

Aeronautical Information Management (AIM) Quality Management Development

Guidance Manual

<u>Acknowledgements</u>

This publication was produced by the AIM Workgroup (AIM WG) of the Civil Air Navigation Services Organisation (CANSO) Operations Standing Committee.

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Foreword

The guidance material contained in this manual has been developed to aid CANSO Members and States in the planning and implementation of a QMS for AIM (AIM), and to fulfil the requirement in ICAO Annex 15 to the Convention on International Civil Aviation — *Aeronautical Information Services* (AIS) for State AIS/AIM service providers to introduce a Quality Management System (QMS).

This manual contains key guidance to provide CANSO Members and States with an understanding of the requirements for a QMS and to assist in the development of a quality manual, which constitutes the basis for the provision of aeronautical information in a manner that will satisfy the requirements for timeliness and quality contained in Annex 15.

Annex 15 recommends that the ISO 9000 series of standards be used when developing a QMS for AIM. The methodology and concepts described in this manual are derived from:

- ▼ ISO 9001:2015 Quality Management Systems Requirements
- ▼ ISO 9000:2015 Quality Management Systems Fundamentals and Vocabulary

An example of a quality manual for AIM, which includes examples of QMS procedures, work instructions and process flow charts, is provided in the attachment. It is emphasised that the specimen of the quality manual merely provides an example of a form and format of a quality manual for AIM, demonstrating only one example of an organisation and division of functions, and a selection of rules and procedures. The content of a quality manual for an actual State AIS/AIM service provider would need to be adapted to reflect its respective organisation, assignment of functions and established procedures in accordance with the QMS requirements.

Policies on Quality Systems for AIM

1.1. Background

assurance-related Standards Recommended Practices (SARPs) first introduced in ICAO Annex 15 to the Convention on Aviation International Civil Aeronautical Information Services, Chapter 3, 3.2.1, which became applicable on 6 November 1997. The Standard provides that "The established quality system shall provide users with the necessary assurance and confidence that distributed aeronautical information/data satisfy stated requirements for data quality (accuracy, resolution and integrity) and for data traceability using appropriate procedures in every stage of data production or data modification process. The system shall also provide assurance of the applicability period of intended use of aeronautical information/data as well as that the agreed distribution dates will be met."

In amendment 30 to Annex 15, a recommendation was added to be in conformity with the ISO 9000 Series of quality assurance standards, and certified. The Standard provides that the quality system established in accordance with 3.2.1 should be in conformity with the International Organisation for Standardisation (ISO) 9000 series of quality assurance standards, and certified by an approved organisation.

1.2. Need for Quality

In Annex 15, Chapter 1 Introduction implies the necessity of the QMS. "Corrupt or erroneous aeronautical information/data can potentially affect the safety of air navigation."

Aeronautical information distributed by means of aeronautical information publications (AIP) including charts and by NOTAM, pre-flight information bulletins (PIB), aeronautical information circulars (AIC) and other products and services

provided by an aeronautical information service, has an inherent and essential need to fulfil specific requirements to serve its intended purpose and meet the needs of users. The basic characteristics of aeronautical information are those of adequacy, availability and timeliness. The degree to which these and other characteristics fulfil requirements is referred to as "quality".

The need for aeronautical information/data of a required quality was never greater than in the current air navigation environment in which a higher accuracy of data is required to support area navigation (RNAV), required navigation performance (RNP) and data-dependent airborne computer-based navigation systems. Quality requirements for aeronautical information/data have evolved to include characteristics for integrity, accuracy, order of publication and charting resolution, and protection of electronic data. These requirements are specified in Chapter 3 of Annex 15.

1.3. Need for a Quality Management System

In addition to specifying the quality requirements for aeronautical data, Annex 15 requires States to introduce a quality system to implement quality management at each of the function stages of originating (or collecting), collating assembling, editing, formatting, storing, publishing and distributing of aeronautical information. Annex 15 also recommends that this requirement be met by establishing a quality system that complies with ISO 9001.

The ISO 9000 series of standards and associated guidelines are based on principles which emphasise satisfying the "Customer" and meeting customer requirements. The underlying justification is that it is the customer upon whom a business or service depends and who ultimately determines the

acceptability of the product or the service delivered. The customers, in an AIM context, are equivalent to users of aeronautical information/data (pilots, aircraft operators, air traffic controllers, flight planning organisations, general aviation, data vendors, etc.).

The ISO QMS approach encourages organisations to analyse customer requirements, define the processes that contribute to the achievement of a product which is acceptable to the customer, and keep those processes controlled. This approach expresses, in a generic way, the requirement in Annex 15 that validation and verification procedures be established which ensure that quality requirements (accuracy, resolution, integrity) and traceability of aeronautical data are met.

At the core of ISO9001 is the "process approach", which defines a process as any activity that resources and transforms inputs into outputs. A simple example of an AIM process is data input to a database which is converted to output for chart production. This process may in be linked to a previous or succeeding process, and within this process may be other processes, such as verification of the data against certain established parameters. ISO QMS requirements focus on systematically identifying, organising, documenting, managing and improving processes, and interactions between processes.

1.4. Relevant provisions in ICAO Annexes and documents

Definitions for QMS have been introduced in ICAO Annex 15 since Amendment 29. The Standard and Recommended Practices related to QMS are given in ICAO Annex 15, Chapter 3, 3.2. In brief, the Standard and Recommended Practices set out the following requirements:

Each Contracting State shall ensure that QMSs are implemented and maintained encompassing all functions of an aeronautical information service. The execution of such QMSs shall be made demonstrable for each function stage, when required.

- Recommendation The QMS should evolve to be applicable to the whole data supply chain from data origination to distribution to the next intended user, taking into consideration the intended use of data.
- ▼ Recommendation The QMS established in accordance with 3.2.1 should follow the International Organisation for Standardisation (ISO) 9000 series of quality assurance standards, and be certified by an approved organisation.
- Within the context of the established QMS, the skills and knowledge required for each function shall be identified and personnel assigned to perform those functions shall be appropriately trained. States shall ensure that personnel possess the skills and competencies required to perform specific assigned functions, and appropriate records shall be maintained so that the qualifications of personnel can be confirmed. Assessments shall be established that require personnel to demonstrate the required skills and competencies.
- States shall ensure that the QMS includes the necessary policies, processes and procedures to assure and verify that aeronautical data is traceable to its origin to allow any data anomalies or errors detected in use to be identified by root cause, corrected and communicated to affected users.
- The established QMS shall provide users with the necessary assurance and confidence that distributed aeronautical data is adequate for its intended use.
- States shall take all necessary measures to monitor compliance with the QMS in place.
- The order of accuracy for aeronautical data, based upon a 95 per cent confidence level, shall be as specified in Annex 11, Chapter 2, and Annex 14, Volumes I and II, Chapter 2. In that respect, three types of positional data shall be identified: surveyed points (runway thresholds, navigation aid positions, etc.), calculated points (mathematical calculations from the known surveyed points of points in space/fixes) and declared points (e.g. flight information region

boundary points).

Annex 4 — Aeronautical Charts, section 2.17 "Aeronautical data" and associated Appendix 6. "Aeronautical Data Quality Requirements" contain similar provisions and Annex 4 refers to the data quality requirements in Annex 15. Quality system is also required in Doc. 8126, AIS manual Chapter 1, 1.3. The accuracy, resolution and integrity of aeronautical data are required in Doc. 9674, WGS-84 Chapter 2. Quality assurance guidance for aeronautical data within instrument flight procedures may be found in Doc.9906, Quality Assurance Manual for Flight Procedure Design.

1.5. The Data Quality Process

The Aeronautical Information data process extends from the original data sources (e.g. surveyors, procedure designers) through AIS and publication to the end-users of the data in aeronautical applications. That data process is not simple: it is a series of complex functions within a sequential flow, particularly from data origination through to the publication of the State Aeronautical Information Publication (AIP) and other media derived from the AIP for end-use.

The aeronautical data management standard is required to:

- Ensure compliance of the data quality reported to National Administrations, as specified in this document:
- Ensure that the data management processes are carried out such that the integrity of the data is not jeopardised at any point in the process;
- Design the data collection and handling processes such that due regard is paid to the risk of error;
- Operate multi-layer data integrity management tools that enable the detection of discrepancies against known and tested logic and the appropriate rules;
- Ensure that data management tools are developed and managed in a controlled manner

- to ensure the integrity of the overall process;
- Provide for the development of appropriate metadata to ensure that complete audit trails are always available.

For the required quality of service/data to be provided, a QMS is required for all organisations operating within the total aeronautical data chain.

The Aeronautical Data Chain (Figure 1) shows the overall data process chain from origination to end-use. This guidance material, however, only applies to those elements of the process shown in green, from origination through to publication. Thereafter, it is considered that the requirements published in e.g. ED-76 (Standards for Processing Aeronautical Data) apply. However, the generic process described in section 8 does place the whole data supply chain in context and much of this material provided would be equally applicable throughout the complete process, to data use.

Such a complex data chain encompassing manifold actors, steps, processes, procedures and tools calls for special arrangements between the various partners to properly organise their interaction, to enable interoperability and quality service provision. Data supply chain management shall be based on a QMS and be supported by Service Level Agreements (SLA) as addressed in Appendix 7 of this Manual.

1.6. The Relationship between Quality and Safety

Quality management is a means of standardising a process and providing the capability to meet a set of pre-defined requirements. QMS offer the ability to formalise an organisation's processes and to provide assurance that process requirements are being met. Organisations define what their quality objectives are, in most cases focused on customer/stakeholder satisfaction (e.g. ISO-9000's reference to "customer focus").

It is possible to meet customer/stakeholder requirements while not meeting the objectives of safety. Requirements for protective systems, such as MS, are based on an objective determination of risk, and define quality in terms of safety requirements instead of customer/stakeholder requirements. Once process requirements are set, though, assurance processes for both safety and QMSs are highly similar. Safety management and

quality management can be highly complementary and must therefore work closely together to achieve the overall organisational product or service goals of Aviation Safety. Depending on a specific State's regulatory requirements, an SMS may not require an organisation to have QMS, but if it has both, they should not conflict with one another. Where there is a conflict, the SMS shall take precedence.

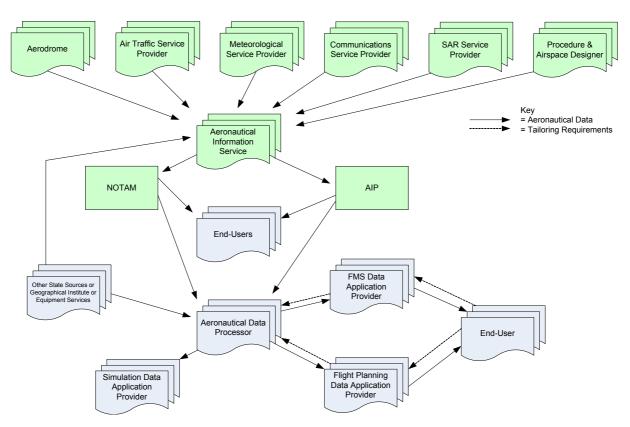


Figure 1-1 Aeronautical Data Chain, reference: Industry Standards

Concept and Vocabulary

2.1. Standards and ISO

Standards provide greater structure in the work environment and thereby make life simpler and easier by bringing about advantages such as better quality, more safety and prompter exchanges. The more widely communicated, accepted and utilised, the better are the standards. Some standards relate to some type of measurements such as weights and dimensions, while others relate to processes, that is, how things are done. Under the framework, ICAO Contracting States follow the standards stipulated in the Annexes to the Convention on International Civil Aviation to ensure safety, regularity and efficiency in the operation of international air navigation.

The International Organisation for Standardisation, established in 1947 and based in Switzerland, prescribes controlling the basic process whereby an ISO International Standard is updated and released. ISO is a worldwide federation of national standards bodies, which are responsible for standards of some 162 countries, many of which are government organisations. The objective of ISO is to promote the development of standardisation and related activities globally with a view to facilitating international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity.

2.2. Background to ISO 9000 Series

The work of preparing International Standards is normally carried out through ISO specialised technical committees (TCs). ISO/TC 176- Quality management and quality assurance, the Secretariat of which is held by the Standards Council of Canada, is the ISO technical committee responsible for developing and maintaining a

universally accepted set of quality management standards.

The ISO 9000 series, as it became known, was first published in 1987 but it was not until 1994 that the first revisions were published. The reason was that management systems were new to many of the organisations engaged in establishing quality systems based on ISO 9000 standards. In this situation, ISO/TC 176 believed that making major changes in the standards could run the risk of disrupting such efforts. Consequently, the 1994 revisions were relatively minor and mostly related to the removal of internal inconsistencies.

There are many reasons why a new series of the standards was published in 2000. First, ISO International Standards have a normal review cycle of five years. Secondly, the user community requested it. The year 2000 revisions represented a thorough overhaul of the standards to take in developments in the field of quality and the considerable body of experience that had built up since implementing ISO 9000. The users demanded a process-oriented approach and a defined route for performance improvement. The ISO 9000 series which standards, represents a major improvement over the two earlier versions, was subsequently published in December 2000.

On November 2008, an updated version of the ISO 9001 Standard, ISO 9001:2008, was released. ISO 9001:2008 was developed to clarify the existing requirements of ISO 9001:2000, and to improve compatibility with ISO 14001:2004.

The latest revision of the Standard, ISO 9001:2015, was released in September 2015. There are many new requirements, and some that were implicit in previous editions of the Standard, are

now made explicit. The main areas to be considered are risk management, change management/change control, performance metrics, and contingency actions (e.g. Business Continuity Planning).

2.3. What is Quality?

The literature on quality management provides a broad range of definitions of quality. Some literature notes that quality is a subjective term and that individuals and organisations have their own perceptions and definitions. However, the common theme or focus of each of these definitions reflects the need for the total characteristics and features of a product or service to satisfy a specified need or use. In terms of AIS products, the word 'quality' should communicate a high level of consistent performance, reliability and overall credibility in meeting and satisfying the aviation industry's identified needs.

As individuals and organisations hold their own perception of what defines quality, there is obviously a need for a common understanding. ISO 9000 provides this in its definition of quality: the "degree to which a set of inherent characteristics fulfills requirements".). "Requirement" signifies "need or expectation that is stated, generally implied or obligatory"; "inherent" signifies "quality is relative to what something should be and what it is, especially as a permanent characteristic". For example, the price of a product may be determined by the cost and profit margin of the supplier. It is an assigned and transient feature but is not necessarily related to the quality of the product. The most important aspect is that, at minimum, it meets specified requirements.

Any feature or characteristic of a product or service that is needed to satisfy user needs or achieve fitness for use is a quality characteristic. When dealing with products, the characteristics are mostly technical, for example accessibility, availability, operability and durability, whereas

service quality characteristics have a human dimension, for example waiting time, delivery time, accuracy and accessibility. These characteristics are measurable and consequently can be used to monitor the quality of the product or service.

AIM has become one of the most valuable and important enabling services in the global air traffic management (ATM) system. Computer-based navigation systems, area navigation (RNAV), required navigation performance (RNP) and ATM requirements introduced a need for new corresponding AIS requirements for quality and timeliness of information.

2.4. Quality Control

The quality control function of an organisation first evolved when inspectors were hired to inspect products to differentiate between the good and the bad. The 100 per cent inspection later evolved into sampling inspection. Quality control is a part of quality management focused on fulfilling quality requirements. In other words, the operational techniques and activities, such as sampling inspection mentioned above, are used to fulfill the requirements for quality. The nature of this approach remains basically detection and that is considered a reactive downstream approach – correction only after problems occur.

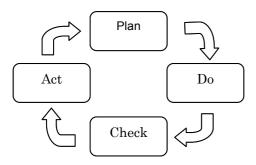
2.5. Quality Assurance

Quality assurance is also a part of quality management, but it is focused on providing confidence that quality requirements will be fulfilled. In other words, it pertains to all those planned and systematic actions necessary to provide adequate confidence that a product will satisfy the requirements for quality. This is a fundamental shift in concept from the reactive downstream approach of quality control by means of detection, to a proactive upstream approach that controls and manages the upstream activities to prevent problems from arising.

2.6. Quality Improvement

Quality improvement is another part of quality management that is focused on increasing the ability to fulfill quality requirements. It is not concerned with correcting errors but concerned with doing things better to improve system efficiency and effectiveness.

ISO offers the Plan-Do-Check-Act (PDCA) cycle as a useful tool for continual improvement. The methodology applies to both high-level strategic processes and to simple operational activities.



Plan - Plan the improvement

Do - Implement the improvement

Check - Monitor, and measure the results against policies, objectives and requirements

Act- Take actions to continually improve the performance

Figure 2-1 PDCA cycle

2.7. Quality Management System (QMS)

As defined in ISO 9000, a QMS is a management system that directs and controls an organisation regarding quality. Activities generally include the following:

- Establishment of a quality policy and quality objectives
- Quality planning
- Quality control
- Quality assurance
- Quality improvement

The intent of the ISO 9000 QMS is to provide a management framework for the organisation to comply with applicable requirements, control its processes and minimise their risk, and ultimately satisfy customer needs and expectations.

Note: The term "customer" is frequently referred to in ISO 9000. The equivalent term used in ICAO documentation is "user".

2.8. Quantifying Quality Costs

The cost of quality, as a measure of quality, is the ultimate test to evaluate the effectiveness of every quality initiative. It consists of four major components, as follows:

- Internal failure costs Costs associated with defects or nonconformance found before the customer receives the product or service, for example correcting wrongly encoded aeronautical information when captured by automatic checking procedures.
- ✓ External failure costs Costs associated with defects or nonconformance found after the customer receives the product or service, for example investigating complaints from a pilot for the late issuance of aeronautical information.
- ✓ Appraisal costs Costs incurred to determine the degree of conformance to quality requirements, for example procedures and resources to enable the verification of aeronautical information, and monitoring of the transit time of the Integrated Aeronautical Information Package.
- ✓ Prevention costs Costs incurred to keep failure or nonconformance and appraisal costs to a minimum, for example training staff in quality practices and procedures.

The advancement in approach from inspection, quality control and quality assurance to quality management reduces the quality cost. At one end of the spectrum inspection is easy to implement, involving only a small part of the

organisation with simple but effective tools and skills. At the other end, quality management involves the entire organisation and is far more complex to implement effectively. Besides the reduction of the quality costs, a well-implemented QMS may bring many other benefits to the whole organisation, including staff motivation.

2.9. Quality Management Principles

From the collective experience and knowledge of the international experts who participated in ISO/TC 176, the Committee derived eight quality management principles on which the standards of the revised ISO 9000:2015 series are based. These principles reflect best practice and are designed to enable continual improvement of the system. They can be used by senior management of AIM authorities as a framework to guide their organisations towards improved performance. These principles are as follows:

- Customer Focus Organisations depend on customers and therefore should understand current and future customer needs, meet customer requirements, and strive to exceed customer requirements. ISO 9001 places much emphasis on customer focus. AIM authorities should document customer requirements and monitor the quality of services as perceived by the customers. The means to achieve this may include the conduct of regular customer satisfaction surveys, liaison meetings with representatives of the customers and visits to the operation facilities of the customers. All customer feedback and complaints should be formally recorded and followed up without delay. Details of action taken recommendations for improvement should be documented. It is also important to give a formal response to the customer before the feedback or complaint is considered "closed".
- ▼ Leadership Leaders establish unity of purpose and direction of the organisation. They should create and maintain the internal environment in

which people can become fully involved in achieving the organisation's objectives. The implementation of a QMS will hardly be successful if there is lack of commitment from top management. As such, it is critical that top management have a sound appreciation and understanding of all facets of quality management, particularly issues pertaining to quality assurance. This understanding and appreciation should be obtained through appropriate training and experience. It must also be remembered that leadership can be found at all levels within an organisation and identifying this quality may be of great benefit in establishing a quality culture within a specific section or throughout the entire organisation.

