMS operation". That implies records for all the actions (processes) that implement the SMS. **Wherever the use of ISO is considered, it should be noted that records have to be produced and maintained for all the actions (processes) included in ESARR 3, and particularly for the results of risk assessment & mitigation**
4.2.2. Quality Manual The organisation shall establish and maintain a quality manual that includes:	***5.2.5. SMS Documentation*** *(within the operation of the SMS, the ATM service provider)* shall ensure that the SMS is systematically documented in a manner, which provides a clear linkage to the organisation's safety policy;	ESARR 3 is less prescriptive. The SMS must be systematically documented but no particular format is required. On the other hand ESARR 3 insists on the need to ensure a clear link between safety policy and SMS. **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.5.**
a) The scope of the QMS, including details of and justification for any exclusions	***5.1.1 Safety Management*** *(have in place a SMS which)* … b) operates in respect to all ATM and supporting services which are under its managerial control *(Supporting services are defined in ESARR 3, Appendix A)*	The intent of these statements is equivalent. ESARR 3 is much more specific and requires a particular scope. **Wherever the use of ISO is considered, it should be noted that the scope of the SMS must be the one specified in ESARR 3, 5.1.1 b)**
b) the documented procedures established for the QMS, or reference to them, and c) a description of the interaction between processes of the QMS	***5.2.5. SMS Documentation*** *(within the operation of the SMS, the ATM service provider)* shall ensure that the SMS is systematically documented in a manner, which provides a clear linkage to the organisation's safety policy;	ESARR 3 is less prescriptive. The SMS must be systematically documented but no particular format is required. On the other hand ESARR 3 insists on the need to ensure a clear link between Safety Policy and SMS. **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.5.**

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
4.2.3 Control of documents Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.	***5.2.5. SMS Documentation*** *(within the operation of the SMS, the ATM service provider)* shall ensure that the SMS is systematically documented in a manner, which provides a clear linkage to the organisation's safety policy;	ESARR 3 is less prescriptive. The SMS must be systematically documented but no particular documentation control procedures are required. Some references to documentation control are included in EAM 3/GUI 1 (Guidance Material) **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.5.**
A documented procedure shall be established to define the controls needed:		
a) to approve documents for adequacy prior to issue		
b) to review and update as necessary and re-approve documents		
c) to ensure that changes and the current revision status of documents are identified		
d) to ensure that relevant versions of applicable documents are available at points of use		
e) to ensure that documents are legible and readily identifiable		
f) to ensure that documents of external origin are identified and their distribution controlled, and		
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.		
4.2.4 Control of Records Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.	***5.3.3. Safety Records*** *(within the operation of the SMS, the ATM service provider)* shall ensure that safety records are maintained throughout the SMS operation as a basis for providing safety assurance to all associated with, responsible for or dependent upon the services provided, and to the safety regulatory authority;	Equivalent statements except with regard to the need of a documented procedure required by ISO and not demanded explicitly in ESARR 3. **The use of these ISO provisions can support the implementation of ESARR 3, 5.3.3, 5.2.5 and 5.3.4**

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
5.1 Management Commitment		
Top management shall provide evidence of its commitment to the development and implementation of the QMS and continually improve its effectiveness by	***5.2.2. Safety Management Responsibility*** *(within the operation of the SMS, the ATM service-provider)* d) shall ensure that the highest level of the service provider organisation plays a general role in ensuring safety management; ***5.1. General Requirement*** An ATM service provider shall, as an integral part of the management of the ATM service have in place a SMS which: ***5.1.1 a) (Safety Management)*** ensures a formalised, explicit and pro-active approach to systematic safety management in meeting its safety responsibilities within the provision of ATM services. ***5.4.2. Safety Improvement*** *(within the operation of the SMS, the ATM service-provider)* … b**)** shall ensure that changes are made to improve safety where they appear needed.	ISO is much more specific as it requires specific evidences to demonstrate top management commitment. Management reviews are not required explicitly in ESARR 3 although the SMS management review is identified in EAM3/GUI 1 (ESARR 3 Guidance Material) as one of the usual elements of the implementation of ESARR 5.4.2 (safety improvement) **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.2 d, 5.4.2 b and 5.1.**
a) Communicating to the organisation the importance of meeting customer as well as statutory and regulatory requirements		
b) establishing the quality policy		
c) ensuring that quality objectives are established		
d) conducting management reviews, and		
e) ensuring the availability of resources		
5.2 Customer Focus		
Top management shall ensure that customer requirements are met with the aim of enhancing customer satisfaction	*No similar requirement in ESARR 3*	N/A
5.3 Quality Policy		
Top management shall ensure that the quality policy:	***5.1.1. Safety Management*** *(have in place a SMS which)* … c) includes, as its foundation, a statement of safety policy defining the fundamental approach to managing safety	Equivalent statements (however, see bullets in ISO on the next page)