- **✓ Involvement of People** People at all levels are the essence of an organisation and their full involvement enables their abilities to be used for the organisation's benefit. Staff must be suitably qualified and competent in their jobs, as the quality of their work directly affects the quality of service. This can be achieved through the provision of appropriate training and evaluation. Quality awareness training should also be provided to all relevant staff to heighten responsibility, accountability and consciousness, that is, to assist in building a culture. With quality-focused implementation of the QMS, staff needs to take on additional responsibilities such as the day-today consistency checks as part of the data for product quality assurance and control processes.
- Process approach A desired result is achieved more efficiently when activities and related resources are managed as a process. A process is a set of interrelated or interacting activities that transform inputs into outputs (ref Doc 9906 Vol 1, chapter 6 "Output of the Quality Process"). A QMS can be thought of as a single large process that uses many inputs to generate many outputs. In turn, this large process is made up of many smaller processes. All activities and resources related to AIM, including operational

and administrative must be managed as processes.

- System approach management to Identifying, understanding and managing interrelated processes as a system contributes to the organisation's effectiveness and efficiency in achieving its objectives. AIM providers may already have documented many of the operational and administrative processes for service provision. These processes should be reviewed and any differences between the ISO requirements and existing processes identified. Quality system procedures should then be developed for these differences and applied so that the processes to achieve the best results can be aligned and integrated.
- Continual improvement Continual improvement of the organisation's overall performance should be a permanent objective organisation. Specifically, effectiveness and suitability of the QMS must be evaluated and areas for improvement identified and rectified. Management reviews must be conducted regularly using the data collected from the monitoring and measurement process to identify areas for further improvement. Channels may need to be established to allow all staff in the organisation to make suggestions on ways to improve the service.
- Factual Approach to Decision-Making Effective decisions are based on the analysis of data and information. Among other things, an AIS automation system should be developed to ensure the accuracy of each of the information elements. Other performance statistics or indicators, such as timeliness and conformance to the specification, user satisfaction survey results and supplier performance records should also be collected in the data and analysis process.
- Mutually beneficial supplier relationships An organisation and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value. Suppliers should be evaluated and

selected on their ability to meet purchase order requirements and on their past performance.

2.10. The ISO 9000 Series of Standards

The ISO 9000 series of standards has been developed on eight quality management principles (see 2.9) with an emphasis on system effectiveness. The entire series has been reduced from more than 20 standards in the 1994 version. There are only 4 standards in the 2015 version, as follows:

- ▼ ISO 9000 Quality Management Systems -Fundamentals and vocabulary. This standard is provide the fundamental intended background information of QMSs and specifies the terminology phrases used in ISO 9000. It facilitates a mutual understanding of the terminology used in quality management (i.e. between the organisation, suppliers, customers, statutory and regulatory requirements).
- PISO 9001 Quality Management Systems Requirements. This standard specifies requirements of a QMS where the organisation needs to demonstrate its ability to provide products that fulfill customer needs and applicable regulatory requirements and aims to enhance customer satisfaction through the effective application of the system. Clauses 4 through 10 contain the required elements of the QMS. The details of the clauses and their meanings are given in Chapter 3.
- Guidelines for performance improvements. This standard provides guidelines beyond the requirements given in ISO 9001 that consider both the effectiveness and efficiency of the QMS. The aim of this standard is to improve the performance of the organisation and satisfaction of customers and other interested parties. This international standard consists of guidance and recommendations and is not intended for certification, regulatory or contractual use or as a guide to the implementation of ISO 9001.

▼ ISO 19011 Guidelines for quality and/or environmental management systems auditing. The standard provides guidance on the principles of auditing, managing audit programmes, conducting QMS audits, as well as guidance on the competence of quality and management system auditors.

For the ISO 9000 family to maintain its effectiveness, the standards are periodically reviewed to benefit from new developments in the quality management field and from user feedback.

Based on input from the user community, ISO/TC 176 will continue to evaluate and adopt new concepts in the field of quality management for incorporation into ISO standards.

The ISO 9000 series of standards and other ISO publications can be purchased from ISO member institutes. A list of existing ISO member institutes is available on the ISO website at www.iso.org. For countries where there is no ISO member institute, a soft copy of the standards can be purchased online from the ISO website.

The Anatomy of the ISO 9001 QMS

3.1. Introduction

The ISO 9001 International Standard specifies the requirements for a QMS applicable to all organisations, products and services. It is the only standard in the ISO 9000 family of standards that can be used for certification of the system. The aeronautical information service provider can only seek certification of the QMS after validating that every ISO 9001 requirement is met. This chapter provides a detailed account of the requirements specified in the international standard, supplemented with an interpretation of their meaning in the context of the provision of aeronautical information services for international air navigation.

Note: ISO 9001 only defines the fundamental requirements and framework for certification. Each aeronautical information service provider needs to formulate its own QMS based on its own needs, processes and circumstances. As operating services that have been running successfully for a long time, it is likely that the aeronautical information service providers will already have a system or practices in place to address the ISO requirements. They would, therefore, quite often be able to address the requirements of ISO 9001 in a simple and cost-effective manner.

ISO 9001 also requires that a "process approach", that is, one of the quality management principles, be followed when developing and maintaining an effective QMS. For an aeronautical information service provider to function effectively, it must identify and manage numerous linked processes. To name but a few, these may include the following:

▼ The process for review of the requirements related to the products;

- ▼ The process for provision of such products; and
- The process for monitoring the quality of the products.

A "process approach" can be defined as the application of a system of processes, together with the identification and interaction of these processes, and their management.

3.2. Structure of ISO 9001

ISO 9001:2015 is organised into the following ten clauses:

- Clause 1 Scope
- ▼ Clause 2 Normative reference
- Clause 3 Terms and definitions
- Clause 4 Context of the organisation
- ▼ Clause 5 Leadership
- Clause 6 Planning
- Clause 7 Support
- ▼ Clause 8 Operation
- ▼ Clause 9 Performance evaluation
- Clause 10 Improvement

The first three clauses are introductory and set the stage for the requirements. The *shall* clauses stipulated in the remaining clauses contain the actual requirements. The QMS described in Clause 4 addresses the major groups of processes, within the process-based QMS.

3.3. The Process Model

Activities that receive inputs and convert them to outputs can be considered a process. In many cases, an output from one process will form the input to the next process, for example data is received from an aerodrome operator, entered into the AIM database, and when combined with other data, is provided as an output for charting or a document.

To function effectively within a quality system, AIM must identify and manage numerous linked processes. Systematic identification and management of these many processes and the interactions between these processes that are used within AIM are often referred to as a "process approach".



Figure 3-1 Simple process

A more sophisticated conceptual process model recognises the role that the customer plays in the definition of requirements as inputs. By monitoring customer satisfaction, or in some cases dissatisfaction, we can monitor and evaluate whether defined customer requirements have been met.

Figure 3-2 demonstrates that the process approach model and the Quality System starts and finishes with the customer. In the first instance there is the customer requirement on the left-hand side of the diagram. On the right-hand side is the degree of customer satisfaction with the product or service that has been provided based on the inputs. Customer satisfaction is measurable against the initial requirements and specifications. Perhaps the most important feature of the model is the need to obtain information about customer satisfaction. This feeds back into the monitoring and evaluation phase, which is in-turn a measure of the overall performance. The loop into management responsibility is there to show that management has an important role to review customer feedback to ensure that the appropriate policies, objectives and strategies are in place, along with the necessary resources, to meet the quality challenges.

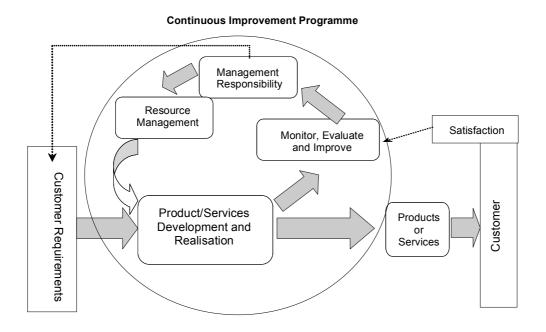


Figure 3-2 Conceptual Model of the "Process Approach"

Resources are a key component of the QMS. Resources are the equipment, materials and people that make the overall system work. Human resources need to be properly trained and competent to achieve the desired outcomes. A QMS will strive for excellence, always looking for ways to do the work better through a programme of continuous improvement. A QMS will continue to challenge the outputs against the customer requirements and specifications to ensure that customer's expectations are met and exceeded. Therefore, all the elements in the Continuous Improvement Programme are important.

3.4. General Requirements

The General Requirements for the implementation of a QMS are to:

- ▼ Identify the processes needed for the QMS
- → Determine the sequence and interaction of these processes
- Determine criteria and methods required to ensure the effective operation and control of these processes
- Ensure the availability of information necessary to support the operation and monitoring of these processes
- Measure, monitor and analyse these processes, and implement action necessary to achieve planned results and continual improvement.

3.5. Management Responsibility

AlM Managers are tasked with many responsibilities within the Quality System. These responsibilities relate to:

- Quality Policy
- Commitment to Quality
- Customer Focus
- Planning

Each of these responsibilities is addressed in further detail below. A QMS is dependent on all

those involved in its provision being quite clear about their responsibilities and authorities. The development and use of accurate position descriptions for all staff in AIM that address both the responsibilities and authorities of each position can accomplish this.

3.5.1. Quality Policy

The International Standards require management to have a Quality Policy in place that is in writing and is visible to staff. The quality policy forms an important element for the work of the AIM, and establishes:

- A commitment to quality;
- What the quality objectives or the organisation are; and
- How the objectives relate to customers' expectations.

The Quality Policy must address these issues and ensure that it:

- ▼ Is appropriate for the needs of the organisation
- Includes commitment to meeting requirements and continual improvement
- Provides a framework for establishing and reviewing quality objectives
- Is communicated, understood and implemented throughout the organisation
- Is reviewed for continuing suitability

A Quality Policy includes AIM's definition of quality and how management and staff will demonstrate their commitment to the policy, and provides an identifiable focus for all staff in their daily activities.

One of the best techniques to develop a Quality Policy is a facilitated meeting of all staff at which individual definitions of "quality" can be consolidated to provide a definition and statement that encapsulates all staff's beliefs and understandings.

3.5.2. Commitment to Quality

AIM Managers must take an active responsibility in the establishment and maintenance of a Quality System. This role includes:

- ▼ Definition and implementation of quality policy
- Communicating the quality policy within the organisation, including the importance of meeting customer, regulatory and legal requirements
- Setting objectives, strategies and targets derived from the policy
- Position descriptions that describe the role, responsibilities and authorities for all staff
- Ensuring that resources are adequate; Regular reviews of the effectiveness of the system

3.5.3. Customer Focus

Meeting customer and regulatory requirements is our primary business. To ensure that these requirements are met, and that customer confidence is maintained, AIM must have a clear understanding and defined specifications in the form of user requirements. Measurement and analysis of outcomes will be difficult, if not impossible without this specification.

3.5.4. Planning

The step that follows the publication of the Quality Policy is the setting of objectives, strategies and targets that will show how the organisation expects to implement the quality policy. Targets need to be realistic, relate to the customer's statement of requirements and measurable. The plan must include details of the continual improvement programme.

Thorough planning sets the scene for other important aspects of the organisation's operations:

- Staff performance measurements;
- Budgets

- Overall business performance measurements
- Asset and facility purchases
- ▼ Staff competencies and training requirements
- ▼ Other resource requirements
- ▼ The continuing improvement programmes

In some cases, planning may be conducted as a matter of routine, for example on an annual basis, whereas in others, specific project planning may be required for new or substantially altered products or services.

Planning enables an organisation to exercise control over routine business and changes to ensure that the QMS is effective during the routine activities and after change.

3.6. Administration

3.6.1. Responsibility and Authority

A QMS requires responsibilities and authorities for all staff members to be defined and communicated. This means that everyone in the organisation knows what they are responsible for, what the level of their authority is and what the reporting arrangements are. Responsibilities and authorities can be identified, recorded and communicated through published job descriptions. An organisational chart should supplement job descriptions.

3.6.2. Quality Representative

Resources should be assigned to look after the Quality System, and who has the responsibility and authority that includes:

- Ensuring that processes for the QMS are established and maintained
- Reporting to senior management on the performance of the QMS, including needs for improvements
- 3. Promoting awareness of customer requirements throughout the organisation

3.6.3. Internal Communications

Internal communications are all about keeping everybody in the team informed about what is going on and to keep abreast of the processes, changes and outcomes. This includes the good news and the bad news.

Effective internal communications will provide the ability to:

- 1. Receive information quickly and act on it
- 2. Build trust among the staff
- 3. Identify business opportunities
- 4. Identify opportunities for improvement

3.7. Resource Management

3.7.1. Provision of Resources

Organisations are required under the International Standards to determine and provide in a timely manner, the resources needed to:

- 1. Implement and improve the processes of the OMS
- 2. Address customer satisfaction

In this context, the term "resource" applies to personnel, facilities and equipment.

3.7.2. Human Resources

Staff who are assigned responsibilities defined in the QMS must be competent with applicable education, training, skills and experience.

People assigned to carry out quality activities are required to be competent to do them, without which a quality product or service is less likely to result. The standards require competence to be based on appropriate or applicable education and training and on skills and experience that they possess. There is however, no requirement to have all four, only those applicable to the task.

Appropriately qualified and experienced staff in sufficient numbers is a pre-requisite for an AIM organisation to provide safe and timely aeronautical information.

The most obvious users of aeronautical information are pilots. Other users of the information represent those engaged in airline operational control and those involved in the provision of ATS. The AIM organisation must be technically oriented for the services being provided. Given the relevance of aeronautical information to global air traffic, it is important to promote the correct level of technical proficiency within AIM and ensure that AIM has the appropriate status in the parent civil or military organisation.

This part of the QMS requires AIM to have procedures in place for assessing the competence of personnel required by the organisation to check, edit and publish aeronautical information. These procedures should include the levels of training, qualification and experience necessary to achieve the expeditious publication of information.

Equally, staff responsible for the collection, collation, checking, coordination and editing of information published in the Integrated Aeronautical Information Package must have a thorough understanding of the content, standards, format and other user requirements related to the material being published.

Ideally, staff responsible for checking, coordinating and editing aeronautical information should have an extensive background as a pilot or within air traffic services, or have received specialist training in AIM.

For example, staff responsible for the operation of the NOTAM office would be:

- Conversant with the standard format, codes and abbreviations for NOTAM;
- Conversant with the operational requirement for air traffic services, flight operations personnel,

flight crews and the services responsible for preflight information to be kept informed of operationally significant information that may affect the safety of air navigation; and

Competent in the operation of the aeronautical fixed telecommunication network (AFTN).

3.7.3. Training, Awareness and Competency

This part of the standard requires an organisation to:

- ▼ Determine competency needs for personnel performing activities affecting conformity to product requirements
- ▼ Where applicable provide training to achieve the necessary competence
- Evaluate the effectiveness of the training provided
- Ensure that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objective
- Maintain appropriate records of education, experience, training and qualifications

3.7.4. Checking Competence and Training

AIM needs to regularly review the competence, experience, qualifications, capabilities and abilities of its staff to ensure that any skills and qualifications needed by AIM are available for the tasks to be completed.

Training is required when deficiencies are noted, or when new employees start work. Any training that is required may be carried out in stages, and may be in the workplace, in-house or at an external location.

The scope of the training and checking is largely a matter for the organisation to determine, but generally, training for AIM would include the following topics:

- Principles of the Aeronautical Information Service
- Organisation of AIM

- Responsibilities and Functions of AIM
- ▼ ICAO Documents
- ▼ AIM Products
- Responsibilities and Limitations
- ▼ The Integrated Aeronautical Information Package
- Relationships with External Agencies
- Change Management
 - ▼ Applicable Policies and Procedures
 - ▼ Standard Operating Procedures
 - Quality Processes
 - Coordination Requirements
 - Collation and Processing
 - ▼ Data Entry and Verification
 - ▼ Data Structures
 - Formats to be used
 - Checking Procedures and Processes
 - ▼ File Management
 - ▼ Record Keeping
 - Publication and Production
 - Distribution
- AIM Automation

Records should be maintained to show what competences staff possess, what training has been carried out and the results of that training. Records that demonstrate successful completion, *i.e.* effectiveness, of a training programme and the competence of staff can and should be kept simple.

At their simplest, records may consist of a 'sign-off' to confirm that staff can carry out specific processes or follow certain procedures. These records should include a clear statement when a person is deemed to be competent to do the task for which they have been trained.

3.7.5. Facilities and the Work Environment

In addition to adequate numbers of suitably experienced and competent personnel, AIM also requires appropriate accommodation and adequate facilities to get the work done and so provide quality services.

This part of the ISO Standards calls for AIM to determine, provide and maintain the facilities it needs to achieve product conformity, including:

- ▼ Workspace
- Equipment, hardware and software
- Supporting services

In simple terms, this means that AIM needs to identify, provide and maintain adequate space, suitable equipment, tools and systems to enable staff to do their job.

Note: ICAO Aeronautical Information Services Manual (Doc 8126) provides guidance on facilities and equipment for aeronautical information services.

AlM organisations are moving more and more towards automated systems to improve the efficiency, accuracy and cost effectiveness of their businesses. AlM needs to ensure that any systems automation and services are designed with the intent of avoiding incompatibilities, divergences and unnecessary duplication of effort and importantly that there is an overall systems integration management plan in place. Standardisation of procedures, products and services is essential for the successful automation of aeronautical information services.

3.8. Product Development and Service Delivery

3.8.1. Production Processes

Production processes are the sequence of processes and sub-processes required achieving the delivery of a product or service. Planning of these processes must be consistent with the other requirements of the organisation's QMS and documented in a form suitable for the organisation's method of operation.

During the planning of the processes to bring a product or service to fruition, AIM would consider the following matters:

- Objectives for the product, service, project or contract
- The need to establish processes and documentation, and provide resources and facilities specific to the product/service
- Verification and validation activities, and the criteria for acceptability
- ▼ The records that are necessary to provide confidence of conformity of the processes and resulting product/service

All this planning information should be documented. For regular product and/or service, this planning activity only needs to be carried out at the initial stage and revised when there is a change in process or resources that will affect the delivery of the service or manufacture of the product.

For project work and 'one-off items', you may have to carry out the planning process for each project and item.

Note: Documentation that describes how the processes of QMS are applied for a specific product, service, project or contract may be referred to as a quality plan.

3.8.2. Identification of Customer Requirements

As with any business, AIM needs to determine its customer requirements. These requirements include:

- Product/service requirements specified by the customer, including the requirements for availability, delivery and support
- Product/service requirements not specified by the customer but necessary for intended or specified use
- Obligations related to product/service, including regulatory and legal requirements

The following definitions are used in this section:

Customer - The eventual (individual) user of the AIM products or services

 Author Area - An identifiable group or organisation that has ownership of the information provided by AIM

Note: For the purposes of these Guidelines and the ISO requirements, the Author Area can be considered a special type of customer since they have a vital role in determining if the information provided to and by AIM is correct and appropriate.

3.8.3. Review of Product/Service Requirements

AlM with an established Quality System, or in the process of establishing such a system would review the identified customer's requirements, together with any additional requirements that might be necessary.

This review must be conducted prior to the commitment to supply a product to the customer, e.g. submission of a tender, acceptance of a contract or order, and to ensure that:

- Product/service requirements are defined
- Where the customer provides no documented statement of requirement, the customer requirements are confirmed before acceptance
- Contract or order requirements differing from those previously expressed (e.g. In a tender or quotation) are resolved
- ▼ The organisation can meet defined requirements.

The results of the review and subsequent follow up actions must be recorded and form part of the quality records.

When product/service requirements are changed, AIM must ensure that any associated documentation; procedures, processes etc. are also amended to reflect the changes, and that the staff are kept aware of the changed requirements.

An example of a customer requirement might relate to the supply of aeronautical data or information in a specific electronic format to meet customer needs and specifications.

3.8.4. Customer Communication

Effective communications with the customers are an important part of the work of AIM. This part of the standard requires the organisation to identify and put arrangements into place for this communication to take place. The communications plan must include information about:

- ▼ Product/service information
- Enquiries, contracts or order handling, including amendments
- Customer feedback, including customer complaints

3.8.5. Understanding and Meeting the Customer's Requirements

All parts of the customer's order or contract need to be reviewed to ensure that you can meet your commitments. The way the customer provides the order may vary in form and may be a:

- ✓ Written order
- Verbal agreement
- Telephone order

Often problems can arise because of a misunderstanding about what was ordered. This makes good communications with the customer an essential part of good business and is essential to resolve any misunderstandings. This might mean that AIM will make someone specifically responsible for communications with the customers.

Written orders, such as those received by mail or facsimile, provide a permanent record of the order details.

When telephone and direct computer link orders are received, special provisions need to be made to record and confirm the order. Methods of handling these could be as follows:

One approach to telephone orders is to provide a pad (these could even be pre-printed forms) for the order receiver to record the details of

the order and read it back to the customer, asking for confirmation. Alternatively, the details may be faxed or mailed back to the customer.

Where electronic media are involved, two options exist: either save permanently on disk or print out the details.

At the time the order is received, AIM needs to determine if there are any design requirements in the order and to see if the commitment to the customer can be met.

The record of the review can be as simple as a notation on the order that it can be fulfilled with the signature of the reviewer and the date. Where a more complex review is called for, how the review is recorded is at discretion.

3.9. Design and/or Development Planning

Many AIM organisations provide an Instrument Flight Procedures Design function. This means that AIM is required to plan and control design and/or development of the instrument procedures. Design and/or development planning is required under this part of the Standard to determine:

- ▼ Stages of design and/or development processes
- Review, verification and validation activities appropriate to each design and/or development stage
- Responsibilities and authorities for design and/or development activities

Interfaces and internal communications between different groups involved in design and/or development must be managed to ensure effective communication and clarity of responsibilities.

3.9.1. A Disciplined Approach to Design and/or Development

It is important to understand that this part of the ISO Standard is intended to provide controls for the design and/or development process and in no way attempts to restrict the creativity of the designer. The design controls should generally cover the following to establish:

- The design aims, planning how the design is to proceed, and who is to carry out the design
- ✓ What is needed to be known for the design to proceed
- ▼ The form of the output from the design, and to
- Review, on completion of the design, whether it has achieved what was wanted (flight validation)
- Modify the design to include changes, which may occur at any stage of the process and for any reason.

3.9.2. Who is going to do what?

AIM needs to plan what is to be done and who is going to do it in relation to the design. Responsibilities for design should be clearly assigned and the methods for the development and updating of the design plans should be established. Design plans do not have to be complex. They can be as simple as a flowchart, showing the steps to be taken and who is to do them. As part of the requirements, AIM should also plan how the design review, verification and validation activities are to be carried out.

3.9.3. Design and/or Development Inputs

Inputs relating to product requirements must be defined and documented, and include:

- ▼ Functional and performance requirements
- ▼ Applicable regulatory and legal requirements
- ▼ Applicable information derived from previous similar designs
- Any other requirements essential for design and/or development

These inputs must be reviewed for adequacy and any incomplete, ambiguous or conflicting requirements resolved.

3.9.4. Does AIM have it Right?

Verification is checking that the results at the end of the design process meet the requirements identified as necessary at the beginning of the design process. For larger projects, the design process is often broken into stages and design verification may be carried out on a stage-by-stage basis. The design plan should identify the verification method to be used, including who is to carry it out, how it is to be performed and what records are to be kept. There are many ways to verify the design, such as:

- ▼ Performing alternative calculations
- Comparing the new design with a similar proven design (if available)
- Undertaking tests and demonstrations e.g. Flight validations
- Reviewing the design stage documents before release

AlM should determine which are appropriate and effective. Sometimes, regulatory agencies will describe the means required to verify the design. Customers may need to be involved in the verification process.

3.9.5. Does it Work?

Validation is the process of checking that the final product and/or service will be capable of meeting or does meet the customer's needs in use. This may include marketing trials or operational testing. It is the final stage in the design process and is an important opportunity to prevent serious financial loss by failure to supply acceptable product and/or service. The results of the verification and validation processes can be fed back into each stage of the design process, leading to modifications and improvements or even the next design revision or product and/or service generation. For many products and/or services, validation is a relatively simple process. An example could be a new design of a visual chart, which could be validated by testing of the prototype, followed by test marketing. For other types of product and/or service, the validation

of the total performance range cannot be achieved until the actual conditions occur. It is also acceptable for the customer to perform the validation and to provide feedback of the results to the designer. Many software projects are validated in this way.

3.9.6. Control of Design and/or Development Changes

Design and/or development changes must be identified, documented and controlled. This includes evaluation of the effect of the changes on constituent parts and delivered products. The changes shall be verified and validated, as appropriate, and approved before implementation. The results of the review of changes and subsequent follow up actions must be documented.

Note: See ISO 10007 for guidance.

3.9.7. Controlling Changes

For AIM, change is a way of life. Changes occurring due to the customer, market, design review, verification or validation activities must be recorded, reviewed and approved. The extent to which the design needs to be to be modified because of the changes needs to be considered. The QMS has formal requirements for document and change control that must be followed. Design changes may also require you to reconsider reviewing with the customer what is required. The design change control process may need to be no more complicated than the system described earlier to control other documents. In other situations, the controls may need to be more complex, e.g. those involved in software design, may have to be involved in configuration management. Further advice on this aspect is available in ISO 10007, Quality Management - Guidelines for Configuration Management.

3.9.8. Product Identification and Traceability

AIM should identify;

- The product by suitable means throughout production and service operations when appropriate
- ▼ The status of the product with respect to measurement and monitoring requirements
- Record the unique identification of the product, when traceability is a requirement.

Examples of this might be the use of amendment numbering or specific page identification.

3.9.9. Keeping Track of What AIM is Doing

Identification is knowing what the product and/or service is which resulted from a process, even an intermediate process. When you need to identify a product and/or service, the methods used and the records to be kept need to be defined. The recording of part numbers, job numbers, bar codes, the name of the person who carried out the service, colour codes or the revision status and version number of a software package being developed are just some examples of identification.

Traceability is knowing where the product and/or service came from, where it is now and in the case of services, what stage it is at. Most businesses, irrespective of size, will have a need in some stage of their operations to keep track of what goes where, what's been done and what still is to be completed. When traceability is a requirement, typical methods used include:

- Job card entries
- Data checked and confirmed, data entry complete
- ▼ Service records, e.g. signing-off a work aspect
- Tagging
- Computer tracking



When servicing a car, the status of each operation on the service checklist is changed from 'to be done' to 'done' by ticking off each operation on completion. In a phone answering service, the status of messages taken is initially 'message received'. On passing the message on to the client, the status changes to 'message delivered'. The phone answering service would have some suitable means of identifying the status. Some of the above techniques may be also used for identification. It should be noted that the need the requirements for traceability may result in additional paperwork and costs. So, be aware of the balance between really needing to know and superfluous information. An example of an AIM checklist is shown on Table 3-1.

AIM needs to establish what the internal requirements are and document them. In AIM, identification and traceability are specified requirements. If the need for a product recall arises, an effective identification and traceability system will make the task a lot easier. An effective identification and traceability system will make it much easier to replace the poor-quality service and initiate steps to avoid recurrence such as retraining or a review of process operations. Records that provide the traceability (including the change requirements) should be retained as part of the Quality Records. The method(s) AIM adopts as being most suited to its business should be described, e.g. in its work instructions, so that everybody knows how it works.

3.9.10. Customer Property

AIM must exercise care with customer property while it is under the organisation's control or being used by the organisation. The organisation must identify, verify, protect and maintain customer property provided for use or incorporation into the product. Occurrence of any customer property that is lost, damaged or otherwise found to be unsuitable

for use shall be recorded and reported to the customer.

Note: Customer property may include intellectual property.

Occasions may arise where the customer gives you material or equipment to be used in producing the items or delivering the service. Examples could include:

- Instruments provided by the customer for measurement purposes
- Training room provided by the customer
- Special hardware of software
- Special paper for specific products

While documented procedures are not required for this aspect, the organisation is responsible for ensuring that the control of customer property is sufficiently documented to describe how it is identified and cared for. The document could simply reference in-house processes that are in use.

3.9.11. Looking After the Product and/or Service

AIM must preserve conformity of product with customer requirements during internal processing and final delivery to the intended destination. This includes identification, handling, packaging, storage and protection. It also applies to the constituent parts of a product. This part of the Standard means that none of these activities can affect the quality of the product and/or service being provided. It is up to AIM to determine how AIM will ensure that this is the case. Depending on the nature of AIM business, some or all the requirements of this part of the Standard may apply. When they do apply the arrangements for handling, storage, packaging, preservation and delivery should be recorded in AIM's process documentation. There are many areas where handling, storage and preservation, packaging and delivery problems can affect the quality of the

product and/or service. Some examples are found in the following areas:

- → Handling This might be the use of computers and/or a filing system, job-cards, or workpackages to control work in progress
- Storage/Preservation Use of computer systems to store work in progress, and off-site or other back-up arrangements
- Packaging/Delivery Use of mailing tubes or electronic transfer of data to deliver charting products to a printer for reproduction

AIM will need to examine the own procedures to determine the extent special handling procedures are needed and to document them. Packaging should be appropriate for the materials. In many cases, little or no packaging will be required. Bulk materials, such as sand, coal, wheat etc. are examples where packing consists simply of filling the carrying container. Even for such bulk transport, there needs to be a check that the container is suitable and does not contaminate the product. Large fabricated components may be simply loaded onto a truck and strapped down. Packaging should be appropriate for the product, the intended transport and end use. AIM should make sure that where packaging and marking materials are used, that they are compatible with the products being packaged or marked. Marking materials can cause corrosion or otherwise damage products and should be selected with care. Additionally, you should be aware if any regulations exist regarding packaging. These could require 'useby-dates', handling instructions or specific information regarding the contents to be displayed on the package. Examples of this might be the packaging required for chart negatives to be dispatched to the printer. Packaging needs to be robust to ensure that the film is not damaged in transit, and may require some marking to ensure that the contents are not bent or folded.

Action		!	Status	
	Reg No.	Completed	Yet to be done	
Change details registered	WP16/00	ü (DS)		
Data checked and verified		ü (DS)		
Data Entry		ü (CS)		
Entered on Charts		ü (CH)		
Airspace Handbook			х	
AIP Book			х	
Document checks complete			х	
Chart checks complete			х	
Publications to printer			х	
Publications to dispatch			х	

Table 3-1 AIM Checklist

3.9.12. Stock Control

Most businesses will probably already have a stock control system. During stocktaking it is usually possible to check the condition of products. You need to identify the storage requirements for your products and assign appropriate storage areas. Each product does not necessarily require a separate storage area. A periodic check of the condition of the product in stock is necessary if it is likely to deteriorate or become contaminated. The frequency is dependent on the nature of the product, with robust types requiring a less frequent check than perishable or fragile products. There may be regulatory and legislative requirements, or the preservation system may be specified in the customer's order. The protection of the quality of the product after final inspection and test now extends to include delivery to destination. If this is to be subcontracted out, then you will have to ensure that appropriate procedures or instructions are given in order that final delivery does not prevent or affect the product and/or service from meeting customer requirements. You may need to carry out a supplier evaluation. This may involve you in taking responsibility for the transport. In such cases, you would need to be aware of any legislation or regulations that might apply.

3.9.13. Control of Measuring and Monitoring Devices

When necessary, AIM must identify the measurements to be made and the measuring and monitoring devices required to assure conformity of product to specified requirements. This part of the standard is only applicable to those AIM where measuring or testing equipment, including test software, is used to check that what you are providing meets your customer's requirements for example the supply of data electronically to a data vendor, for example the use of cyclic redundancy checks (CRC). If, however, for example, your inspection method is visual inspection such as that use for some maps and charts, you may not need to have any measuring equipment or instruments and

this part of the Standard does not apply. Measuring and monitoring devices must be used and controlled to ensure that measurement capability is consistent with the measurement requirements. When applicable, measuring and monitoring devices must:

- Be calibrated and adjusted periodically or prior to use, against devices traceable to international or national standards; where no such standards exist, the basis used for calibration must be recorded
- → Be safeguarded from adjustments that would invalidate the calibration
- → Be protected from damage and deterioration during handling, maintenance and storage
- → Have the results of their calibration recorded
- → Have the validity of previous results re-assessed if they are subsequently found to be out of calibration, and corrective action taken

Note: See ISO 10012 for additional guidance

Software used for measuring and monitoring of specified requirements must be validated prior to use.

3.9.14 Having Confidence in the Equipment Used to Check Your Work

If use is made of measuring and testing equipment for checking compliance with the customer's requirements, AIM will need to consider how it is controlled, stored, used and its accuracy maintained at the level needed. It should be emphasised that the requirement applies only to equipment that can affect quality. If AIM is using measuring and testing equipment for indication purposes only, it does not necessarily have to be calibrated. The key message here is do not automatically calibrate everything. Calibration is the process of periodically comparing the equipment against a reference standard to determine how accurate it is and whether it is still capable of meeting the accuracy required for measurements made with it. 'Periodically' can mean

on a time basis (monthly, annually) or a usage basis (before each use or after a certain number of times used). The reference standard may have been provided with the equipment. For example, a paint thickness meter is normally supplied with a set of thickness standards. In other instances, AIM may have to have access to a suitable reference standard by buying one or using a supplier. For a reference standard to have validity, it needs to be traceable back to an appropriate recognised accurate source. This will normally be a national or international standard. There are cases where a national standard does not exist. In these cases, the sources or frame of reference needs to be described. AIM also needs to consider just how accurate the measurements need to be. How accurate the equipment needs to be will depend upon how much tolerance is permissible in what AIM is measuring. A measuring device usually must be capable of measuring to a tolerance greater than the tolerance specified for the item being measured. However, there is no point in having measuring devices calibrated to unnecessarily high precision if AIM does not need that precision for the operations. Allied with these factors is how skilled the personnel need to be to use the equipment. To make sure the measuring equipment operates effectively and gives reliable results, AIM needs to:

- Make sure it is looked after, regularly calibrated and adjusted as needed
- Describe how this will be done so that records are available which show calibration is traceable to national standards
- Make sure it is possible to identify which equipment has been calibrated and that it is suitable for use, e.g. Label the equipment

If equipment is found to be faulty, AIM needs to find out at what stage it went wrong. AIM needs to decide whether AIM needs to do anything about product AIM has passed using that equipment. The results of any review may indicate that no action is required or that a product recall is required. Test software needs to be subject to some form of validation to make sure that it can

perform the required measurements. One way is to ensure that this software can accurately and reliably identify product with a known set of faults and deficiencies. The details of how the test software is validated should be documented. Unlike hardware test equipment, test software does not experience 'drift' or ageing, so periodic revalidation may not appear to be necessary. However, software can be subject to unintended errors. Therefore, the purpose of revalidating test software is to ensure its continuing ability to perform the required measurements. Some type of secure write protection should be used, in the same manner as seals are used on hardware calibration adjustments, to minimise inadvertent adjustments. If AIM decides to carry out its own calibrations, AIM will need to have procedures for calibrating each type of equipment you use. If AIM decides to use a supplier, some additional points AIM will need to consider are:

- ✓ Ideally, the organisation should be endorsed as a calibrating service by a suitable certifying body
- The organisation should issue a certificate of calibration, which states the uncertainty of measurement. (this is another way of stating how accurately the instrument can measure)
- ▼ The certificate should indicate that the organisation can trace your calibration back to a national or international standard

AIM is free to use an organisation that has not been endorsed as described above to carry out its own calibration if this is practical, e.g. original equipment manufacturer or neighbouring company. However, the resulting records must confirm that the reference standards used for calibration are of known accuracy, normally traceable to a national or international standard. It may be possible, if AIM has several measuring instruments of a similar type, for the most accurate of these to be calibrated by a supplier then used as the basis for calibration of the others. For example, an accurately calibrated digital thermometer may be suitable as a reference standard for other less accurate temperature measuring equipment. Calibration is an expensive

operation. For AIM, the costs of calibration can be considerable. You should ensure, therefore, that AIM knows the difference between checking that process control equipment is fit for purpose and calibrating equipment that is required to give in inspection confidence your and measurements. AIM needs to make sure that the calibration frequency, and standards of accuracy specified are appropriate to the actual equipment usage and not excessive. Once having determined the initial calibration procedure it does not have to remain fixed forever; it can be adjusted based on experience. In addition to calibrating equipment, records need to be kept showing:

- When the equipment was last calibrated, who did it, the calibration procedure, the acceptance criteria, what the result was, its acceptability and how this affects the equipment suitability (calibration status)
- When the next calibration is due-the period is dependent on the type of equipment, its usage and how critical the measurements are to the process
- Measuring equipment needs to be suitably stored when not in use, to protect it from damage or deterioration. It should also be suitable for use in the proposed operating environment. These precautions apply even more so to any 'master' measuring equipment or reference standards used for calibration purposes.

3.9.15. Measurement and Monitoring of Products

AIM must measure and monitor the characteristics of the product to verify that requirements for the product are met, and must be carried out at appropriate stages of the product realisation process. Evidence of conformity with the acceptance criteria must be documented, and records must indicate the authority responsible for release of product. Product release and service delivery must not proceed until all the specified activities have been satisfactorily completed, unless otherwise approved by the customer.

3.9.16. Checking Things are Right

This part of the Standards requires that you establish how you intend to check and monitor the process and the product and/or service. Frequently there will be considerable overlap between the two and in many cases the same monitoring processes will be adequate for both purposes. Some examples of measurement and monitoring include:

- Measuring dimensions
- ▼ Proof-reading publications
- Matching colours
- Looking at things and deciding if they are what were asked for

AIM needs to decide what its measurement and monitoring requirements are and how they are to be carried out. People who carry out measurement and monitoring may need to be trained for what they are doing. AIM also needs to decide and record who has the authority to say a job is finished and the product and/or service can be delivered. Individuals may check their own work, without secondary checking by another person. Such flexibility is sometimes necessary in AIM where excessive duplication of effort should be avoided.

Verification, i.e. examining something to see if it meets requirements, is also a measurement and monitoring operation. In some industries, such as publishing industry, visual verification may be the main form of measurement and monitoring carried out. Somebody must be responsible for the actual measurement and monitoring. The person does not have to have a staff or managerial status. For example, in a small AIM with only a few employees, it may be necessary for cartographers to inspect their own work before passing it on to the printing and dispatch area. A job card may follow the work, and the operator signs off the work performed on the job card. This works well because the work of the next operator down the line is affected if the incoming work is not correct.