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
a) is <u>appropriate</u> to the purpose of the organisation b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system c) provides a framework for establishing and reviewing quality objectives d) is communicated and understood within the organisation, and e) is reviewed for continuing suitability	***5.1. General Requirement*** *(The General Requirement includes high level statements that will be normally considered at policy level due to their policy nature. This concerns 5.1.1 Safety Management, 5.1.2 Safety Responsibility, 5.1.3 Safety Priority, and 5.1.4 Safety Objective of the ATM service)*	ISO requires addressing some specific aspects in the quality policy. Although the inclusion of those aspects at policy level is not explicitly required in ESARR 3, such ISO policy principles may provide the SMS with a positive input. Secondly, ESARR 3 contains some high level statements that should normally be addressed in the Safety Policy (e.g. Safety Priority) as pointed out in EAM3/GUI1 (ESARR 3 Guidance Material). However, ISO is very generic on the actual contents of the quality policy. ISO Section 5.3 (see below) requires the policy to be "appropriate" for the purpose of the organisation. **Wherever the use of ISO is considered, it should be noted that any objective defined by ATM service providers <u>must be consistent with the minimum common objective</u> defined for all ATM providers in ESARR 3, Section 5.1.4.** **Wherever the use of ISO is considered, it should be noted that the Safety Policy <u>should normally include</u> statements to address ESARR 3 Sections 5.1.1, 5.1.2, 5.1.3 and 5.1.4.**
5.4 Planning		
5.4.1. Quality Objectives – Top management ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organisation. The quality objectives shall be measurable and consistent with the quality policy. *(ISO definition for quality objective: something sought, or aimed for, related to quality)*	***5.1.4. Safety Objective of the ATM service*** *(have in place a SMS which)* ensures that while providing an ATM service, the principal safety objective is to minimise the ATM contribution to the risk of an aircraft as far as reasonably practicable ***5.2.3. Quantitative Safety Levels*** *(within the operation of the SMS, the ATM service provider)* shall ensure that, wherever practicable, quantitative safety levels are derived and are maintained for all systems	ESARR 3 is much more specific as it identifies a minimum safety objective for all service providers while ISO only requires defining appropriate objectives In the light of the ISO definition for 'quality objective', the ISO statement can also be applicable to the implementation of ESARR 3, 5.2.3 (Quantitative Safety Levels) **The use of these ISO provisions can support the implementation of ESARR 3, 5.1.4 and 5.2.3, provided that:** **Wherever the use of ISO is considered, it should be noted that any objective defined by ATM service providers <u>must be consistent with the minimum common objective</u> defined for all ATM providers in ESARR 3, Section 5.1.4.**

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
5.4.2. QMS planning Top management shall ensure that: a) the planning of the QMS is carried out in order to meet the requirements given in 4.1,as well as the quality objectives, and b) the integrity of the QMS is maintained when changes to the QMS are planned and implemented	***5.1. General Requirement*** An ATM service provider shall, as an integral part of the management of the ATM service have in place a SMS which: ***5.1.1 a) (Safety Management)*** ensures a formalised, explicit and pro-active approach to systematic safety management in meeting its safety responsibilities within the provision of ATM services.	No explicit requirements exist in ESARR 3 regarding planning, although this issue could be considered as embedded in the need for 'systematic safety management'. **The use of these ISO provisions can support the implementation of ESARR 3, 5.1 and 5.1.1 a)**
5.5. Responsibility, authority and communication		
5.5.1. Responsibility and authority Top management shall ensure that responsibilities and authorities are defined and communicated within the organisation	***5.1.2 Safety Responsibility*** *(have in place a SMS which)* ensures that everyone involved in the safety aspects of ATM service-provision has an individual safety responsibility for their own actions, and that managers are responsible for the safety performance of their own organisations;	ESARR 3 is much more specific than ISO. ESARR 3 emphasises three key aspects: a) the notion of individuality in the safety responsibility concept b) the link between responsibility and own actions c) the responsibility of managers for the performance of their organisation. **Wherever the use of ISO is considered, it should be noted that safety responsibilities must be defined for individuals in relation to their own actions, and that the responsibilities of managers must be related to the safety performance of the part of the organisation they manage.**

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
5.5.2 Management representative Top management shall appoint a member of the management who, irrespective of other responsibilities, shall have responsibility and authority that includes:	***5.2.2 Safety Management Responsibility*** *(within the operation of the SMS, the ATM service provider)* a) shall ensure that a safety management function is identified with organisational responsibility for development and maintenance of the safety management system; b) shall ensure that this point of responsibility is, wherever possible, independent of line management, and accountable directly to the highest organisational level … d) shall ensure that the highest level of service provider organisation plays a general role in ensuring safety management	ESARR 3 requires independence of line management while ISO only requires the appointment of a member of the management irrespective of other responsibilities. On the other hand, it should be noted that ISO explicitly requires the quality manager to be part of the management team. ESARR 3 does not include explicit mandatory provisions in that regard. However, that notion is stressed in EAM3/GUI1 (ESARR 3 Guidance Material) as a key aspect that stems from the requirement for a SMS as part of the overall management function (ESARR 3, 5.1). Besides, the use of the term "authority" in ISO seems to reinforce significantly the role of the quality manager. Its use within the context of ESARR 3 may provide a positive input to the implementation of the safety management function. The use of the ISO expressions '*member of the management*' and '*authority*' can support the implementation of ESARR 3, 5.2.2, provided that: **Wherever the use of ISO is considered, it should be noted that the safety managerial function should be independent of line management (except in the case of some small organisations)** *NOTE: independence of line management could not be required in the case of small organisations in accordance to ESARR 3, 5.2.2 c (For further details see EAM3/GUI2 Safety Regulatory Aspects of the Implementation of ESARR 3 in Small Organisations, Edition 1.0)*
a) ensuring that processes needed for the QMS are established, implemented and maintained b) reporting to top management on the performance of the QMS and any need for improvement, and c) ensuring the promotion of awareness of customer satisfaction throughout the organisation	***5.2.2 Safety Management Responsibility*** *(within the operation of the SMS the ATM service provider)* a) shall ensure that a safety management function is identified with organisational responsibility for development and maintenance of the safety management system; b) shall ensure that this point of responsibility is, wherever possible, independent of line management, and accountable directly to the highest organisational level	The ISO statements are much more specific that the expression "*development and maintenance of the SMS*". Their use may add clarity to the role of the safety management function and are in line with EAM3/GUI1(ESARR 3 Guidance Material) **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.2**