The final approval phase includes not only checking the finished product and/or service, but that all the inspections and tests that ought to have been done, have in fact been done and that if any paperwork is to go with the product and/or service, that it has been prepared and is satisfactory. In other words, if you were the customer, these are all the things you would want to know have happened before you took delivery of the product and/or service.

The measurement and monitoring to be carried out may be listed in a number of ways, such as:

- A quality plan
- A sampling plan
- An inspection and test plan
- ✓ A procedure
- ✓ An instruction
- The customer's order

There needs to be a consistent method of recording that the measurement and monitoring has been carried out. In AIM, the supervisor could sign off a checklist to show all the inspections have taken place. Your QMS should be capable of identifying the job and include a procedure to recall the job if the item subsequently proves defective. You need to have a system for keeping the necessary testing and inspection records or have other means of showing that the inspections have taken place. Your records should indicate whether any failures occurred and the proposed action. Inspection and test failures are handled by the activities described for non-conforming products. Inspection and test failures should not be confused with normal processing activities to bring the product and/or service within specification before it is released to the next stage of operations. A typical example might be a publishing company that measures, adjusts and readjusts colour densities on a chart until the required levels are achieved. Such an iterative approach does not constitute an inspection failure. However, if the printer signs the system off as meeting specification, and it is subsequently found to be outside specification, this is a non-conformance.

3.10. Measurement, Analysis and Improvement

3.10.1. Control of Non-conformity

AIM must ensure that products that do not conform to requirements are identified and controlled to prevent unintended use or delivery. These activities shall be defined in a documented procedure. Non-conforming products must be corrected and subject to re-verification after correction to demonstrate conformity. When non-conforming products are detected after delivery or use has started, the organisation shall take appropriate action regarding the consequences of the non-conformity.

Some customers may require notification of any non-conforming product and/or service and approve what steps should be taken. If this is the case, it will be necessary to notify the customer following detection of the non-conforming product and/or service. You may wish to include the steps you propose taking along with the notification. Records will need to be kept of any decision made, approval given by the customer, any rework or repair procedure, and the results on the inspection and testing on any rework or repair.

If, for example, a publishing company discovers that it has inadvertently used inks that are beyond their 'use by-date' (or shelf life) in the printing of maps and charts, several actions may be required to fix the problem:

- Investigation to find out the extent of the problem
- Segregation and quarantine of the remaining ink supply from that consignment
- Segregation and quarantine of affected maps and charts awaiting delivery
- Recall of those maps and charts likely to be similarly affected, and that could affect safety.

Depending on the potential risks, there may be a need to involve the applicable regulatory authorities and to make the public aware of the problem.

3.10.2. Analysis of Data

This part of the Standard requires AIM to collect and analyse appropriate data to determine the suitability and effectiveness of the QMS and to identify improvements that can be made. This includes data generated by measuring and monitoring activities and other relevant sources. In this regard, AIM must analyse data to provide information on:

- Customer satisfaction and/or dissatisfaction
- ▼ Conformance to customer requirements
- Characteristics of processes, product and their trends
- Suppliers

3.10.3. Do the Measurements Reveal Any Trends?

As a result of the measuring and monitoring activities, AIM probably will have collected significant amounts of data, which can be analysed to indicate any trends. Any trends that AIM may find could suggest where there are problems in the QMS, which indicates areas where improvement is needed. AIM may also find activities that, although effective as they are now performed, could be improved further. AIM may find that statistical techniques are useful tools for the analysis process. The Standard identifies four areas where analysis is to be applied but AIM can extend data analysis to whatever areas provide AIM with useful information.

3.10.4. Planning for Continual Improvement

Understandably, AIM must plan and manage the processes necessary for the continual improvement of the QMS to facilitate the continual improvement of the QMS through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive action and management review.

3.10.5. What Improvements Do AIM Plan to Make?

Continual improvement of the QMS is now a mandatory requirement. It is important to understand that continual improvement doesn't mean that it occurs without a break or without ceasing. Instead, improvement should be interpreted as a repeated activity to be implemented as each opportunity is identified and there is justification for proceeding. The standard lists several tools and inputs that AIM can use to both plan and implement improvement.

3.10.6. Corrective Action

AIM must take corrective action to eliminate the cause of non-conformities to prevent recurrence. Corrective action must be appropriate to the impact of the problems encountered. The documented procedure for corrective action must define requirements for:

- Identifying non-conformities (including customer complaints)
- ▼ Determining the causes of nonconformity
- Evaluating the need for actions to ensure that non-conformities do not recur
- Determining and implementing the corrective action needed
- Recording results of action taken reviewing of corrective action taken

3.10.7. Preventive Action

AIM must identify preventive action to eliminate the causes of potential non-conformities to prevent occurrence. Preventive actions taken shall be appropriate to the impact of the potential problems. The documented procedure for preventive action must define requirements for:

- Identifying potential non-conformities and their causes
- Determining and ensuring the implementation of preventive action needed
- Recording results of action taken
- Reviewing of preventive action taken

3.10.8. Fixing the Causes of Problems

Both corrective and preventive action may be seen as steps in a quality improvement cycle. The need for corrective action can arise when an internal nonconformity (product and/or service or QMS) occurs, or from external sources such as a customer complaint or warranty claim, or problems encountered with a supplier. Corrective action involves finding the cause of the problem and then putting in place the necessary actions to prevent the problem recurring. Preventive action starts with considering and analysing the data from all the incidences of non-conformities, all the customer complaints, all the warranty claims, all the problems with suppliers as well as any other sources of problems to find out if any trend is occurring. Where this analysis shows that the potential for problems exists, preventive action then involves putting in place the necessary steps to eliminate potential causes. The documented procedures for both corrective and preventive actions should define the responsibilities and authorities for these activities.

3.10.9. Fixing the Cause of Known Problems

There is a difference between carrying out corrective action and fixing non-conformity. Fixing non-conformity is about making good the problem either by reworking, replacing or any of the other activities described in the guidance material. A corrective action is concerned with finding out why the nonconformity occurred and making sure that the problem does not occur again. The need for corrective action could be indicated by several factors, some of which could be:

- Customer complaints
- ▼ Non-conformances
- Rework or repairs
- Audit reports

Analysis of the causes may suggest some solutions such as retraining employees or amending a process control practice. The size of the problem and the associated risks to the business will

determine the actions that AIM need to take. When corrective action is taken, it should be recorded and followed up within a reasonable period to find out whether it has worked. It may be necessary to change the quality manual, documented procedures, instructions and any other relevant documentation. Changes should be made in accordance with the provisions shown for the Control of documents.

3.10.10. Fixing the Cause of Potential Problems

AlM should use your records to see if any trends exist which show a potential problem could arise. Typical examples of where information might be found and used for such analysis are from such sources as:

- Difficulties with suppliers
- In-process problems, rework rates, wastage levels
- ▼ Final inspection failures
- Customer complaints and customer surveys

Other sources might include market surveys, audit reports and quality records. Where a potential problem is identified, a course of action may need to be developed and put in place to reduce or eliminate the risk of the problem. If preventive action is found to be necessary, it should be recorded and followed up within a reasonable period to find out whether it has worked. Because of preventive action, the quality manual, documented procedures, instructions and any other relevant documentation may need to be changed. Examples of where preventive action may be applied include:

- Identifying possible situations where product damage may occur and implementing practices to prevent it from happening
- Feedback from personnel may indicate a more efficient process
- Re-assessment of suppliers to overcome potential supply problems

In AIM, there is little justification in separating management review arrangements from long-term corrective and preventive action. Where there are few personnel and the same people are involved in both activities, an artificial separation may result in duplication of effort. If this approach is taken, it should be included in the quality manual.

3.10.11. Customer Satisfaction

The Standards require AIM to monitor information on customer satisfaction and/or dissatisfaction as one of the measurements of the performance of the QMS. The methodologies for obtaining and using this information must be determined.

How Satisfied are the Customers? - AIM is required to monitor its performance as a supplier to the customers. More specifically, AIM is required to monitor information on satisfaction or dissatisfaction. To do this AIM will need to find out how satisfied your customers are.

More Than One Type of Customer - Firstly, it is important to remember that AIM may have more than one type of customer. For example, a map or chart manufacturer may sell to wholesalers who then sell to retailers who then sell to the general public. In this case he has three types of customer and they all have different requirements. He may be satisfying one group and upsetting another. For his product and/or service to sell successfully he will need to satisfy them all.

Satisfaction and Dissatisfaction - Another important point is to understand that satisfaction is not the opposite of dissatisfaction. The customers are entitled to be satisfied and may take good quality of products and/or services for granted. On the other hand, if they are dissatisfied, they may react quite badly or strongly. So, satisfaction may produce a neutral response whereas dissatisfaction may produce a strong negative response. There is a third possibility, which is a strong positive response. This is sometimes referred to as 'delight', something beyond the normal level of satisfaction.

Monitoring Satisfaction - There are many ways of finding out what the customers think of his AIM. Amongst the most widely used are:

- ▼ Telephone calls made periodically or after delivery of product and/or service
- Questionnaires and surveys
- Using a market research company
- ▼ Focus groups/conferences

Each has their merits and disadvantages. For a small AIM organisation, it recommended that AIM starts with simple methods such as calling the customers. AIM may gain a useful insight by calling someone who is senior to the one that AIM normally deals with. Such a person is likely to know how AIM performs and is likely to tell AIM, good or bad. Surveys and questionnaires are being extensively used. For example, how many does AIM receive in a year? AIM may get some good ideas from the ones sent to AIM. AIM can give the customers the option of giving their name or staying anonymous. AIM may get more negative responses from anonymous people, because some people do not like being the bearer of bad news. If they can hide their identity, they may tell AIM something they would not otherwise Remember criticism is vital information, which will help grow your business. Questionnaires and surveys have their disadvantages because they are time consuming. If using a questionnaire, keep it Choose the questions very carefully. Ensure that they are clear. Why not test it out on a trusted friend before AIM sends it out?

If AIM really wants to know what the customers think, it is probably best left to the professional market research companies. Their independence enables them to gather an objective perspective of the performance and the customers' satisfaction. Customer focus groups or conferences are a powerful tool for finding out the reasons behind the measure of satisfaction. A group of customers is brought together in a small meeting where they discuss the merits of your product and/or service. This needs facilitation, which is best left to a professional.

Satisfaction as a Measure of the System

Performance - AIM is to use customer satisfaction as a measure of the performance of the QMS. At its simplest, this could be the percentage of dissatisfied, satisfied and delighted customers. Reality is it tends to be more complicated than that. One customer may be both satisfied and dissatisfied. He or she may be satisfied with the product and/or service but dissatisfied with the delivery performance, for example. Therefore, AIM needs to think it through and come up with a practical measure. Perhaps AIM could ask the customers to rate the performance on a scale from 1 to 10. Alternatively, perhaps it would be worthwhile measuring several aspects of the business, for example, appearance, delivery performance, packaging, functionality, and value for money.

3.10.12. Internal Audit

Civil Aviation Authorities (CAA) should conduct periodic internal audits to determine whether the QMS:

- Conforms to the requirements of the International Standard; and
- Has been effectively implemented and maintained.

CAAs should plan the audit programme taking into consideration the status and importance of the activities and areas to be audited as well as the results of previous audits. The audit scope, frequency and methodologies must be defined. Audits must be conducted by personnel other than those who performed the activity being audited. A documented procedure must include responsibilities and requirements for conducting audits, ensuring their independence, recording results and reporting to management. Management must take timely corrective action on deficiencies found during the audit. Follow-up shall include the verification implementation of corrective action and the reporting of verification results.

AIM should provide auditors with training on how to conduct the audit.

Note: See ISO 10011 for guidance.

What is the Internal Audit? - Audits are about getting information, in a planned way, from a variety of sources and comparing it all to confirm that things are being done properly. The steps of gathering this information should include:

- Reading the documented procedures
- Reading relevant process control documents
- Observing processes being carried out;
- ▼ Talking to the people carrying out the processes
- ▼ Looking at the records

All these need to tell the same story; i.e. that you are doing things right, the way you said you would. For a well-organised and run AIM, where familiarity with the day-to-day activities is the norm, a properly conducted audit can be beneficial. AIM should use audits to stand back and look at the business objectively to confirm that the QMS is helping AIM does what AIM wants to do and what AIM needs to do. AIM needs to find some form of evidence, documented or otherwise, which can confirm that the QMS is performing in the way it was intended. It is not sufficient to simply do an overview and conclude without any proper basis or supporting evidence that the QMS is operating satisfactorily. This requirement is reinforced to require you to develop some means for measuring how the QMS is performing.

Seeking out areas for improvement is now particularly important as it is this information that is required to be added to the data to be analysed. The information from internal audits should also be used as part of the management review. The better the audit, the more useful the management review will be. When an internal quality audit shows up non-conformances and inconsistencies, you need to develop the necessary corrective actions and then put them in place.

These may be as simple as:

- Writing or revising a documented procedure or a process control document
- Redesigning a form to incorporate more information
- Arranging for employee retraining

Audits should be scheduled to cover all the quality-related activities and all the requirements of the standard. In deciding how to manage the audit schedule and how often an aspect should be audited, the following factors may be considered:

- ✓ Are there any complex procedures or processes that would justify individual audits?
- Are there any aspects or areas that have a history of problems?
- ▼ Does your 'hands-on' approach indicate a need for less frequent audits?

A report or summary of each audit should be made out, listing the findings and what action if any is to be taken. The record need not necessarily be complex. For example, a simple entry in a daybook may be sufficient. If the previous audit recommended or required action to be taken, the current audit should check how effective the change was and this should be recorded. There is a requirement in the Standards that "audits shall be

conducted by personnel other than those who performed the activity being audited". For example, it is acceptable for the office personnel to audit the production/service activities and viceversa. This can provide benefits in developing an understanding of each other's problems.

In a small AIM where there may be only one or two people in the entire management structure, this requirement may not be achievable. It is suggested that in such cases, the manager, carrying out the duties of an auditor tries to step back from direct involvement in the business operations and be very objective about the audit.

Another approach would be to seek the cooperation of another work area and each provides the internal quality audit facility for the other. This may prove attractive if there are good relations between the two businesses.

Effective use of internal quality audits is an area that AIM may use to minimise the ongoing costs of certification/registration. If the auditor from the can see that internal quality audits are being used to effectively monitor and control the QMS, then less time is needed verifying the QMS operation. Again, it must be emphasised that what the auditor will be seeking is objective evidence with respect to internal quality audits.

QMS Documentation

4.1. Structure of QMS Documentation

The ISO 9000 series of standards requires that the QMS be properly documented. In addition to describing the QMS, the documentation also communicates to the staff their role in the organisation, the expectations of their work performance, and at the same time provides a basis for evaluating the effectiveness and continuing suitability of the QMS. The documentation in the QMS is constructed in a hierarchical form as shown in Figure 4.1. To make the Standard relevant to a wide range of enterprises, the 2015 revision of the ISO 9001 standard has become less prescriptive regarding documented information. A Quality Manual is no longer a specific requirement. However, it is included in Figure 1, as it provides a useful role in the hierarchical structure illustrated.

Level 1 documentation defines the principles and approaches of the aeronautical information service provider to quality-related issues. It consists of the quality manual, the quality policy and objectives of the organisation.

Level 2 documentation consists of procedures by which the aeronautical information service provider manages the QMS.

Note that while ISO 9001:2015 explicitly requires documented information, particularly on the following:

- Control of documents
- Control of records
- ▼ Internal audit
- Control of nonconforming product
- Corrective action
- Preventive action

The aeronautical information service provider may need to document additional processes to ensure the effective operation and control of such processes.

Level 3 documentation provides detailed instructions, in the form of work instructions or procedure manuals, which the staff need to follow in carrying out specific operational activities.

Level 4 documentation consists of all forms and records that serve as the objective evidence of conformity to requirements and of the effective operation of the QMS.

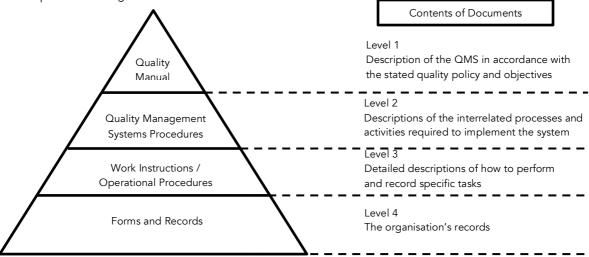


Figure 4-1 Hierarchy of QMS Documentation

The QMS documentation usually includes the following:

- Quality policy and objectives
- Processes showing sequence, inputs required and expected outputs
- ▼ Performance indicators metrics
- Documented information e.g. Process Manuals, Work instructions/ operational procedures
- External documents documents which can include specifications, statutory and regulatory requirements, standards, codes, etc. ICAO Annex 15/AIS Manual, States' AIPs and regional air navigation plans also fall under this category
- Forms and records
- Quality plans usually used in complex projects, products, processes or contracts. ISO 10005 refers

ISO 9000 defines a quality plan as a "document specifying which procedures and associated resources shall be applied by whom and when to a specific project, process or contract". It is an output of the process for planning of product realisation and covers all the quality practices and resources to be applied to a specific product. It makes the quality requirements of the product more readily understandable and can be used to demonstrate how such requirements will be met. Sometimes, a contract may specify a requirement for quality plans but otherwise it is up to the aeronautical information service providers to decide if quality plans should be prepared for their products.

The aeronautical information service provider will need to document additional processes to ensure the effective operation and control of such processes. For example, there should be a documented procedure for the management review process, considering the importance of this process to the effective operation of the QMS and the complexity and possibility of deviation from the requirement.

Work instructions operational and procedures are developed to describe the performance of specific tasks. The extent and level of detail depend largely on the complexity of the tasks concerned. Instructions will be essential, the absence of which will lead to inconsistency of outputs, and hence a degradation of quality of the final products or services. However, with a team of highly skilled and competent personnel provided with adequate training and information necessary to perform the tasks, the level of detail of the instructions can be reduced. In the context of information aeronautical service providers, extensive work instructions and operational procedures should naturally be expected from the products and services. Whenever appropriate, references to those relevant external documents contain the product requirements.

It must be noted, however, that the main reason for establishing a written procedure is to ensure consistency of the outputs, regardless of who performs the procedure. As such, the procedure should not be unnecessarily complex. It should be made as simple and comprehensible as possible, as if it were written for someone new to the process.

Forms and records provide evidence of what the aeronautical information service provider has performed and, therefore, would indicate whether not the QMS implemented and maintained is in conformance with ISO 9000 standards. They should be kept long enough for the purposes of both internal and external audits during which they are the subjects of scrutiny. In general, a retention period of one year is adequate but a longer period may be required for certain records such as training records, which should be retained throughout the employment history of the staff concerned.

4.2. General Documentation

Requirements

Documentation for a QMS must include:

- Documented procedures (see the section that follows for a description of Documented Procedures); and
- Documents required by the organisation to ensure the effective operation and control of its processes.

The extent of the QMS is, however, dependent on the following, and may be in any form or type of medium:

- Size and type of the organisation
- Complexity and interaction of the processes
- ▼ Competence of personnel

4.3. Documentation

The purpose of documentation in a QMS is provide a ready reference for how, when, where, by whom, and, if necessary, why an activity is performed. It should be designed so that tasks are performed systematically and with repeatable outcomes. It is important to keep written documentation simple, consistent and easy to amend. It should provide the basis for continual improvement and the evidence that a QMS is in place and is operating effectively.