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
5.5.3 Internal Communication Top management shall ensure that <u>appropriate</u> communication processes are established within the organisation and that communication takes place regarding the effectiveness of the QMS	***5.4.1.Lesson Dissemination*** *(within the operation of the SMS, the ATM service provider)* shall ensure that the lessons arising from safety occurrence investigations and other safety activities are disseminated widely within the organisation at management and operational levels. ***5.4.2 Safety Improvement*** *(within the operation of the SMS, the ATM service provider)* a) shall ensure that all staff are actively encouraged to propose solutions to identified hazards, and b) shall ensure that changes are made to improve safety where they appear needed.	ISO addresses the issue from a generic perspective, while ESARR 3 has defined some very specific actions such as the dissemination of lessons learnt and the establishment of mechanisms to ensure that all staff are actively encourage to communicate. In that context, ESARR 3 gives the interpretation of the expression “appropriate” that appears on ISO, and defines specific features to be implemented. **Wherever the use of ISO is considered, it should be noted that <u>there are specific internal communication actions that must be implemented</u> in accordance to ESARR 3, 5.4.1 and 5.4.2 a).**
5.6 Management Review		
5.6.1 General Top management shall review the organisation’s QMS, at planned intervals, to ensure continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records for management reviews shall be maintained ***5.6.2 Review input*** The input to the management review shall include information on: a) results of audits b) customer feedback c) process performance and product conformity d) status of preventive and corrective actions e) follow-up actions from previous management reviews f) changes that could affect the QMS g) recommendations for improvement ***5.6.3 Review output*** The output of the management review shall include any decisions and actions related to: a) improvement of the effectiveness of the QMS and its processes	***5.1.1 Safety Management*** *(have in place a SMS which)* a) ensures a formalised, explicit and pro-active approach to systematic safety management in meeting its safety responsibilities within the provision of ATM services ***5.2.2 Safety Management Function*** *(within the operation of the SMS, the ATM service provider)* d) shall ensure that the highest level of the service provider organisation plays a general role in ensuring safety management; ***5.4.2 Safety Improvement*** *(within the operation of the SMS, the ATM service provider)* … b) shall ensure that changes are made to improve safety where they appear needed	ISO is much more specific about he minimum mechanisms needed to implement continuous improvement within the organisation and involve the highest level of the organisation. No specific requirements exist in ESARR 3 to explicitly mandate management reviews. However, some sort of management review may be needed to implement ESARR 3, 5.2.2 and 5.4.4. Consequently, SMS management reviews have been identified in EAM3/GUI1 (ESARR 3 Guidance Material) as one of the elements to be normally found in the implementation of ESARR 3. **The use of these ISO provisions can support the implementation of ESARR 3, Sections 5.2.2 d) and 5.4.4 b).**

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
b) improvement of the product related to customer requirements, and	*(see previous page)*	*(see previous page)*
c) resource needs		
6.1 Provision of Resources		
The organisation shall determine and provide the resources needed	*No similar requirement in ESARR 3*	No explicit requirements exist in ESARR 3 requiring the provision of resources, although this notion could be considered as embedded in some requirements (notably ESARR 3, 5.1 and 5.1.1a) **The use of these ISO provisions can support the implementation of ESARR 3, particularly in regard to ESARR 3, 5.1, 5.1.1a) and 5.2.2 d).**
a) to implement and maintain the QMS and continually improve its effectiveness, and		
b) to enhance customer satisfaction by meeting customer requirements	*No similar requirement in ESARR 3*	N/A
6.2. Human Resources		
6.2.1 General Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience	***5.2.1 Competency*** *(within the operation of the SMS, the ATM service provider)* shall ensure that staff are adequately trained, motivated and competent for the job they are required to do, in addition to being properly licensed if so required;	Equivalent statements, although ESARR 3 explicitly makes reference to the licensing issue.
6.2.2 Competence, awareness and training The organisation shall:		ISO is much more detailed than ESARR 3. However, EAM3/GUI1 (ESARR 3 Guidance Material) identifies a very similar series of actions as one of the elements to be normally found in the implementation of ESARR 3. **The use of these ISO provisions can support the implementation of ESARR3, 5.2.1** *NOTE: ESARR 5 includes further details about processes to be conducted by the service-provider to ensure competency.*
a) determine the necessary competence for personnel performing work affecting product quality		
b) provide training tom take other actions to satisfy these needs		
c) evaluate the effectiveness of the actions taken		
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and		
e) maintain appropriate records of education, training, skills and experience		
6.3. Infrastructure		
The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:	*No similar requirement in ESARR 3*	The use of these ISO provision may address complementary aspects not tackled in ESARR 3.
a) buildings, workspace and associated utilities		
b) process equipment (both hardware and software)		

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
c) supporting services (such as transport or communication)	*(see previous page)*	*(see previous page)*
6.4 Work environment		
The organisation shall determine and manage the work environment needed to achieve conformity to product requirements	*No similar requirement in ESARR 3*	The use of these ISO provisions may address complementary aspects not tackled in ESARR 3.
7.1 Planning of product realisation		
The organisation shall plan and develop the processes needed for product realisation. Planning of product realisation shall be consistent with the requirements of the other processes of the QMS. In planning product realisation, the organisation shall determine the following, as <u>appropriate</u>: a) quality objectives and requirements for the product b) the need to establish processes, documents and provide resources specific to the product c) required verification, validation, monitoring, inspection and test activities specific to the product criteria for product acceptance d) records needed to provide evidence that the realisation processes and resulting product meet requirements The output of this planning shall be in a form suitable for the organisation's method of operations *(NOTE: ISO definition for product: result of a process)*	*No specific ESARR 3 requirements address the planning of the processes needed for service-provision realisation.* *However, to note that:* ***5.2.4 Risk Assessment and Mitigation*** *(within the operation of the SMS, the ATM service provider)* a) shall ensure that risk assessment and mitigation is conducted to an appropriate level to ensure that due consideration is given to all aspects of ATM; b) shall ensure that changes to the ATM system are assessed for their safety significance, and ATM system functions are classified according to their safety severity; c) shall ensure appropriate mitigation of risks where assessment has shown this to be necessary due to the safety significance of the change;	ESARR 3 does not require planning, but requires risk assessment and mitigation in the provision of ATM services. Therefore when an ISO-based approach is implemented, any planning of the processes needed for ATM service provision should determine the risk assessment and mitigation actions intended to meet ESARR 3, 5.2.4 (notably 5.2.4a). Therefore, the "need to establish processes" as referred to in ISO should include the need for risk assessment and mitigation processes intended to meet ESARR 3, 5.2.4. Additionally, the determination of the other related elements mentioned in ISO (records, verification, requirements, etc) should also be considered as regards risk assessment and mitigation processes in any ISO-based planning of the processes needed for ATM service provision. **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.4, provided that:** **Wherever the use of ISO is considered, any ISO-based planning of the processes needed for ATM service provision <u>should plan (explicitly) the processes needed for risk assessment and mitigation</u> in accordance to ESARR 3, 5.2.4.** *(NOTE: ESARR 4 provides more detailed requirements with regard to risk assessment and mitigation processes)* *(NOTE: in the light of the ISO definition for quality objectives, the ISO bullet a) is also related to the implementation of ESARR 3, 5.2,3.) (See also 5.4.1 in ISO)*

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
7.2 Customer related processes		
7.2.1 Determination of requirements related to the product the organisation shall determine: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities b) requirements not stated by the customer but necessary for specified or intended use, where known c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organisation ***7.2.2 Review of requirements related to the product*** The organisation shall review the requirements related to the product. This review shall be conducted prior to the organisation's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders) and shall ensure that: a) product requirements are defined b) contract or order requirements differing from those previously expressed are resolved, and c) the organisation has the ability to meet the defined requirements Records of the results of the review and actions arising from the review shall be maintained Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organisation before acceptance Where product requirements are changed, the organisation shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements	***5.2.4 Risk Assessment and Mitigation*** *(within the operation of the SMS, the ATM service provider)* … c) shall ensure appropriate mitigation of risks where assessment has shown this to be necessary due to the safety significance of the change;	Within risk assessment and mitigation, ESARR 3 requires appropriate mitigation of risks. ESARR 4 has developed that idea further and made clear that risk mitigation should be based on the determination of a set of safety requirements. These safety requirements (sometimes known as "mitigation measures" too) are defences intended to meet safety objectives and reduce or eliminate risks induced by hazards. Those are additional requirements to be determined by the organisation in the light of the results of its risk assessment and mitigation processes (in line with bullet d. in ISO) **The use of these ISO provisions can support the implementation of ESARR 3, provided that:** **Wherever the use of ISO is considered, any ISO-based determination (and review) of requirements should include (explicitly) the determination of safety requirements (also known as mitigation measures) derived from risk assessment and mitigation processes.**
7.2.3 Customer communication The organisation shall determine and implement effective arrangements for communicating with customers in relation to:	*No similar requirement in ESARR 3*	The use of these ISO provisions may address complementary aspects not tackled in ESARR 3.

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
a) product information	*(see previous page)*	*(see previous page)*
b) enquiries, contracts or handling, including amendments, and		
c) customer feedback, including customer complaints		
7.3 Design and development		
7.3.1 Design and development planning the organisation shall plan and control the design and development of product.	***5.2.4. Risk Assessment and Mitigation*** *(within the operation of the SMS, the ATM service provider)* a) shall ensure that risk assessment and mitigation is conducted to an appropriate level to ensure that due consideration is given to all aspects of ATM; b) shall ensure that changes to the ATM system are assessed for their safety significance, and ATM system functions are classified according to their safety severity; c) shall ensure appropriate mitigation of risks where assessment has shown this to be necessary due to the safety significance of the change;	ESARR 3 requires risk assessment and mitigation and refers to the changes to the ATM system as the subject for assessment (ESARR 3, 5.2.4 b). ESARR 4 has developed that idea further and made clear that the organisation should conduct risk assessment and mitigation for any changes to those parts of the ATM system and supporting services within the managerial control of the organisation. On the other hand, ISO includes provisions with regard to "design and development" which is defined as "a set of processes that transforms requirements into specified characteristics or into the specification of a product, process or system". The outcome of design and development will normally involve proposals for changes to the ATM system. Therefore, parallel risk assessment and mitigation will need to be conducted in association with design and development. **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.4, provided that:** **Whenever the use of ISO is considered, the ISO-based design and development planning <u>should include (explicitly) the planning of risk assessment and mitigation</u> in regard to any associated changes to the ATM system.** *(NOTE: ESARR 4 provides more detailed requirements with regard to risk assessment and mitigation. Full compliance with ESARR 4 may involve additional aspects when using ISO)*
During the design and development planning, the organisation shall determine:		
a) the design and development stages		
b) the review, verification and validation that are <u>appropriate</u> to each design and development stage, and		
c) the responsibilities and authorities for design and development		
The organisation shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.		
Planning output shall be updated, as <u>appropriate</u>, as the design and development progresses.		