There is no need to rewrite what has already been documented. Existing documentation, such as operating or work instructions, should be referred to in the quality manual and controlled.

Implementation of the QMS should not create unnecessary paperwork. Documented procedures should show how a job is done, not how it should be done. Only documentation that is relevant to the work of AIM should be included in the QMS documentation.

Procedures, forms, instructions, job descriptions and records should be developed according to a standard format. Whether an existing format is used or whether a new format is created, document templates should be created to simplify and standardise the work of developing documentation.

4.4. Documented Procedures

ISO requirements for a Quality System call for procedures to be in place to support production processes. These are typically written procedures that describe how the organisation performs the activities described below:

- ▼ Control of Documents
- ▼ Control of Records
- ▼ Internal Audit
- ▼ Control of nonconforming product
- Corrective Action
- Preventive Action

The above procedures need not be standalone procedures, and may be combined with other documented activities. Documented Procedures should indicate who does what, where and when they do it, why they do it, and how. It is up to the organisation itself to decide the level of detail that is included in the Documented Procedures. Largely, this will depend on:

- Methods used
- Skills needed
- Training
- Extent of supervision required

Documented Procedures should not contain what you would like to happen in the organisation, but rather an accurate description of what really happens. A robust QMS will involve staff, to the extent that they can contribute, in the writing of Documented Procedures. The earlier and the more

staff that are involved will lead to greater staff involvement, understanding and 'buy-in' to the procedures and practices.

4.5. Document Master List

Each controlled document has one master copy to which all changes are made and from which further copies are issued. Each controlled document also has an owner who is the person (or persons) authorised to review and approve changes to the document. The location of the master copy and the name of the document owner are recorded on a document master list.

4.6. Quality Manual

A quality manual is a controlled document that is perhaps the most important part of the Quality System. This is where it begins and includes the details of:

- ▼ The scope of the QMS
- ▼ The documented procedures or a suitable reference
- ▼ A description of the sequence and interaction of the processes included in the QMS

The Quality Manual is the 'map' for the organisation, and where the following items would be found:

- ▼ The quality policy
- ▼ The activities of the business
- → How the documentation works and where people might look to find information about how to do things
- → A definition of any terms having a unique meaning to your business
- ▼ Statements of responsibility and authority

The quality manual should also include information about AIM and its activities, about the manual itself and where to find information and guidance, a description of the organisational structure and statements of responsibilities and

authorities, and, if appropriate, a glossary and appendices for supportive data.

It is not necessary for QMS procedures to be included in the quality manual. They may be published and maintained as a separate AIM standards and procedures document. However, reference to the QMS procedures should be made in the quality manual.

As a final step in the preparation of the quality manual, a draft of the manual should be circulated to personnel for review comment to ensure the material included is completes and correct.

4.7. Control of Documents

The procedures required for the control of documents relate to documents originated by AIM as well as those used for AIM activities that originate elsewhere, and the need to ensure that personnel have access to information that is relevant to their activities and can rely on it to be up to date. In this regard, it is necessary that there are procedures in place to:

- ▼ Approve documents for adequacy prior to issue
- Review and update documents as necessary and re-approve documents
- Ensure that changes and the current revision status of documents are identified
- Ensure that relevant versions of applicable documents are available at points of use
- Ensure that documents remain legible and readily identifiable
- ▼ Ensure that documents of external origin are identified, and their distribution controlled
- Prevent the unintended use of obsolete documents and apply suitable identification to them if they are retained for any purpose

Documents defined as Quality Records must also be controlled. Document control is about making sure that the document in use is the 'right' document. A controlled document will be the latest

approved and applicable version for the work to be done. This is particularly important if staff is to have the information they need to do the job correctly. The simplest way to control documents is to make them available on the computing network, preferably without any paper copies. Many computing software packages make document control relatively simple. For example, the 'save date' can be saved in a footer or header of every page. A statement can be added to the effect that any paper copy is uncontrolled and that it is up to the reader to ensure that the copy being used is the latest version by checking on the network.

There is no limit to the number of documents that can be controlled in a Quality System, but the additional overhead in controlling the document must be balanced against any potential problems caused by using an inaccurate or obsolete version.

4.8. Document Master Copy

Each controlled document has one master copy. This is the copy to which all changes are initially made and from which further copies are made and issued as required. The location of the master copy is recorded on the Document Master List.

4.9. Document Owner

Each controlled document has an owner. This is the person or persons authorised to review and approve changes requested to the document. The document owner is also recorded on the Document Master List.

4.10. Controlled and Uncontrolled Copies

Documents may be issued as controlled or uncontrolled copies. Controlled copies are those issued to persons with a record of who has which copy. This record is kept with the document master copy. For controlled copies the document owner is responsible for ensuring that the registered holder of the copy is given an updated copy when the document is modified.

Uncontrolled copies are issued with no record of who has a copy. For uncontrolled copies the document holder is responsible for ensuring that the copy they have is up-to-date.

4.11. Control of Quality Records

Records exist in all organisations. Quality Records are required to provide evidence of conformance with requirements and of effective operation of the QMS. Procedures must be documented for the identification, storage, retrieval, protection, retention time and disposition of quality records.

A Quality Record is a record produced following a procedure in a Quality System document. This record provides a reference when reviewing progress and/or performance, and is often a form.

Each Quality System document must include definitions of the Quality Records to be produced and kept.

Quality records will provide AIS with information to help manage the business better. This is the part that is enabled to 'show how you did it'.

In some instances, retention periods will be dictated by legal or regulatory requirements, financial requirements or customer's specifications. Details about specific retention periods should be recorded in the documented procedures.

Records are an essential element of a QMS. Quality records are required to review requirements and verify whether quality issues are being addressed and requirements are being met. Quality

records are needed for verification, validation, monitoring, inspection and testing of quality. Quality records provide the information needed for continual improvement by recording actions that have been taken or tasks that have been carried out and provide evidence of same for audits and reviews. Examples of quality records are listed below.

- Document records
 - ▼ Document change request form
 - ▼ Controlled documents master list
- ▼ Human resources records
 - Training
 - Education
- Process and product review records
 - ▼ Non-conformance reports
 - ▼ Management review results
 - Status of corrective actions
 - ▼ Requirements and changes to requirements
 - Minutes of meetings
 - Audit reports
- Miscellaneous quality records
 - ▼ Files on customers and suppliers
 - Records of resources and goods received
- What is produced to show a procedure has been completed

Records, indexing and filing can be in any appropriate form; hard copy, or electronic. Storage needs to be appropriate to the circumstances and

the medium and should be such that the risk of deterioration, damage or loss is minimised.

The International Standards also call for the organisation to identify and document who has access to the quality records.

To help in deciding what quality records need to be kept, it is useful to consider that all quality records can be considered following three different categories:

- ▼ What is received before a procedure starts
- ✓ What is produced to show intermediary steps have been completed

Quality records are usually produced internally. However, they may also be produced outside the AIS, for example a customer's order, or an external auditor's report.

For each quality record identified, the following aspects need to be defined:

- ▼ What the record is
- Who is responsible for its filing
- How long the record is required to be kept
- ▼ Where the record will be kept
- ▼ Who is responsible for the record's disposal?

Below is a tabular layout sample which is useful to present the information required.

	Responsibility	Minimum Retention Period	Location
Define the Record	Who is responsible for its filing? Who is responsible for its eventual	The minimum time the record must be retained for	Where the record is kept
	disposition?		

Figure 4-2 Sample of Tabular Layout

In some ways, by default, the person deemed responsible for the record's filing is also responsible for and authorised to dispose of the record. In this case, one position can be listed as responsible for the record, and for the filing and disposition. A minimum period is specified to supply an audit trail for accountability purposes. The audit trail may be required for official inquiries or litigation. Specification of a minimum retention period allows us to keep records longer if required. Records are often kept on hand for as long as there is space to accommodate them.

In summary, the records management process ensures that all quality records are identified and controlled, to provide a ready reference to the effectiveness of our Quality System documents.

The records management process occurs over an extended period and interleaves with other processes, particularly with those for document development and control.

An example of how the records management process might be managed follows in the table below.

Stage	Description	Explanation	
1.	The need for a record is identified		
2	The record definition is produced and documented		
3.	The record is produced		
4.	The record is indexed	Uniquely identifying individual records assists in filing and retrieval. Records with no unique identifier can be marked by allocating a specific location for storage. Whatever approach is taken should be recorded as part of the record definition.	
5.	The record is filed in the location specified in the record definition	The location should be chosen to ensure that the record is not damaged for the period it is to be retained.	
6.	The record is stored for the period specified in the record definition	Depending on the retention period, it may be necessary to regularly review the storage to ensure that the records are not being damaged.	
7.	The record is disposed of	The person responsible for its storage (as provided for in the record definition) is authorised to dispose of the record.	

Figure 4-3 Example of Records Management Process

4.12. Quality Manual Template

Appendix 2 of this Guidance Manual contains a template of Quality Manual to be used by an AIM organisation.

4.13. Quality Manual Samples

Appendix 3 of this Guidance Manual contains some samples of Quality Manual.

Auditing Processes

5.1. Audit Objectives

ISO 9000 defines an audit as a "systematic, independent and documented process obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled". The term "audit criteria". according to the same standard, refers to a "set of policies, procedures or requirements" used as a reference. In effect, they are those materials contained in the QMS documentation. The policies and procedures are developed by the aeronautical information service provider and the requirements may originate from ISO 9001, users, regulatory and legislative bodies and the aeronautical information service provider itself. During the audit, the certification body/registrar will try to verify if the aeronautical information service provider is doing what it says it will do (according to the QMS documentation) and to confirm if the QMS is effectively implemented.

While the obvious reason for the aeronautical information service provider to conduct an audit is to obtain or retain the ISO 9000 certification, the real importance of such audits is to confirm that the QMS is effectively implemented and maintained as planned so that the benefits of establishing such a system are realised.

It is the responsibility of the auditors to ensure that the audits are conducted in an objective and fair manner. The main objectives of an audit are as follows:

- ▼ To confirm conformance of the QMS with ISO 9001
- ▼ To confirm that the QMS has been properly implemented and maintained
- To confirm the commitment and ability of management to review the QMS for continuing suitability, adequacy and effectiveness, and for continual improvement
- To identify opportunities to further improve the QMS

5.2. Types of Audit

First-Party Audit - First-party audit refers to an internal audit conducted by, or on behalf of, the aeronautical information service provider for compliance with the associated requirement of ISO 9001 and for other internal purposes such as staff development, preparation for certification audit and opportunities for improvement. It is important to note that the internal auditors selected to conduct the internal audits must be independent of the function being audited. Formal training on the fundamentals of QMS auditing should be provided to these internal auditors to ensure that they are competent to perform the audits. Results of the internal audits should indicate the readiness of the aeronautical information service provider and the QMS for the next visit of the certification body/registrar.

Second-Party Audit - Second-party audit refers to an audit conducted by an interested party, such as a user of the aeronautical information service provider or ICAO. The aeronautical information service provider may be audited by a user to determine the awarding a service contract, or evaluating the performance of the aeronautical information service provider.

Third-Party Audit - Third-party audit refers to an audit conducted by an external, independent auditing organisation, such as an accredited certification body/registrar that provides certification of conformity to the requirements of ISO 9001. The third-party audit could demonstrate the ability of the aeronautical information service provider to consistently provide services that meet the user and applicable regulatory requirements, thereby eliminating the need for repeating second-party audits conducted by various interested parties. Second and third-party audits are collectively known as "external audits".

5.3. Auditing Process Approach

ISO 9000 promotes the adoption of "process approach" in implementing the QMS. Consequently, in contrast with the audits described in previous versions of ISO 9000 that focused on procedure compliance and record verification, the ISO 9000 audit emphasises the practice of process auditing that identifies the inputs and outputs of the subject process and determines if the process can deliver the desired output consistently. In general, the auditors will look at the following aspects of the process being audited:

- Inputs and outputs of the subject process
- Process activities
- Process ownership
- Quality objectives
- Continual improvement of the process
- Interrelation and interaction with other processes
- ▼ The risks to the process

Auditors will spend much time going through the process flow diagrams and the associated procedures when auditing a process. They will try to make certain that the aeronautical information service provider is meticulous in following the published procedures and in controlling the process. Therefore, the procedures should be designed and maintained as simple as possible while still ensuring consistency of the outputs.

5.4. Certification/Registration Audit

The certification/registration audit is a third-party audit and is conducted by an accredited certification body/registrar engaged by the aeronautical information service provider. Upon satisfactory completion of the certification/registration audit, the QMS of the aeronautical information service provider becomes certified or registered to ISO 9000.

The audit team of the certification body/registrar is composed of a lead auditor, who takes the leading role in the audit team to coordinate the audit and to handle the main communication with the aeronautical information service provider, and one or more auditors depending on the size and scope of the QMS being audited. Technical experts in the aeronautical information field may be employed by the certification body/registrar to assist in dealing with technical matters related to aeronautical information during the audit.

The certification/registration audit typically consists of two phases. In the first phase, the auditors conduct an audit, usually off-site, of the QMS documentation including, among others, the quality manual, external documents that contain information on users of the aeronautical information provider. applicable statutory regulatory requirements, and records such as reports of internal audits and management reviews. By examining the documentation, the auditors will determine the adequacy of the documentation for the QMS. This process is called "document review", "adequacy audit" or "pre-assessment audit".

The second phase $\circ f$ the certification/registration audit refers to the actual on-site audit of the QMS. It will be arranged after the auditors are satisfied with the document review/adequacy audit process. The auditors will conduct the audit following the process auditing approach (see 5.3). During the audit, the auditors will collect objective evidence by interviewing the employees of the aeronautical information service provider and observing their work. They will sometimes ask to inspect certain documents, samples of products or the records maintained by the aeronautical information service provider.

At the end of the last audit day, the auditors will conduct a closed meeting and report their findings to the management of the

aeronautical information service provider. The auditors should advise of any nonconformity identified in the QMS during the audit. All such nonconformities must be corrected within a certain period as agreed between the certification body/registrar and the aeronautical information service provider. The certification audit can be halted and require immediate corrective action if a major nonconformity is found at this point. Minor non conformities can be addressed during surveillance audits. The certification body/registrar may again conduct a full or partial audit to confirm that proper corrective action has been taken before the certificate of registration can be issued. An explanation of the types nonconformities and the corrective action process is provided in Chapter 6.

An optional preliminary assessment visit by the auditors may sometimes be arranged before the conduct of the second phase of the certification/registration audit. The purpose of this preliminary assessment is to allow the identification and closing of any significant discrepancies in the implementation of the QMS before the actual audit is carried out. This preliminary assessment could be very useful to the aeronautical information service provider especially if it has not had the assistance of consultants or experienced ISO 9000 auditors in the implementation process of the QMS.

The amount of the auditor's time required on the initial certification/registration, that is, the very first formal on-site certification/registration audit, is largely dependent on the number of employees within the scope of the QMS. And it also depends on remote sites if any. For example, it will normally take three auditor days to complete the initial certification/registration audit of an aeronautical information service provider with 20

employees.

The various steps of the certification/registration audit are summarised in Figure 5-1.

5.5. Surveillance

Certification/registration is only beginning. After certification/registration, certification body/registrar will conduct surveillance audits regularly to confirm the continued conformance of the QMS with ISO 9000. The auditors will follow the same general steps as the certification/registration audit to conduct the surveillance audits. They will also point out the effectiveness of the QMS regarding achieving the organisation's objectives, changes improvements implemented to the QMS since the visit. areas that last have generated nonconformities and results of the corrective actions taken by the aeronautical information service provider. The minimum frequency of surveillance audits is once every 12 months, but some certification bodies/registrars will audit once every six months.

The certification expires after three years. A recertification audit is required at the end of the third year after initial certification and the whole cycle begins again. As the certification itself is not a mandatory requirement of the ISO 9001 standard, the organisation must decide whether the ISO 9001 QMS should be implemented as an internal improvement instrument or as an external business tool in most cases involving aviation services.

5.6. Sample of Certification/Registration Audit

Appendix 4 of this Guidance Manual contains a sample of certification/registration audit.

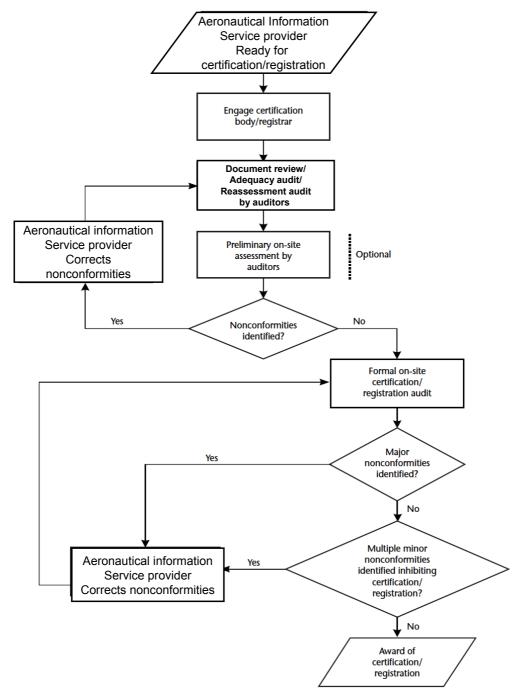


Figure 5-1 Steps of a Certification/Registration Audi

Non-Conformance Reports and Corrective Action

6.1. What Does Certification and Registration Mean?

Starting Out - Certification/registration of QMS is recommended and therefore the following provides a brief outline for those wishing to follow this path. Before the actual certification/registration can take place, it is essential to have all aspects of the QMS in place and running for several months. AIM can then see the QMS in operation and could improve it. Any improvements AIM can achieve at this stage can simplify the certification/ registration process. This can save time and money. Certification/registration bodies do not operate on the principle of 'what is going to happen'. They want to see what has happened. AIM will need sufficient records to demonstrate that the QMS has become established and effective.

Who Does the Certification/Registration? -

There are two types of certification/ registration; one is carried out by your customer(s) and the other by an independent party. The outline below is based on that typically adopted by independent third-party certification/registration bodies.

Brief Outline - The process generally takes the form of the following steps: AIM makes a formal application to the certification/registration body. The application normally includes a description of your business activities, the product and/or service range, and any other information requested. The certification/ registration body may ask for a questionnaire to be filled out.

Next, the certification/registration body will review your quality manual. What it will be looking for is how well the quality manual describes what you say happens against what the standard says should happen. When there are deficiencies, the certification/registration body will indicate where

the problems are. Amendments to the quality manual will usually overcome most problems, but you may also have to develop additional procedures.

A further review of any changes is carried out and is often combined with one of the subsequent stages. The certification/registration body may then hold a pre-assessment check or go straight to the certification/registration audit.

In the certification/registration audit, the auditor (and there may be more than one) will use the quality manual and any procedures as a guide to how your business operates. The auditor's operative words will be 'show me'. The auditor will be looking for records, documents, or other objective evidence to see that you are doing what your quality manual/procedures say you do.

Where inconsistencies (non-conformities) are found, the auditor's actions depend on how serious these are. For major non-conformities, the certification/registration could be withheld pending rectification. For minor non-conformities, a qualified certification/registration might be issued, pending rectification by the next surveillance audit.

Once certification/registration is granted, the certification/ registration body will carry out compliance audits of the QMS over the period for which the certification/ registration is valid. These audits are not as comprehensive, in that the full QMS is not necessarily assessed at each surveillance audit.