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
7.3.2 Design and development inputs Inputs related to product requirements shall be determined and records maintained. These inputs shall include: a) functional and performance requirements b) applicable statutory and regulatory requirements c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	***5.2.4. Risk Assessment and Mitigation*** *(within the operation of the SMS, the ATM service provider)* a) shall ensure that risk assessment and mitigation is conducted to an appropriate level to ensure that due consideration is given to all aspects of ATM;	ESARR 3 requires risk assessment and mitigation and refers to the need to ensure that due consideration is given to all aspects of ATM (ESARR 3, 5.2.4 a) ESARR 4 has developed that idea further and made clear that risk assessment and mitigation should involve a determination of the scope, boundaries and interfaces, as well as an identification of functions to be performed and the environment of operations. Those are inputs to be normally considered in any risk assessment and mitigation process. **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.4, provided that:** **Whenever the use of ISO is considered, the ISO-based design and development inputs <u>should identify (explicitly) the inputs needed to conduct risk assessment and mitigation</u> with regard to any associated changes to the ATM system.** *(NOTE: Full compliance with ESARR 4 may involve additional aspects when using ISO)*
7.3.3 Design and development outputs The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release. Design and development outputs shall: a) meet the input requirements for design and development b) provide <u>appropriate</u> information for purchasing, production and for service provision c) contain or reference product acceptance criteria d) specify the characteristics of the product that are essential for its safe and proper use.	***5.2.4. Risk Assessment and Mitigation*** *(within the operation of the SMS, the ATM service provider)* … c) shall ensure appropriate mitigation of risks where assessment has shown this to be necessary due to the safety significance of the change;	Within risk assessment and mitigation, ESARR 3 requires appropriate mitigation of risks. ESARR 4 makes clear that risk mitigation should be based on the determination of safety requirements (mitigation measures). Those outputs obtained from the risk assessment and mitigation process should normally be related to the outputs identified by ISO (the four bullets listed) if an ISO-based approach is used. **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.4, provided that:** **Wherever the use of ISO is considered, the ISO-based design and development <u>outputs should identify (explicitly) the outputs from risk assessment and mitigation</u> undertaken in regard to any associated changes to the ATM system (notably the safety requirements).** *(NOTE: Full compliance with ESARR 4 may involve additional aspects when using ISO)*

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
7.3.4 Design and development review At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements	*No specific ESARR 3 requirements address the review, verification and validation steps specifically related to risk assessment and mitigation or design and development processes.*	The use of these ISO provisions can support the implementation of ESARR 3, 5.2.4. *(NOTE: ESARR 4 provides more detailed requirements with regard to risk assessment and mitigation. Full compliance with ESARR 4 may involve additional aspects when using ISO.* *(e.g. ESARR 4 requires risk assessment and mitigation processes to include verification that all identified safety objectives and requirements have been met. Wherever the use of ISO is considered, ISO based review, verification and validation should consider this ESARR 4 requirement)*
a) to evaluate the ability of the results of design, and		
b) to identify any problems and propose necessary actions		
Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained		
7.3.5 Design and development verification Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.		
7.3.6 Design and development validation Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained.		
7.3.7 Control of design and development changes Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and products already delivered	***5.3.4. Risk Assessment and Mitigation Documentation*** *(within the operation of the SMS, the ATM service provider)* shall ensure that the results and conclusions of the risk assessment and mitigation process of a new or changed safety significant system are specifically documented, and that this documentation is maintained throughout the life of the system.	ESARR 3 requires specific documentation of the results from risk assessment and mitigation processes. The comparison conducted above concluded that risk assessment and mitigation needs to be specifically addressed within the use of ISO-based design and development. The documentation related needs to be addressed specifically too. **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.4, 5.3.4, provided that:** **Wherever the use of ISO is considered, the control of design and development should include specific documentation to present the results and conclusions of the risk assessment and mitigation related to associated changes to the ATM system**
Records of the results of the review of changes and any necessary actions shall be maintained		
7.4 Purchasing		

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
7.4.1 Purchasing process		
The organisation shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realisation or the final product		The ESARR 3 definition of "External Services" is wide and may include various types of external inputs. Some possible examples: - Services provided by external organisations (e.g. CNS, MET, AIS, telecom, power supply, fire-fighting, etc), - Procurement of equipment, - Operational inputs from adjacent sectors, radar data from other organisations, etc, etc. The ISO approach, based on good procurement practices, appears effective as a means to deal with those situations in which external suppliers can be selected. However, the use of external services in ATM may involve some situations where there are no options and external inputs need to be used as the only possible ones. As explained in EAM3/GUI1 (ESARR 3 Guidance Material), in those situations any external input (product, service, information, etc) can be managed through a risk assessment and mitigation approach. A process should identify the hazards associated with the input and ensure that their risk is mitigated to a tolerable level. Appropriate mitigation measures could include techniques such as monitoring, redundancy, operational or contingency procedures, etc, etc. **The use of these ISO provisions can support the implementation of ESARR 3, 5.2.6, provided that:** **Wherever the use of ISO is considered, complementary arrangements are put in place <u>to deal with those situations in which external suppliers can not be selected</u>. Those additional arrangements should normally be based on a risk-based approach.**
The organisation shall evaluate and select suppliers based on their ability to supply product in accordance with the organisation's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained		
7.4.2 Purchasing information	***5.2.6 External Services*** *(within the operation of the SMS, the ATM service provider)* shall ensure adequate and satisfactory justification of the safety of the externally provided services, having regard to their safety significance within the provision of the ATM service. *To note the definition of External Services included in ESARR 3, Appendix A:* *External Services – All material and non-material supplies and services, which are delivered by any organisation not covered by the ATM service provider's SMS.*	
Purchasing information shall describe the product to be purchased including where <u>appropriate</u>:		
a) requirements for approval of product, procedures, processes and equipment		
b) requirements for qualification of personnel, and		
c) QMS requirements		
The organisation shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.		
7.4.3 Verification of purchased product		
The organisation shall establish and implement the inspection or other activities needed for ensuring that purchased product meets specified purchase requirements		
Where the organisation or its customer intends to perform verification at the supplier's premises, the organisation shall state the intended verification arrangements and method of product release in the purchasing information.		
7.5 Production and services provision		

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
7.5.1 Control of production and service provision		
The organisation shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include as applicable:		
a) the availability of information that describes the characteristics of the product		
b) the availability of work instructions as necessary		
c) the use of suitable equipment		
d) the availability and use of monitoring and measuring devices		
e) the implementation of monitoring and measurement, and	*No specific ESARR 3 requirements address explicitly the means to control or validate the processes for service provision (that is to say, the means to control or validate the ATM operational procedures)*	
f) the implementation of release, delivery and post-delivery activities		The approach proposed by ISO could be used in the risk assessment and mitigation processes conducted as regards ATM operational procedures.
7.5.2 Validation of processes for production and service provision	*However, to note that:*	**The use of these ISO provisions can support the implementation of ESARR 3, 5.2.4, with regard to ATM operational procedures, provided that:**
The organisation shall validate any processes and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered	***5.2.4 Risk Assessment and Mitigation*** *(within the operation of the SMS, the ATM service provider)* a) shall ensure that risk assessment and mitigation is conducted to an appropriate level to ensure that due consideration is given to all aspects of ATM; … c) shall ensure appropriate mitigation of risks where assessment has shown this to be necessary due to the safety significance of the change;.	**Wherever the use of ISO is considered, the validation of processes for service provision <u>should (explicitly) include appropriate risk assessment and mitigation activities</u>.**
Validation shall demonstrate the ability of these processes to achieve planned results		
The organisation shall establish arrangements for these processes including, as applicable:		
a) defined criteria for review and approval of the processes		
b) approval of equipment and qualification of personnel		
c) use of specific methods and procedures		
d) requirements for records and		
e) revalidation		

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
7.5.3 Identification and traceability Where appropriate the organisation shall identify the product by suitable means throughout product realisation	***5.3.3. Safety Records*** *(within the operation of the SMS, the ATM service provider)* shall ensure that safety records are maintained throughout the SMS operation as a basis for providing safety assurance to all associated with, responsible for or dependent upon the services provided, and to the safety regulatory authority;	**The use of these ISO provisions can support the implementation of ESARR 3, 5.3.3, 5.3.4.**
The organisation shall identify the product status with respect to monitoring and measurement requirements		
Where traceability is a requirement, the organisation shall control and record the unique identification of the product		
7.5.4 Customer property The organisation shall exercise care with customer property while it is under the organisation's control or being used by the organisation. The organisation shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.	*No specific ESARR 3 requirements address explicitly this issue*	The use of these ISO provisions may address complementary aspects not tackled in ESARR 3.
7.5.5 Preservation of product The organisation shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of the product.	*No specific ESARR 3 requirements address explicitly this issue*	The use of these ISO provisions may address complementary aspects not tackled in ESARR 3.
7.6 Control of monitoring and measuring devices		
The organisation shall determine the monitoring and measurement undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.	***5.3.2 Safety Monitoring*** *(within the operation of the SMS, the ATM service provider)* shall ensure that methods are in place to detect changes in systems or operations which may suggest any element is approaching a point at which acceptable standards of safety can no longer be met, and that corrective action is taken.	Equivalent statements To note the need for an explicit monitoring of safety.
The organisation shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements		
Where necessary to ensure valid results, measuring equipment shall:	***5.3.2 Safety Monitoring*** *(within the operation of the SMS, the ATM service provider)* shall ensure that methods are in place to detect changes in systems or operations which may suggest any element is approaching a point at which acceptable standards of safety can no longer be met, and that corrective action is taken.	To note that the expression "methods" in ESARR 3 could embed the actions listed by ISO in regard to measuring equipment. The use of these ISO provisions may address complementary aspects not tackled in ESARR 3.
a) be calibrated or verified at special intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.		
b) be adjusted or re-adjusted as necessary		