If non-conformities are found during a compliance audit and not rectified within specified times, certification/registration may be withdrawn. Minor non-conformances will be required to be corrected by the next surveillance audit, which under these circumstances may seem to come around very quickly.

6.2. Control of Non-Conforming Product

There should be a procedure for dealing with data and information that does not conform to the required standards. This could be done by having a method of identifying such information – e.g. stamped 'Non-Conforming'. The purpose of this is to ensure that such information cannot inadvertently be used in the published AIP.

Data or information presented to AIM for publication in the Integrated Aeronautical

Information Package that does not conform to the specified requirements of the AIS product must be marked as Non-Conforming by Aeronautical Information Services Provider, e.g. stamped, hand endorsed.

Aeronautical Information Services Provider is responsible for advising the originator that the material submitted does not conform.

The steps of control of non-conforming are shown in Table 6-1.

Step	Action	Responsibility
1.	Record non-conformities	<insert></insert>
2.	Determine the causes of non-conformity	<insert></insert>
3.	Determine actions required to prevent re-occurrences of non-conformities	<insert></insert>
4.	Advise originator	<insert></insert>
5.	Implement corrective action	<insert></insert>
6.	Filing records created after corrective action taken	<insert></insert>

Table 6-1: The Steps of Control of Non-Conforming

6.3. Corrective Action and Error Analysis

If an error is determined to be hazardous or have the potential to be hazardous, remedial action appropriate to the operational significance of the error will be initiated by any user or AIM personnel themselves. The operational significance of the error should be determined by AIM in consultation with the data originator.

Appropriate action may include:

Issue of NOTAM. If a NOTAM is issued, the error should be scheduled for correction in the next scheduled amendment. If the next scheduled

- amendment will not be within 90 days, the information should be published by AIP Supplement at the next available issue
- Issue of AIP Supplement. Errors should only be corrected by AIP Supplement when the page or chart is not scheduled for reissue at the next AIP amendment;
- Issue of an AIP amendment at next available amendment; and
- Correct at next scheduled issue of page or chart.

To ensure continuous quality improvement, procedures need to be in place to record and analyse errors and implement both corrective action and preventative action.

For the purposes of recording and analysis, an error is defined as follows:

- Any instance where information is incorrectly or inaccurately published; and
- Any instance where the accuracy, structure or format of published information does not conform with required standards

Attention should be given to whether an occurrence has created or had the potential to create a hazard. If it cannot be determined whether an error could or could not have been hazardous, the error should be recorded. For instance, there is probably little to gain from recording and analysing minor typographical errors.

6.4. Error Tracking Process

This instruction describes the procedures to be used when an error is detected in a component of the Integrated Aeronautical Information Package.

The steps of error tracking action are exemplified in Table 6-2.

Step	Action	Responsibility
1.	Confirm the error and raise an ETF (Error Tracking Form)	<insert></insert>
2.	Register the ETF	<insert></insert>
3.	Analyse the safety aspects associated with the error and determine if NOTAM or other action is appropriate	<insert></insert>
4.	Initiate corrective action as a NOTAM or AIP SUP and process through the NOTAM officer/NOF	<insert></insert>
5.	Attach a copy of the NOTAM request/Draft AIP SUP to this form	<insert></insert>
6.	Analyse the cause of the error	<insert></insert>
7.	Discuss the error with the officer responsible	<insert></insert>
8.	Determine remedial action	<insert></insert>
9.	Brief AIM Manager as necessary	<insert></insert>
10.	Initiate change action when required	
11.	Amend or establish procedures as required to strengthen processes	<insert></insert>
12.	Sign-off the ETF when completed	<insert></insert>
13.	Forward the completed form to <insert> for filing</insert>	<insert></insert>

Table 6-2 The Steps of Error Tracking Action

Error Analysis

To assist with the analysis of errors, it could be useful to establish a system of categorising errors as shown below. The following guidelines are used to determine the categorisation of errors:

Critical - Any instance where the published information directly compromises the safety of air navigation:

- Where the published information could compromise aircraft clearance from terrain, e.g. Incorrect instrument approach minima
- ▼ Where there is an error in navigational or route information, e.g. Incorrect track
- Any error in the depiction or publication of airspace information, e.g. Incorrect vertical limits

Major - Any instance where the published information intended for communications or air

navigation purposes is missing, ambiguous or difficult to interpret, e.g. incorrect ATS frequency.

Minor - Any instance of typographical, grammatical, printing or formatting deficiencies which do not directly cause operational difficulties, but do not meet expected standards such as:

- ✓ Any 'typographical' error, where the information published is correct in context and content but could contain spelling or grammatical errors; and
- Freventive Action Good error analysis should identify where necessary the preventive action required to ensure the error does not re-occur. The steps of Preventive Action are exemplified in Table 6-3.

Step	Action	Responsibility
1.	Collate information relating to non-conformities, error tracking forms and customer complaints/suggestions	<insert></insert>
2.	Determine causes of non-conformity	<insert></insert>
3.	Determine what action is necessary to prevent non- conformities re-occurring	<insert></insert>
4.	Determine and implement corrective action	<insert></insert>
5.	Record and file results of action taken	<insert></insert>

Table 6-3: The Steps of Preventive Action

6.5. Change Procedures

Staff are encouraged to suggest changes that will improve the quality system. To facilitate this process, suggestions should be made in the format of Table 6-4

Each suggestion is recorded with an individual number, details entered of the action taken and advice to the originator.

The steps of change procedure action are shown in Table 6-5.

AIM Quality System - Staff Suggestion			
No.	To: <insert are<="" suggestions="" th="" the="" who=""><th>From:</th></insert>	From:	
	directed to for example the AIM Manager>		
Details:			

Table 6-4 Suggestions of change procedures

Step	Action	Responsibility
1.	Register the suggestion	<insert></insert>
2.	Determine course of action to be taken	<insert></insert>
3.	Advice provided to the originator	<insert></insert>
4.	Record filed	<insert></insert>

Table 6-5: The Steps of Change Procedure Action

Chapter 7

Steps to Certification and Other Practical issues

7.1. Responsibility for Initiating a QMS

In some States, there may already be a QMS in place for the entire civil aviation administration. The QMS for AIM could then form part of, and be aligned with, the overall QMS. In such a case, the need for and benefits of implementing a QMS would already be well understood and supported by senior management, and there would be experience and expertise available in the organisation to assist AIM with its QMS implementation project. However, it is possible an all-encompassing QMS for the entire CAA may not contain enough detail to address all the requirements of every line office. So, the CAA can require or mandate an individual line office to establish a QMS.

The AIM section in any organisation will have been operating with a certain level of quality management to provide, at the very least, aeronautical information of a required quality and timeliness. The task at hand, however, is to implement a QMS that can be proven by audit to comply with the Standard or that conforms to ISO and is certified by an approved organisation in accordance with the Recommended Practice in Annex 15. This AIM task cannot be undertaken without the full commitment and support of senior management of the administration.

Depending on the organisation and size of the State's civil aviation administration, the senior management responsible for directing the activities and overseeing the resources of AIM may be represented by the head of the air navigation division in which AIM resides, the director of the civil aviation authority, or a ministry at the government level.

It is strongly recommended that the highest level of senior management support be obtained for the implementation of the QMS for AIM. Decisions must be taken at this level to invest time and funds in the short term to reap benefits in the long term. This is also where the commitment and leadership needed for a successful QMS are to be found.

The initial steps for senior management planning to implement the QMS are to:

- Learn about ISO
- Formulate a quality policy and establish the quality objectives of AIM
- Convey the quality policy and quality objectives to the entire AIM organisation
- ▼ Define the roles and responsibilities of the quality representative
- ▼ Appoint quality resources
- ▼ Arrange for ISO training of the quality resources
- Arrange ISO training of the staff

A clear understanding of ISO QMS standards and guidelines will inform senior management decisions related to developing a quality policy and quality objectives, setting priorities, assigning responsibilities and providing resources. The ISO document titled Quality Management Principles describes the principles on which the ISO 9000 QMS standards are based, provides examples of the benefits derived from their use and actions that senior management typically take in applying the principles to improve organisation's performance. information is found in ISO 9000 - Quality Management Systems — Fundamentals and vocabulary, ISO 9001 — Quality Management Systems — Requirements and ISO 9004 — Quality Management Systems Guidelines performance improvements. information for those not already familiar with the ISO 9000 QMS standards is provided on the ISO Web site www.iso.org.

The quality policy is a concise statement of the intent of AIM to meet requirements and pursue quality in, and continual improvement of, the products and services it delivers, as well as continual improvement of the QMS. It serves to communicate the commitment to quality to users of AIM products and services. The quality policy directs and reminds AIM staff and senior management to concentrate efforts, time and resources on implementing and improving the quality system and maintaining quality. It also provides the foundation for the development of quality objectives.

Quality objectives are tangible goals that are established and reviewed with respect to the quality policy. Quality objectives should have measurable outcomes on which basis improvements in the QMS are planned. Quality objectives should be reviewed quarterly for applicability. One of the fundamental goals of a QMS is to introduce quality checks from the outset, into each and every process, rather than do so after the failure of a process is manifested. Another is to provide products and services that satisfy the users' needs and expectations.

Once the AIM quality policy and objectives have been defined, they should be communicated to all staff. At the same time, the importance of implementing a QMS should be fully explained. Resistance to change is a common and sometimes formidable obstacle to implementing a new system. Visible commitment by senior management to the QMS will help overcome this resistance.

While there will be more involvement in the QMS implementation project by some staff than by others, all staff must eventually be engaged in and guided by the quality policy and quality objectives for the QMS process to succeed. It should be emphasised that implementing a QMS is an opportunity to improve the way AIM carries out its

work and that, to achieve this, each person has an important contribution to make.

7.2. QMS Implementation Project

This chapter describes the four basic phases of the AIM QMS implementation project: planning, design, deployment and testing, and registration. It also explains the tasks to be undertaken to complete each phase.

7.2.1. Phase 1 - Planning

The key task in the planning phase is to review the existing quality system and assess where there is a need to develop and extend existing features of the system to meet the requirements of ISO 9001. This gap analysis reveals where additional procedures and documentation will be needed. This information is then used to estimate the time and resources required for the QMS implementation project. The information on what needs to be developed, along with the estimates of how long it will take, and the resources required, is used to develop a project proposal which is presented to senior management for approval. Depending on the size and complexity of the QMS implementation project, the quality resources may require the assistance of a project implementation team.

Project implementation team - The project implementation team may be drawn from existing AIM staff, seconded from other areas of the administration or, should financial resources be available, from outside the administration. The team may be composed of a few or many team members. The implementation project may be completed more expeditiously by dividing tasks among a large group of people. On the other hand, the project implementation team should not be so large as to create difficulties in communication and coordination.

It is the responsibility of the project manager to define the roles and responsibilities of

the project implementation team members. It should be noted that the assignment of duties and responsibilities related to the work of the project implementation team need not imply that team members will continue to perform similar functions with similar responsibilities within the QMS once it has been implemented.

If team members are selected internally, they may be chosen from each of the major functional groups of AIM. Depending on the organisation of AIM, these functional groups may be based on products and services (aeronautical information publication (AIP), AIP Amendments and Supplements, etc.), departments (international NOTAM office (NOF), pre-/post-flight briefing, etc.) or processes (data entry, verification, data processing, etc.).

Gap Analysis - Before work can begin on designing the QMS for AIM, the project manager must assess whether, and, if so, where, gaps exist between the current system of procedures and documentation and a QMS that is ISO 9001 compliant. This assessment, called a gap analysis, begins with evaluating what AIM does, how it is done and what are the supporting procedures and documentation, as follows:

- Organisational perspective. List the functional groups of AIM and its organisational structure. Show how the organisational structure of each functional group relates to the others and how the AIM functional groups relate to functional groups outside AIM. (This may be represented best as a flow chart.)
- Products and services, and customers. List the products and services provided by AIM. List the customers for the products and services provided.
- Activities. List the activities performed within each functional group and link them to the products and services provided.
- Processes. List the processes involved in each of the activities listed, the inputs and outputs of each process and the sequence of the

- processes. Describe where inputs are derived from outputs of previous processes and where outputs are linked to succeeding processes.
- Customer requirements. List the customer requirements (including standards and regulations) and the requirements of other functional AIM groups. Link the processes to these requirements. Note processes that serve neither customers nor other AIM functional groups. Take note of where processes are still needed to meet requirements, need to be improved or changed to be effective.
- Procedures. List the procedures used in each of the processes. Note where procedures required to ensure quality are undocumented or nonexistent.
- Duties and responsibilities. List the duties and responsibilities of each person involved in processes. Link those responsibilities to processes. Note the differences between actual responsibilities and those documented in the job descriptions, as well as the lack of documented responsibilities.
- Skills and competencies. List the skills and competencies needed to perform the duties and responsibilities described above. Note where lack of training led to tasks not being carried out.
- Infrastructure. List the workspace, hardware, software and equipment required to effectively carry out activities. Also note where activities are adversely affected due to a lack of infrastructure.
- Documentation. Create a log with existing documentation on all the above items. This documentation may be in various formats, such as flow charts, procedures, checklists, records, forms, job descriptions, manuals or style guides. Note any missing documentation related to all the above.

One way to approach the gap analysis task is to have every person in the functional group write down the following details for each of the activities they perform:

- How a job is initiated
- How the work gets started
- ▼ Who monitors the progress
- How the work is processed and controlled
- What documentation is used to support the task
- → What are the skills and competencies needed to perform the task
- → What hardware, software and other equipment and materials are used to perform the task
- ▼ Who decides when the work is finished;
- ▼ How delivery is made
- ▼ What follow up action is needed and who does
 it
- ▼ What records are kept and who keeps them

Once the assessment of the existing system of procedures and documentation has been completed, it must be evaluated in consideration of the requirements of ISO 9001, clause by clause by asking the following questions:

- Has AIM identified its products and services?
- → Have all the requirements for each of these products and services been determined?
- Do processes and procedures exist for effectively meeting these requirements?
- ✓ In addition to the processes required to meeting requirements for AIM products and services (including those that may be outsourced), do the following QMS processes exist for:
 - Control of documents, including records
 - Control of resources
 - ▼ Communication (internal and external)
 - Planning
 - Training
 - Monitoring and measurement of process performance and quality
 - Dealing with non-conformities
 - Continual improvement of process performance and of the QMS, including corrective and preventive actions
 - Management review of the QMS
 - Internal audit of the QMS

- Identification and management of risks and opportunities
- Are all these processes and the interconnections between these processes identified and documented?
- Do records exist to verify whether processes have been carried out, and to register the outcome of processes and the actions taken regarding the outcome of processes?
- ✓ Are the resources needed to achieve effective outcomes of the processes defined?

Each negative response corresponds to a gap in the existing system of quality management. The tangible elements required that transform the negative responses to positive responses represent the deliverables of the QMS implementation project.

Deliverables - The items of documentation identified during the gap analysis as requiring development to meet the requirements of ISO 9001 constitute the deliverables of the QMS implementation project. In addition to a quality manual, the following are required for each product or service provided by AIM:

- Documented statements of quality objectives and quality requirements
- Documented procedures
- Quality records
- Documents needed to ensure the effective planning, operation and control of processes, such as:
 - Document templates
 - Instructions
 - Checklists
 - **▼** Forms

Target Dates - Once the list of deliverables has been assembled, the project implementation team needs to arrive at a delivery schedule which includes target dates of the individual activities associated with each item to be delivered. Target dates define a timescale for planning purposes, provide goals in the form of milestones for the

project team and assist in providing continuing interest and support from senior management.

The target dates for deliverables are contingent upon the resources available, both internal and external. The more work days available, the sooner the deliverables are completed. The fewer work days available, the longer it will take to complete the deliverables. Target dates, therefore become a function of resources. It is also possible to allocate resources in accordance with set deadlines in a timetable. What is important is to first, analyse the internal resources available; next, whether and to what extent external resources can be provided; and finally, to arrive at realistic and achievable target dates.

Resources - Internal Resources - The introduction of a QMS should not necessitate the creation of new posts to be filled, but may increase work responsibilities for a certain period and for certain staff members, particularly for the members of the project implementation team. However, creation of a new post(s) is desirable if resources allow. Estimates of the total (extra) time required for the project by existing personnel should be made before estimating the extent and cost of external support needed.

External Resources - External support by professionals experienced in implementing a QMS may be needed to assist with the correct interpretation of ISO 9001 and to ensure that the project implementation team is kept on track for compliance. External support may also be required to provide initial QMS and internal auditor training.

Other Support Costs - Consideration should be given to whether additional or new equipment (e.g. computer hardware or software) will be required for the implementation of the QMS. Although ISO certification of the QMS is not required, but only recommended in Annex 15, it may be useful for planning purposes to obtain information concerning cost and schedules for certification assessment.

Project Proposal - Implementing a QMS may require extra-budgetary funding for training or for the hiring of consultants and a rearranging of work priorities. For senior management to make proper decisions about these matters, a project proposal should be prepared. This proposal includes a programme description that briefly outlines the tasks to be undertaken in each of the four phases of development of the QMS, a project plan which lists the deliverables with estimated target dates for completion, the composition of the QMS project team, and an estimate of the resources that will be required to proceed with the project. The project proposal should also state the and benefits objective, scope QMS implementation.

The project plan for senior management should restate the quality policy and objectives. The scope of the QMS implementation project would include all the activities and functional groups, at all locations in the State, which contribute to AIM.

When seeking approval for resources from senior management, it is important to highlight the dividends that are likely to accrue after implementing a QMS. Cost benefits, time savings, increased reliability and quality of outputs, enhanced processes and conformance to standards are all benefits that typically result from the implementation of a QMS.

Once all the necessary information has been complied to complete the project proposal it should be presented or submitted to senior management for approval. It may be necessary for the AIM manager to enter negotiations with senior management about scheduling and costs for the QMS implementation project and the anticipated costs of maintaining the QMS, once implemented.

After the approval of the project proposal by senior management, the resources, as approved or modified by the negotiations, need to be mobilised and put into place to undertake the design, deployment and testing, and, if desired, certification phases of the QMS.

7.2.2. Phase 2 - Design

Overview - The goal of the design phase of the QMS implementation project is to provide all the components of a QMS capable of producing quality in a reliable and repeatable manner, and to ensure that this capability can be proven by audit. The work to be done, the resources to be used and the time scale for completing the design of the QMS is recorded in the project proposal. This becomes the basic planning document for the design of the QMS. The design of the QMS should be guided by the principles of simplicity and functionality. The processes, procedures and documentation developed must be entirely relevant to the activities of AIM.

The principle tasks in the design phase are to:

- Create new procedures where required, ensuring consistency with existing ones;
- Document the qms;
- Develop training plans;
- Develop a plan for certification of the qms by audit.

Existing procedures and documentation should be incorporated in the QMS whenever information may be included in the record itself, as much as possible. The task of writing procedures and developing checklists may be best undertaken by personnel directly involved in the process concerned.

Processes and Procedures - A QMS that is ISO 9001 compliant is one in which documented processes exist for all activities that have a bearing on quality. The gap analysis carried out during the planning phase would have indicated where processes still need to be developed to ensure requirements are effectively met. In addition to these, ISO 9001 specifies the generic processes to

be developed by any organisation that delivers products or services. These processes relate to:

- Document control (including control of quality records)
- Control of outsourced processes
- Design and development
- Provision of resources
- ▼ Product realisation
- Communication
- Training
- Purchasing
- ▼ Non-conformance
- Corrective and preventive action
- Monitoring, measurement and analysis of products and processes
- Management review
- Programme management

Documented procedures should adhere to consistent structure. This will facilitate standardisation in the development interpretation of procedures. Procedures should describe (to the degree of detail required for adequate control of the activities concerned) the responsibilities, authorities and interrelationships of the personnel who manage, perform, verify or review work affecting quality, how the different activities are to be performed, the documentation to be used and the controls to be applied.