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
c) be identified to enable the calibration status to be determined		
d) be safeguarded from adjustments that would invalidate the measurement result		
e) be protected from damage and deterioration during handling, maintenance and storage		
In addition the organisation shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organisation shall take appropriate action on the equipment and any product affected. Records of the results of calibration shall be maintained	*(see previous page)*	*(see previous page)*
When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary		
8.1 Measurement, Analysis and Improvement (General)		
The organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed	***5.3.1. Safety Surveys*** *(within the provision of the SMS, the ATM service provider)* shall ensure that safety surveys are carried out as a matter of routine, to recommend improvements where needed, to provide assurance to managers of the safety of activities within their areas and to confirm conformance with applicable parts of their Safety Management Systems. ***5.3.2. Safety Monitoring*** *(within the provision of the SMS, the ATM service provider)* shall ensure that methods are in place to detect changes in systems or operations which may suggest any element is approaching a point at which acceptable standards of safety can no longer be met, and that corrective action is taken. ***5.4.2. Safety Improvement*** *(within the provision of the SMS, the ATM service provider)* … b) shall ensure that changes are made to improve safety where they appear needed.	Equivalent statements To note the need for explicit monitoring, analysis and improvement with regard to safety.
a) to demonstrate conformity of the product		
b) to ensure conformity of the QMS		
c) To continually improve the effectiveness of the QMS		
This shall include determination of applicable methods, including statistical techniques, and the extent of their use.		

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
8.2 Monitoring and measurement		
8.2.1 Customer satisfaction As one of the measurements of performance of the QMS, the organisation shall monitor information relating to customer perception as to whether the organisation has met customer requirements. The methods for obtaining and using this information shall be determined	*No specific ESARR 3 requirements address explicitly this issue*	The use of these ISO provisions may address complementary aspects not tackled in ESARR 3.
8.2.2 Internal audit The organisation shall conduct internal audits at planned intervals to determine whether the QMS system: a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the QMS requirements established by the organisation, and b) is effectively implemented and maintained An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2)	***5.3.1. Safety Surveys*** *(within the operation of the SMS, the ATM service provider)* shall ensure that safety surveys are carried out as a matter of routine, to recommend improvements where needed, to provide assurance to managers of the safety of activities within their areas and to confirm conformance with applicable parts of their Safety Management Systems.	EAM3/GUI1 (ESARR 3 Guidance Material) explicitly recognises that internal auditing based on ISO-9001:2000 can be used for designing safety survey processes. EAM3/GUI1 also points out that in dealing with the implementation of safety surveys, service providers should normally establish processes in a manner which: - Ensures independence of the area being surveyed; and - Ensures systematic planning, assessment of all factors affecting safety, identification of corrective actions, record of results, initiation and follow up of corrective actions, as the key elements of safety surveys. Those aspects are in line with the ISO approach. **The use of these ISO provisions can support the implementation of ESARR 3 Section 5.3.1** **The use of ISO-19011:2002 can also support the implementation of ESARR 3, Section 5.3.1, as it provides detailed guidance to support the implementation of those ISO provisions.** *(NOTE: ISO-9001:2000 refers to guidance material on auditing techniques. At the time of developing this document, ISO-19001:2002 included the latest ISO material available on that matter)*

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
8.2.3 Monitoring and measurement of processes The organisation shall apply suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product	***5.3.1. Safety Surveys*** *(within the operation of the SMS, the ATM service provider)* shall ensure that safety surveys are carried out as a matter of routine, to recommend improvements where needed, to provide assurance to managers of the safety of activities within their areas and to confirm conformance with applicable parts of their Safety Management Systems. ***5.3.2. Safety Monitoring*** *(within the provision of the SMS, the ATM service provider)* shall ensure that methods are in place to detect changes in systems or operations which may suggest any element is approaching a point at which acceptable standards of safety can no longer be met, and that corrective action is taken.	The Safety Surveys can be considered as a "suitable method" to achieve the objectives stated in ISO as regards SMS processes. However, ISO is more detailed and may help to define the scope and intent of the Safety Surveys as regards monitoring of processes **The use of these ISO provisions can support the implementation of ESARR 3 Section 5.3.1**
8.2.4 Monitoring and measurement of product The organisation shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realisation process in accordance with the planned arrangements (see 7.1)		ESARR 3 Section 5.3.2 covers the issue pointed out by ISO. However, ISO is more detailed and may provide useful criteria to conduct the safety monitoring of systems and operations. To note that ESARR 3 Section 5.3.1 may complement Section 5.3.2 in achieving the objectives outlined by ISO. **The use of these ISO provisions can support the implementation of ESARR 3 Sections 5.3.2, 5.3.1**
Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorising release of product		
Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.		
8.3 Control of non-conforming product		
The organisation shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with non-conforming product shall be defined in a documented procedure.	*No equivalent requirements explicitly included in ESARR 3* *However, to note:* ***5.3.2. Safety Monitoring*** *(within the provision of the SMS, the ATM service provider)* shall ensure that methods are in place to detect changes in systems or operations which may suggest any element is approaching a point at which acceptable standards of safety can no longer be met, and that corrective action is taken.	It should be noted that the ATM services provided in real time can not be verified before being delivered. The ATM services are indeed the final "product" produced by the ATM service providers. However, "product" is defined by ISO as "result of a process". Therefore these ISO provisions may also be applicable to any intermediate process whose outputs are used to produce the final ATM service (e.g. radar data is an output of a particular process, and is normally used to provide the final ATC services output). These ISO provisions can therefore provide useful guidance when dealing with intermediate outputs, and support the safety monitoring actions required in ESARR 3. **The use of these ISO provisions can support the implementation of ESARR 3, particularly as regards ESARR 3 Section 5.3.2 (and 5.2.4)**
The organisation shall deal with non-conforming product by one or more of the following ways:		
a) by taking action to eliminate the detected non-conformity		
b) by authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer		
c) by taking action to preclude its original intended use or application		
Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained, shall be maintained		