Document Control - AIM is required to have document control as described in paragraph 4.7. Additionally, a document master list must be kept as defined in paragraph 4.5. This document also describes the procedures for the control of quality records. ISO 9001 specifies that a procedure must be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. Some of this in the example below:

Record name	Reference number	Responsibility	Location	Minimum retention
				period

Figure 7-1 Example of Records Management Table

The minimum retention period for records would depend on requirements to maintain a paper trail for the purposes of audit, inquiries or proof in the event of litigation. Records may be kept longer than the minimum period if there is adequate space. Regardless of whether records are stored in paper form or electronically, a procedure must be created for storage and disposal of records to be kept beyond the minimum retention period.

Design and Development of Products and Services - The design and development process uses raw ideas as the input to create a product or a service. If an AIM undertakes activities related to design and development, such as procedure design, the procedures involved must be documented.

Resources - The processes related to the provision of resources are intended to ensure the availability of resources necessary to support AIM activities, including those required to support and maintain the QMS. Resources encompass the financial and the human resources, as well as infrastructure (buildings, workspace, equipment, etc.), and information. Procedures and forms need to be developed to control the provision, disbursement and maintenance of, and requests for, such resources.

Production of Products and Services - The procedures necessary for the product realisation process are first to determine customer

requirements, and second to review requirements. Customer requirements to be determined include:

- Requirements for delivery and post-delivery activities
- Requirements not stated by the customer but necessary for specified or intended use, where known
- ▼ Statutory and regulatory requirements
- Any additional requirements determined by the organisation (including the quality objectives and requirements)

Procedures for verifying, validating, monitoring, inspecting and testing need to be developed to ensure AIM products and services meet the requirements.

Procedures for the review of requirements must ensure that:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- Aim can meet the defined requirements

Communication - Procedures must be developed to ensure effective communication within AIM and with customers. Within AIM procedures must exist to inform of changes in:

- Policy
- Requirements
- Procedures

Procedures are necessary to allow for feedback and communication from personnel to management regarding opportunities for improvement. Communication procedures must also be developed to inform customers of product information.

It is essential for QMS to also use communication that effectively provides feedback from customers. Procedures for dealing with:

- Enquiries
- Complaints
- Surveys

Vendors, suppliers and contractors - Controlling provision/production is of little consequence if the raw materials brought into AIM are unsatisfactory. Complying with the part of the Standard therefore requires:

- Documented procedures for ensuring purchased products meet requirements
- ▼ The evaluation, selection and reviewing of contractors
- Clear definitions of requirements of contractors
- Procedures for verifying and allowing customer verification of contractor operation at the contractor's premises

As with any other business, AIM needs to, and the ISO Standards require that its purchasing processes are controlled to ensure that the purchased product conforms to requirements. The type and extent of control shall be dependent upon the effect on subsequent realisation processes and their output.

Examples of products or services that AIM might purchase are:

- Hardware
- Software
- Aeronautical data
- Cartographic services
- Distribution services

The organisation must evaluate and select suppliers based on their ability to supply products in accordance with AIM's requirements. Criteria for selection and periodic evaluation need to be defined and recorded.

Monitoring and measuring resources -When necessary, AIM must identify measurements needed and the measuring and/or required assuring monitoring devices conformity product specified of the requirements.

This standard is only applicable to those AIM where measuring or testing equipment, including test software, is used to check that what you are providing meets your customer's requirements for example the supply of data electronically to a data vendor, for example the use of cyclic redundancy checks (CRC). If, however, for example, your inspection method is visual inspection such as that use for some maps and charts, you may not need to have any measuring equipment or instruments and this part of the Standard does not apply.

Measuring and monitoring devices must be used and controlled to ensure that the measurement capability is consistent with the measurement requirements.

AIM must measure and monitor the characteristics of the product to verify that requirements for the product are met, and must be carried out at appropriate stages of the product realisation process.

Evidence of conformity with the acceptance criteria must be documented, and records must indicate the authority responsible for release of product.

Product release and service delivery must not proceed until all the specified activities have been satisfactorily completed, unless otherwise approved by the customer.

These standards require that AIM establishes how AIM intends to check and monitor the processes and the product and/or service. Frequently there will be considerable overlap between the two and in many cases the same monitoring processes will be adequate for both purposes. Some examples of measurement and monitoring include:

- Measuring dimensions
- Proof-reading publications
- Matching colours
- Looking at things and deciding if they are what were asked for

AIM needs to decide what the measurement and monitoring requirements are and how they are to be carried out. People who carry out measurement and monitoring may need to be trained for what they are doing. AIM also needs to decide and record who has the authority to say a job is finished and the product and/or service can be delivered.

Individuals may check their own work, without secondary checking by another person. Such flexibility is sometimes necessary in AIM where excessive duplication of effort should be avoided. Verification, *i.e.* examining something to see if it meets requirements, is also a measurement and monitoring operation. In some industries, such as publishing industry, visual verification may be the main form of measurement and monitoring carried out.

Someone must be responsible for the actual measurement and monitoring. The person does not have to have a staff or managerial status. For example, in a small AIM with only a few employees, it may be necessary for cartographers to inspect their own work before passing it on to the printing and dispatch area, although a second check is desirable. A job card may follow the work, and the operator signs off the work performed on the job card. This works well because the work of the next

operator down the line is affected if the incoming work is not correct.

The final approval phase includes not only checking the finished product and/or service, but that all the inspections and tests that ought to have been done, have in fact been done and that if any paperwork is to go with the product and/or service, that it has been prepared and is satisfactory. In other words, if you were the customer, these are all the things you would want to know have happened before you took delivery of the product and/or service.

The measurement and monitoring to be carried out may be listed in a number of ways, such as:

- A quality plan
- A sampling plan
- An inspection and test plan
- A procedure
- ✓ An instruction
- ▼ The customer's order

There must be a consistent method of recording that the measurement and monitoring has been carried out. In AIM, the supervisor could sign off a checklist to show all the inspections have taken place.

The QMS should be capable of identifying the job and including a procedure to recall the job if the item subsequently proves defective. It needs to have a system for keeping the necessary testing and inspection records or have other means of showing that the inspections have taken place.

The control records should indicate whether any failures occurred and the proposed action. Inspection and test failures are handled by the activities described for non-conforming products. Inspection and test failures should not be confused with normal processing activities to bring the product and/or service within specification before it is released to the next stage of operations.

Non-Conformance - AIM must ensure that products that do not conform to requirements are identified and controlled to prevent unintended use or delivery. These activities shall be defined in a documented procedure.

Non-conforming products must be corrected and subject to re-verification after correction to demonstrate conformity. When non-conforming products are detected after delivery or use has started, the organisation shall take appropriate action regarding the consequences of the non-conformity.

The control records will need to be kept of any decision made, approval given by the customer, any rework or repair procedure, and the results on the inspection and testing on any rework or repair.

A number of actions might be required to fix the problem:

- ✓ Investigation to find out the extent of the problem
- Segregation and quarantine of the remaining ink supply from that consignment
- Segregation and quarantine of affected maps and charts awaiting delivery
- Recall of those maps and charts likely to be similarly affected, and that could affect safety

Management Review - Procedures and appropriate forms to collect and maintain information required for the management review process need to be developed related to:

- Results of audits
- Customer feedback
- Process performance and product/service conformity
- Status of preventive and corrective actions
- ▼ Follow-up actions from previous management reviews
- Changes that could affect the qms

- Recommendations for improvement
- Effectiveness of actions taken to address risks and opportunities
- ▼ Adequacy of resources

Programme Management - The programme management process encompasses the processes of training and assignment of responsibilities and authorities, as well as the managing and controlling the QMS, including internal audit.

Exclusions - Some of the ISO 9001 requirements may relate to activities and processes that are not performed by AIM, (e.g. calibration). Previous editions of the ISO 9001 standard accommodated exclusions. The 2015 edition does not accommodate exclusions. Any rationale for not complying with ISO 9001 requirements must be clearly justified within the appropriate policy-level document within the QMS.

Documentation - The purpose of documentation in a QMS is provide a ready reference for how, when, where, by whom, and, if necessary, why an activity is performed. It should be designed so that tasks are performed systematically and with repeatable outcomes. It is important to keep written documentation simple, consistent and easy to amend. It should provide the basis for continual improvement and the evidence that a QMS is in place and is operating effectively.

There is no need to rewrite what has already been documented. Existing documentation, such as operating or work instructions, should be referred to in the quality manual and controlled.

Implementation of the QMS should not create unnecessary paperwork. Documented procedures should show how a job is done, not how it should be done. Only documentation that is relevant to the work of AIM should be included in the QMS documentation.

Procedures, forms, instructions, job descriptions and records should be developed according to a standard format. Whether an existing format is used or whether a new format is created, document templates should be created to simplify and standardise the work of developing documentation.

Quality Manual - A Quality Manual is not an explicit requirement of ISO 9001, but plays a useful role in the QMS. It records and communicates the quality policy, procedures and requirements, provides the documented basis for auditing of the QMS and for demonstrating compliance with ISO 9001, provides continuity of the QMS, and can be used for QMS training of personnel.

Note - The detail of a quality manual is provided in chapter 4.

Training Plans - There are two aspects of training to be considered: training related to implementation of the QMS and training needed to full current job requirements.

Staff need to understand how the QMS works and how it is kept up to date, what they are responsible for, how to make changes, how documents are controlled, how to report problems, and how to put forward ideas for improvement. This can be carried out for each functional group, focussing on aspects of the QMS relevant to their work. This training would need to be carried out before the QMS is implemented.

The gap analysis may have revealed areas where quality is adversely affected by the lack of competence of persons performing the tasks. The appropriate person would need to draw up a training plan for review by management to address these deficiencies.

Planning for the Audit Process -Understandably, AIM must plan and manage the processes necessary for the continual improvement of the QMS to facilitate the continual improvement of the QMS through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive action and management review.

Determine the timing and frequency of internal audits. In the initial stages, more frequent audits may be necessary in order to fine tune the QMS and provide on-the-job training for internal auditors.

Trained internal auditors must conduct one or more internal audits before certification. The internal audits will identify any nonconformity in the QMS and offer opportunities for further improvement of the system. Proper corrective and preventive action should be taken against the nonconformities/potential nonconformities identified during the internal audits.

7.2.3. Phase 3 - Deployment and Testing

Overview - The implementation of the QMS. This includes the formal application of quality procedures, deployment of quality functions, monitoring and measurement of the results and initiation of the improvement actions, that is the activation of the Plan–Do–Check–Act (PDCA) cycle.

QMS training - This should be provided to the entire workforce of the aeronautical information service provider or section seeking ISO 9000 certification. It is an integral part of the QMS. The training should include the following:

- ▼ Basic awareness training for all staff to increase their awareness about the QMS
- Documentation writing for staff who are responsible for the preparation of documentation required by ISO 9001
- ✓ Internal auditor training for staff selected to conduct the internal audits

QMS Documentation - The quality policy and objectives, quality manual, documented procedures for various processes as appropriate and quality records will be developed and communicated to all staff. Details on the documentation required by the 2015 edition of ISO 9001 (ISO 9001:2015) can be found in Chapter 4.

Management Review Meeting - Deal with the discrepancies by determining the action required, implementing non-conformance procedures, and corrective action and follow-up procedures.

Internal Audit - Should certification be planned for the AIM QMS, internal audit will also serve to prepare for and simplify the certification process.

7.2.4. Phase 4 - Certification

Overview - Annex 15 includes a recommendation that the QMS put in place be certified by an approved organisation. Certification in accordance with ISO 9001 by an independent party provides formal recognition that the QMS has been implemented and is effective. During the ISO certification, the standards contained in ISO 9001:2015 — Quality Management Systems—Requirements are used to assess the effectiveness a QMS in meeting regulatory, customer and an organisation's own requirements. However, these standards are not intended to impose a particular system of documentation or a specific structure for the QMS.

In simple terms, certification is a process in which the QMS is audited to verify whether or not, over a period of time, AIM has undertaken its activities as recorded in its documented procedures.

Application for Certification - Certification begins with an application to a certification organisation. The certification organisation may request that AIM provide information on its activities, services and products verification of the QMS.

During the audit process, evidence will be sought to demonstrate that the QMS has been operating and is effective. The certification process begins with a pre-assessment, in which the quality manual is reviewed and the QMS is evaluated in terms of how well it adheres to ISO 9001. Corrective action arising from the pre-assessment must then be undertaken by AIM.

This is followed by a certification audit. During this time, the auditor will review documents, records and other evidence to verify whether procedures are carried out as documented. Certification could be withheld pending rectification of major non-conformities. For minor non-conformities, a qualified certification may be issued pending rectification by the next audit.

Maintaining Certification - Once certification is granted, the certification organisation carries out compliance or surveillance audits over the period for which the certification is valid. If major non-conformities are found during a compliance audit, certification may be withdrawn.

7.3. An Example of Implementation into AIM

Appendix 5 of this Guidance Manual contains some samples of templates and planning QMS implementation into AIM.

The Data Quality Process

8.1. Introduction

As introduced in Chapter 1, the data process consists of a series of complex functions within a sequential flow, particularly from data origination through to the publication of the State Aeronautical Information Publication (AIP) and other media derived from the AIP for end-use.

The objective of this guidance material is to ensure that aeronautical data of high quality and integrity are provided throughout the data chain, through the use of processes and procedures which eliminate manual data entry and/or transfer.

The following figure depicts the concept of the Aeronautical Data Chain with its 5 main functions performed by various actors at distinct organisational levels. Those functions are: data origination, publication, application integration, end-use and transmission.

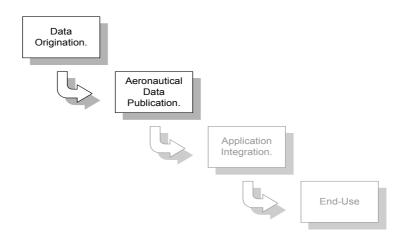


Figure 8-1: Aeronautical Data Chain

The introduction of complex flows within any of these elements of the Aeronautical Data Chain, such as the transition from data to document or from data import to data export, creates barriers to the maintenance of the quality/integrity of the aeronautical data.

Although, to an increasing extent, source data is being produced, distributed and stored electronically, transformation from one environment to another provides the greatest challenge to the protection of data integrity throughout the process.

8.2. The Generic Aeronautical Information Data Process

In order to ensure the end-to-end integrity of aeronautical data, it is essential that the data process is fully identified, mapped and understood. The establishment of this process is critical as it identifies the key participants, processes, inputs and outputs that must be addressed in any regularised process.

Any process is made up of three key elements: inputs, actions and outputs. The end-to-end data quality (integrity) process is no exception. Data originators (e.g. surveyors, ATS Personnel, service organisations etc.) will initiate inputs to the

process. The activities that are then performed in order to turn inputs into outputs will form actions associated with the process.

The outputs of the process will be products and services that meet the specific needs of users for aeronautical data. These users may be human-based or system-based e.g. a pilot using information derived from an AIP, or a Flight Management System (FMS) using its integrated geospatial data.

8.3. Organisations in the Supply Chain

The generic Aeronautical Information data process identifies the following main functional groupings:

- Surveyors
- Requesting Authorities CAAs, ANSPs (Air Navigation Service providers), ATSPs (Air Traffic Service Providers), aerodrome/airport authorities and, possibly, equipment suppliers (such as those developing terrain awareness warning systems – TAWS) that require surveys of, and survey

- information for, aeronautical facilities (NAVAIDS, aerodromes, obstacles, etc.)
- Originating Authorities organisations responsible for creating facilities related to other ATM facilities. These organisations may perform procedure or airspace design, airspace planning etc. and create facilities such as ATS routes or instrument flight procedures
- ▼ Publishing Authorities usually States' AIS that issue Aeronautical Information
- Users

8.4. The Generic Data Process

The generic data process may be best described by way of a diagram (figure 8-3) supported by explanatory text. It should be understood that although this process is designed to describe, at a high-level, those processes which have been found to exist within representative States, it may not immediately appear to fit the practices of all States. However, once its description is understood, readers should find that it provides a reasonable approximation to their individual process flow.

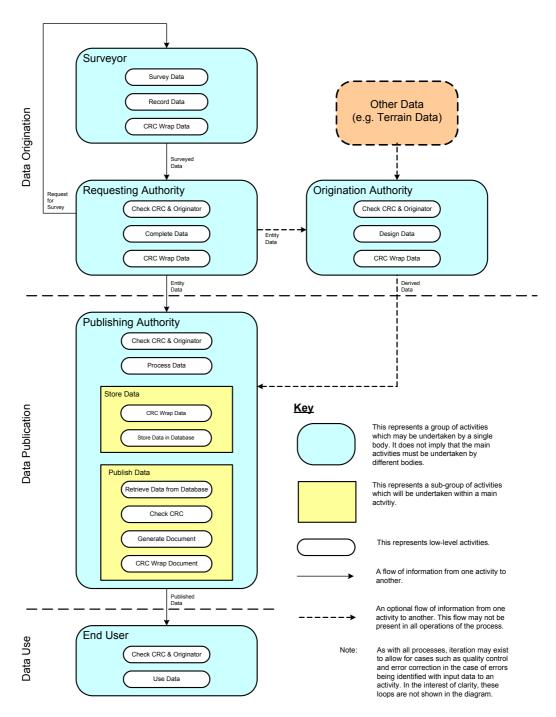


Figure 8-3 Generic Process Diagram

8.5. Generic Process - High-Level View

The following paragraphs outline the generic process. A high level generic process for all Aeronautical Information/data is as follows:

- Data/information is provided by defined/approved/certified, ISO9001, ISO accredited companies in accordance with legal and regulatory requirements
- Data/information is held in electronic media, preferably through use of standard worksheets which are used throughout the process
- In order to ensure that data/information being transferred electronically is received at the next activity without having suffered any change, be it accidental or malicious, it is necessary that a Cyclic Redundancy Check (CRC) value be calculated. This activity is usually referred to as CRC wrapping
- Data/information being transferred electronically is encrypted to provide further protection to its integrity
- Data/information is checked/verified by the Responsible Organisation (Aerodrome Authority, ANSP, CAA etc.) if provided by a subcontractor e.g. a surveyor
- Data/information is transferred electronically to AIS
- AIS verifies completeness and integrity of data
- → AIS processes the data to publication using electronic media

Data Origination - Data Origination addresses the functions performed by Requesting Authorities, Originating Authorities, Surveyors and any other third-party organisations supplying aeronautical data to such authorities.

Surveyed Data - Those surveyed data functions are:

- Geodetic datum specification and use
- Establishment of Aerodrome survey control networks

- Recommended procedures for achieving minimum data requirements
- ▼ Documentation of survey control stations
- ▼ Production of survey reports
- Ongoing maintenance of data
- ▼ Data management and quality assurance

Document configuration management.