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
When non-conforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	*(see previous page)*	*(see previous page)*
When non-conforming product is detected after delivery or use has started, the organisation shall take action appropriate to the effects, or potential effects, of the non-conformity.	***5.2.7. Safety Occurrences*** *(within the provision of the SMS, the ATM service provider)* shall ensure that ATM operational or technical occurrences which are considered to have significant safety implications are investigated immediately, and any necessary corrective action is taken.	There is a correspondence between this ISO statement and ESARR 3 Section 5.2.7. However, ESARR 3 is more detailed and specific. **Whenever this ISO statement is considered as a possible means to implement ESARR 3, Section 5.2.7, it should be noted that the appropriate actions mentioned in ISO should necessarily include an immediate investigation of occurrences and the implementation of corrective actions resulting from such investigation.**
8.4 Analysis of data		
The organisation shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to: a) customer satisfaction b) conformity to product requirements c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers	*No equivalent requirements explicitly included in ESARR 3* *However, to note:* ***5.4.2. Safety Improvement*** *(within the operation of the SMS, the ATM service-provider)* ***…*** b**)** shall ensure that changes are made to improve safety where they appear needed. *(in addition, these ISO statements are related to actions required in 5.3.2 Safety Monitoring and 5.3.1 Safety Surveys)*	ISO is much more specific. To note that management reviews are not required explicitly in ESARR 3 although EAM3/GUI 1 (ESARR 3 Guidance Material) identifies SMS management reviews as one of the usual elements of the implementation of ESARR 3 Section 5.4.2 (Safety Improvement). In that context, EAM3/GUI 1 points out that ATM service providers should normally use SMS management reviews: - To review the SMS - To agree and authorise changes in the SMS. The collection and analysis of data explicitly suggested by ISO can support that review. **The use of these ISO statements can support the implementation of ESARR 3, Section 5.4.2 (and 5.3.1, 5.3.2)**
8.5 Improvement		
8.5.1 Continual improvement The organisation shall continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review	***5.4.2. Safety Improvement*** *(within the operation of the SMS, the ATM service-provider)* ***…*** b**)** shall ensure that changes are made to improve safety where they appear needed.	ISO is much more specific about the means to use for achieving improvement. **The use of these ISO statements can support the implementation of ESARR 3, Section 5.4.2**

ISO 9001:2000 provisions	ESARR 3 requirements related	Comments/Assessment
8.5.2 Corrective action The organisation shall take action to eliminate the cause of non-conformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the non-conformities encountered.	***5.2.7. Safety Occurrences*** *(within the provision of the SMS, the ATM service provider)* shall ensure that ATM operational or technical occurrences which are considered to have significant safety implications are investigated immediately, and any necessary corrective action is taken. *(also related to 5.3.1 Safety Surveys)*	There is a correspondence between this ISO statement and ESARR 3 Section 5.2.7. However, ESARR 3 is more detailed and specific. **Whenever this ISO statement is considered as a possible means to implement ESARR 3, Section 5.2.7, it should be noted that the actions proposed by ISO should necessarily include an immediate investigation of occurrences.** To note that the steps proposed in ISO can also be useful to address non-conformities raised by other SMS mechanisms (e.g. Safety Surveys). In fact, that approach develops further the generic indications provided in EAM3/GUI1 (ESARR 3 Guidance Material) in relation to the conduct of Safety Surveys.
A documented procedure shall be established to define requirements for:		
a) reviewing non-conformities (including customer complaints)		
b) determining the causes of non-conformities		
c) evaluating the need for action to ensure that non-conformities do not recur		
d) determining and implementing action needed		
e) records of the results of action taken		
f) reviewing corrective action taken		
8.5.3 Preventive action The organisation shall determine action to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.	***5.3.1. Safety Surveys*** *(within the operation of the SMS, the ATM service provider)* shall ensure that safety surveys are carried out as a matter of routine, to recommend improvements where needed, to provide assurance to managers of the safety of activities within their areas and to confirm conformance with applicable parts of their Safety Management Systems. ***5.3.2. Safety Monitoring*** *(within the provision of the SMS, the ATM service provider)* shall ensure that methods are in place to detect changes in systems or operations which may suggest any element is approaching a point at which acceptable standards of safety can no longer be met, and that corrective action is taken. *(also related to 5.2.4 Risk Assessment and Mitigation, notably as regards the mitigation of risks required in 5.2.4 bullet b)*	EAM 3/GUI 1 (ESARR 3 Guidance Material) points out that a safety survey is a preventive activity which main purpose is to confirm that an existing situation is satisfactory. It is therefore a "routine" activity to identify problems and facilitate the definition of remedial actions when problems are identified or suspected. According to EAM 3/GUI 1, surveys are complementary to incident investigation, since they examine systems under normal conditions to identify weaknesses that have not yet been seen to contribute directly or indirectly to an occurrence. The steps proposed in ISO can also be useful to develop further the generic indications provided in EAM3/GUI1 (ESARR 3 Guidance Material) in relation to the conduct of Safety Surveys. To note that the Safety Monitoring required in ESARR 3, section 5.3.2 is also focused on detecting problems before they appear. **The use of these ISO statements can support the implementation of ESARR 3 Section 5.3.1, 5.3.2.**
A documented procedure shall be established to define requirements for:		
a) determining potential non-conformities and their causes		
b) evaluating the need for action to prevent occurrence of non-conformities		
c) determining and implementing action needed		
d) records of results of action taken, and		
e) reviewing preventive action taken		

**** End of Document ****