Calculated and Derived Data (Originating Authority activities):

- Geodetic datum specification and use
- Airspace design
- Instrument flight procedure design;
- Audi
- ▼ Data management and quality assurance
- Document configuration management

Data Publication - Data publication addresses the functions undertaken by, usually, State AIS authorities, or their delegated agent(s), receiving surveyed, calculated and derived data from their receipt to publication. These apply to both electronic and paper publication. Data publication includes:

- Document management
 - Quality assurance
 - Data management
 - ▼ Document processing requirements
 - ▼ Document modification
 - ▼ Document configuration management
- ▼ Document publication tool
- Guidance for specific publication types

8.6. Aeronautical Data Processing Model

Since this guidance material is intended primarily to assist States and their AIM services in the implementation of the quality system, from the five-aeronautical data chain function links described above, only aeronautical data preparation and transmission are discussed further in this chapter. Usually, the AIM services process the original, raw data received from the data originators and once

prepared, aeronautical information is then distributed to the subsequent participant in the data processing chain. Consequently, in addition to data preparation, the AIM organisation performs the aeronautical data transmission function.

There are four phases of the aeronautical data preparation function link, i.e. assemble, translate, select and format, while the transmission functional link consists of two phases; receive and distribute. Figure 8-4 Highlights the AIM processes, the aeronautical data preparation and transmission functional links. While Figure 8-5 depicts an aeronautical data processing model related to data flows from preparation to transmission (distribution).

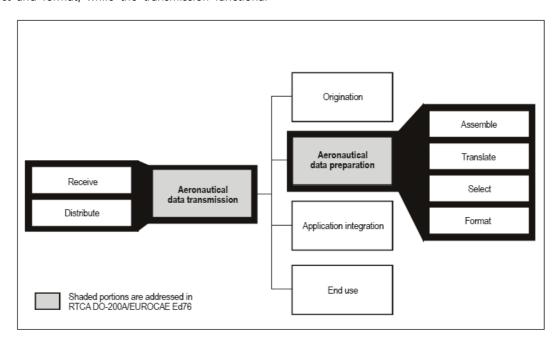
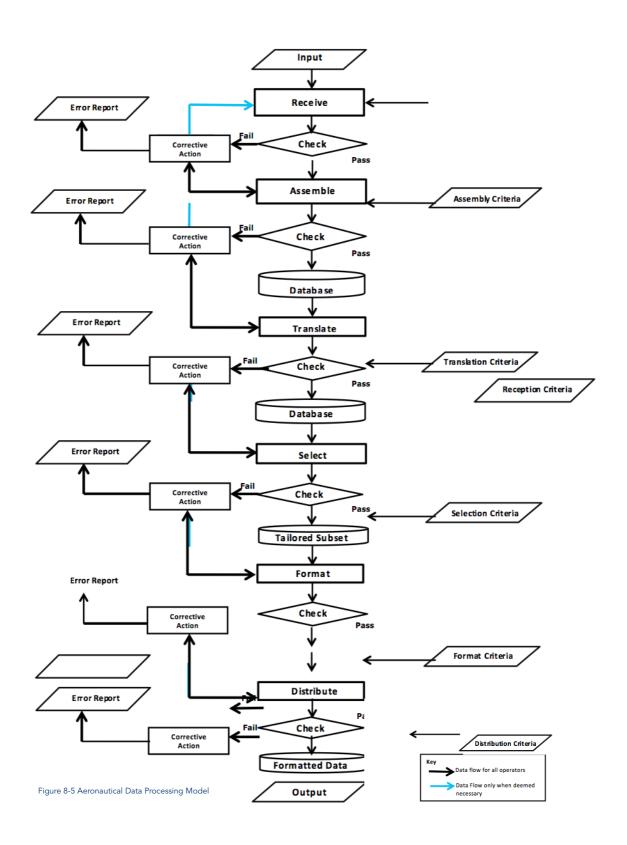


Figure 8-4 AIM Related Processes



8.7. How to connect and enhance quality as data travels along the key steps

These paragraphs trigger two important conclusions for the implementation of an AIS/AIM QMS system:

- ▼ The process applied needs to be identified, documented and understood
- ▼ The 'glue' between the key process steps shall be provided/supported by Service Level Agreements (SLA) - see Appendix 7

8.8. Measurement of Integrity

The integrity of data can be regarded as the degree of assurance that any data item retrieved from a storage system has not been corrupted or altered in any way since the original data entry or its latest authorised amendment. This integrity must be maintained throughout the data process from origin/origin to application.

8.8.1. Integrity of Data

Integrity is expressed in terms of the probability that a data item, retrieved from a storage system with no evidence of corruption, does not hold the same value as intended. For example, an integrity of 1 x 10-8 means that an undetected corruption can be expected in no more than one data item in every 100 000 000 data items processed.

Loss of integrity does not necessarily mean loss of accuracy. However, it does mean that it is no longer possible to prove that the data is accurate without a further verification of the data from the point at which integrity can be confirmed.

The integrity requirements for data are not absolute. The risk associated with a point being in error is dependent upon how that data point is being used. Therefore, the integrity used of a point at

threshold for landing needs to be at a higher integrity than one used for guidance in cruise.

The use to which a data item is put also forms the basis for determining its integrity requirement. A data classification is proposed which defines requirements based upon the potential risk resulting from corruption of the data and this classification is published on ICAO Annex 15 which states in Chapter 3:

3.2.10 - The integrity of aeronautical data shall be maintained throughout the data process from survey/origin to distribution to the next intended user (the entity that receives the aeronautical information from the aeronautical information service provider). Aeronautical data integrity requirements shall be based upon the potential risk resulting from the corruption of data and upon the use to which the data item is put.

Consequently, the following classification and data integrity levels shall apply:

- a) Critical data, integrity level 1 x 10-8: there is a high probability when using corrupted critical data that the continued safe flight and landing of an aircraft would be severely at risk with potential for catastrophe;
- b) Essential data, integrity level 1 x 10-5: there is a low probability when using corrupted essential data that the continued safe flight and landing of an aircraft would be severely at risk with the potential for catastrophe; and
- c) Routine data, integrity level 1 x 10-3: there is a very low probability when using corrupted routine data that the continued safe flight and landing of an aircraft would be severely at risk with the potential for catastrophe.

Note 1 — Distribution to the next intended user will differ in the delivery method applied which may either be:

Physical distribution in which aeronautical information/data distribution is achieved through the delivery of a physical package, such as postal services, or

Direct electronic distribution is where aeronautical information/data distribution is achieved automatically through the use of a direct electronic connection between the AIS and the next intended user.

Note 2 — Different delivery methods and data media may require different procedures to ensure the required data quality.

3.2.11 The Aeronautical data quality requirements related to classification and data integrity are provided in tables A7-1 to A7-5 of Appendix 7 of ICAO Annex 15.

The value for the Critical Data was derived from the maximum level of accidents from all causes in 10⁷ approaches. For that purpose, the results of flight tests in the Final Approach Segment Data Block were derived as defined in ICAO Annex 14. As data errors can be one of the causes of these accidents the same value was adopted for the required data integrity.

The value for Routine Data was set at the value that could realistically be achieved using multiple entry methods. The value for Essential Data was set as an intermediate value between the two extremes.

8.8.2. How is Integrity Measured?

An example of integrity measurement would be an integrity level of 1x10-8 means that the acceptable rate of loss of integrity is 1 in every 100,000,000. It is highly improbable that a single data item will ever be stored, retrieved, transmitted and used that many times.

In fact, if the life of a data item is five years (the typical time for a resurvey of data), then it would have to be acted upon over 50,000 times every day

to achieve 100,000,000 transactions over which its integrity is measured.

Let's take the data item again and assume that it is the latitude/longitude of a NAVAID, held in the traditional form of 'N dd mm ss / E ddd mm ss'. Straight away, a single data item may be considered to have two components, the latitude and longitude. Going further, it could be interpreted as having eight components: two each of a direction, degrees, minutes and seconds. Alternatively, it takes twenty-two characters to hold the value and if these are typical seven-bit ASCII characters, this is 154 bits of information.

If assessed the individual data item in these terms, and working on the premise that each data bit must have integrity whenever it is subjected to a transaction, 50,000 transactions a day needed over five years becomes 'only' 325 times a day. This is still more than expecting to be possible, or is it? Given that today more and more information is being stored and accessed from databases, published using Intranets and Internets, the number of accesses, and therefore transactions, is increasing all the time.

That said 325 times a day is still a high number of transactions for a single data item. But what if group data items? By this, it does not mean all latitudes and longitudes but rather the grouped data using its integrity classification given by ICAO.

If there were one hundred co-ordinates within a State, each of which is considered to be critical (and the real number in the average State is probably much higher than this), then each would have to be accessed only four times each day, over a five-year period, to confirm the 1x10-8 integrity.

The sums used in this calculation are shown below:

- Critical points: 100
- Characters per point: 22
- Bits per character: 7
- **→** Bits per point: 22 x 7 = 154
- \checkmark Bits for all critical points: 154 x 100 = 15,400

- Access per day: 4
- ▼ Bits subject to transactions / day: 4 x 15,400 = 61,600
- Days per year: 365
- ▼ Bits subject to transactions / year: 365 x 61,600 = 22,484,000
- Number of years for 1x10-8: 100,000,000 / 22,484,000 = 4.45 years

In reality, the number of critical points in a State is likely to far exceed the 100 used here. Given that each runway direction used for precision approach alone has at least six critical values, only nine runways (assuming two directions per runway) used for precision approach within a State, will be needed to exceed this figure.

In this way, it has been demonstrated that it is possible to measure the integrity of information, provided it is considered at a low level and across categories.

Current Approach in European region - EUROCONTROL has been developing the Specification for Data Assurance Levels (DAL) that is required on the quality of aeronautical data and aeronautical information for the single European sky. The DAL provides all parties from origination to publication with a set of objectives that elaborate on ICAO requirements for Data Integrity, as described in Annex 15, and enables providers of data to demonstrate compliance with the specified Integrity Levels.

The DAL objectives define the manner in which processes, tools and procedures should be applied at each stage of the aeronautical data chain. The DAL is defined at three levels corresponding to those as defined by ICAO Annex 15 Data Integrity requirements and the effectiveness in achieving the requisite data quality will be realised by compliance to the objectives.

- DAL 1 for Critical data items
- DAL 2 for Essential data items
- ▼ DAL 3 for Routine data items

The assurance of data quality at higher levels of data integrity will generally require multiple layers of defence to prevent data errors being introduced or missed during the data processing or checking activities. For example, for objectives at DAL 1 and DAL 2 a greater degree of independence¹ is required than for objectives at DAL 3.

The DAL objectives are split through several sections: Evidence Requirements; Dataset; Data Interchange; Data Quality Aspects; Consistency, Timeliness and Personal Performance; Tools and Software Requirements; Data Protection; Quality Management, Safety and Security Requirements; Conformity or Suitability for Use of Constituents; Verification of Systems; Additional Requirements.

Below is an extract of the Data Interchange section, listing the specific objectives for Direct Electronic Connection. It describes how the objective is associated with each DAL (a dot means that the objective should be satisfied; a blank means that satisfaction of the objective is at stakeholders' discretion). The level of independence required for each DAL is indicated by the black dot and a letter corresponding to the required separation between the primary activity and the validation activity (in these cases a D for a person within a separate group or department and an P for a person within the same group or department).

It is now recognised that it is often difficult or unjustifiable, to demonstrate the numerical targets required for safety through testing alone, as required failure rates are often very small. Not only would a significant period of testing be required (e.g. could be thousands of years) but many errors that can cause accidents are mathematically unpredictable in nature (i.e. do not occur randomly). These types of errors are normally addressed by qualitative rather than quantitative methods.

¹ Independence is the functional separation between the person, department or organisation performing the primary activity, and the person, department or organisation verifying or validating the activity output.

Given that data integrity is defined numerically in ICAO Annex 15, and from a safety perspective the acceptable occurrence rate for essential/critical errors is very small, then a qualitative method is preferable for assuring data for use in safety related ATM applications.

The ICAO Annex 15 (Article 3.2.12) recognises the application of Cyclic Redundancy Checks (CRC) as a mean of providing a high-degree of assurance that if aeronautical data and information becomes corrupted, this may be identified. In other words, they help detect if the integrity of the data has been compromised. The use of CRCs is widespread and is the most common form of check used to ensure that the information contained within a dataset has not been changed.

8.8.3. How do I Measure the Integrity of a Process?

Having in consideration the recognised difficulty to measure quantitatively the requested integrity levels all along the aeronautical data chain, the use of CRCs and the compliance with the relevant DAL objectives is enough to address the data integrity requirements of the data quality process.

OBJECTIVE	OBJECTIVE	DAL1	DAL	DAL	GUIDE
REFERENCE			2	3	REFERENCE
DAL-DI-10	Whenever data is transmitted from one user to the	0	0	0	
5,125110	next, processes shall be established to protect the				
	data during the transfer.				
DAL-DI-020	For data transmitted by electronic means, the	0	0	0	
	integrity of the data shall be protected by applying				
	a CRC to the data before transmitting it to the next				
	intended user				
DAL-DI-021	For eleka kongressiska diku unangan sangan akan intersita.				
DAL-DI-02 I	For data transmitted by paper means, the integrity	0	0		
	of the data may be protected by including the associated CRCs				
	associated Circs				
DAL-DI-030	The applied CRCs shall be robust enough to protect	•	•	0	
	the data from corruption over transfer from one user	_	_		
	to the next	D	Р		
DAL-DI-040	For data received by electronic means, the integrity	0	0	0	
	of the data shall be confirmed by checking the CRC.				
DAL DI OFO					
DAL-DI-050	On receipt of data, it shall be verified that the	0	0	0	
	received data is from an authorised and approved				
	source.				
DAL-DI-060	The means for determining authorisation of data	0	0		
	shall be appropriate to the method of data transfer.				
DAL-DI-070	Documentation shall be maintained that identifies	0	0		
	all the suppliers of data used by the organisation				
	and the approval status of data.				
DAL-DI-080	Data that cannot be authenticated shall not be	0			
	used.				
DAL-DI-090	After receiving data but before use data	•	•	0	
	reasonableness checks shall be performed.	Р	Р		
		,	Ċ		
DAL-DI-100	For data received by means other than electronic	•	•	0	
	and/or where manual entry of the data is required,	_	_		
	the entered data shall be checked against the	D	D		
	source data.				
DAI DI 110	If a many and althous and in the control of the col				
DAL-DI-110	If errors are discovered in the received data, the data supplier shall be informed immediately	0	0	0	
	data supplier shall be informed infinediately				

Figure 8-6 Specification for Data Assurance Levels (DAL)

Safety Management System (SMS) and QM

9.1. Introduction to SMS

An SMS is a systematic and proactive approach of managing safety, including the necessary organisational structures, accountabilities, policies and procedures.

SMS can be considered as a management chain which defines the essential elements for hazard identification and safety risk management. SMS is created for a constant, never-ending operation of safety risk management.

Relationship between SMS and QMS

Both SMS and QMS achieve the overall organisation goals, and in particular, the organisation's safety goals through a management system. (For example: policies, objectives, organisational structure, procedures, monitoring and the improvements of organisational management)

QMS provides assurance for the management of quality by means of a process method-PDCA (refer to paragraph 2.6). SMS provides assurance of safety by identifying, preventing and controlling the safety hazards existing in an operation.

QMS can assure safety as proposed by quality dogma in combination with SMS which contains the function of identifying (and therefore controlling) safety risks which are inevitable during operations. The integration of SMS into QMS enhances the possibility of achieving safety goals significantly.

The relationship between SMS and QMS is synergistic rather than antagonistic. Establishing a complementary relationship between SMS and QMS leads to the complementary contributions of each system to the attainment of the organisation's safety goals. The figure 9-1 depicts the relationship between SMS and QMS, and the table 9-1 demonstrates commonalities and differences between SMS and QMS.

QMS provides a structured and standardised approach for processes and procedures, enabling SMS to identify hazards and keep safety risks under control. The relationship therefore allows SMS to operate as planned and make improvements to prevent or mitigate deviations when they occur.

9.3 Integration principle and method of QMS and SMS

There are three possible options when developing SMS and QMS.

➤ Separation - Separation approach establishes two different systems for Quality Management (QM) and Safety Management (SM). Particular instances of QMS and SMS collaboration will be the subject of case-bycase definition. Within this approach, complete development of separate systems is needed. The co-ordination and the

communication between these two systems are not explicitly defined, but are part of the general organisation process of coordination and communication.

- ▼ Collaboration Common subjects might be partially implemented in a shared manner. SMS is usually for new or additional threats to safety, while QMS prevents any erosion of safety. Thus, SMS is more proactively concentrated and QMS is more reactively oriented. SM is looking ahead for safety problems ensuring they are addressed before an incident occurs whilst QM is checking what has not been done and correcting non-conformances so that old problems do not recur. This approach suggests that common subjects might be implemented partially in a shared manner.
- ▼ Inclusion This approach suggests either SMS to be implemented in QMS, or QM elements to be added to SMS. It suggests common subjects might implemented in whole or in a shared manner. Two variants are possible. The first option considers the existence of the QMS in the organisation. SMS is added at the top of QMS. Safety is managed within this approach as an attribute of quality. All SM principles, objectives, procedures and processes are included in the existing QM elements. The second approach envisages some useful QM elements and techniques together with those mandatory for the particular environment quality requirements to be added to the SMS. The first inclusion option makes sense for AIS/AIM providers considering the already existing QMS and the relatively small size of the organisation.

The principle of integrating SMS into QMS is to add relative risk management requirements where risk management is needed in the following four QMS processes:

- Management responsibility
- ▼ Resources management
- Operation
- ✓ Improvement

Consequently, the management goals will be upgraded from 'stable quality' to 'assured safety'.

9.4. QMS as the basis of SMS

The implementation of QMS can greatly reduce the potential problems and risks in operations. Without QMS, the processes and procedures of an operation cannot be guaranteed; resulting in a significant increase in hazard potential and risk control will then become compromised.

The integration of SMS and QMS is achieved by adding the content concerning the policies, organisational structure, safety assurance and other elements of SMS into the counterparts of QMS.

The processes and procedures of SMS elements which are considered to be included into QMS.

Policy - Quality policy would be an enabler to achieve the safety. Quality policy shall reflect organisational commitments regarding safety.

▼ Safety Risk Management

- Hazard identification Develop and maintain a formal process that ensures that hazards in operations are identified. Hazard identification is based on a combination of reactive, proactive and predictive methods of safety data collection.
- Risk Assessment and Mitigation -Develop and maintain a formal process that ensures analysis,

assessment and control of the safety risks in operations.

→ Safety Assurance

- ▼ Safety performance monitoring and measurement - Develop and maintain the means to verify the safety performance of organisation and to validate the effectiveness of safety controls. The safety performance of the organisation is verified in reference to the performance indicators and safety performance targets of the SMS.
- The Management of Change Develop and maintain a formal
 process to identify changes within
 the organisation which may affect
 established processes and
 services; to describe the
 arrangements to ensure safety
 performance before

implementing changes; and to eliminate or modify safety risk controls that are no longer needed or effective due to changes in the operational environment.

→ Safety Promotion

- Safety Communication Develop and maintain formal means that ensures that lessons learned from investigations and case histories or experiences are distributed widely.
- Safety Improvements Develop and maintain processes that encourage personnel to propose solutions to identified hazards as well as safety improvements; dealing with proposals systematically and ensuring feedback to the originator

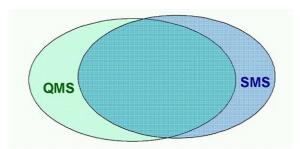


Figure 9-1 Relationship between SMS and QMS

SMS	QMS
Safety Occurrences	Control of non-conforming products
Safety Surveys	Monitoring and measurement, audit
Safety Records	Documentation requirements

Management	Management
	Customer Focus
	Resource management
	Production
Risk assessment and mitigation	
Lesson dissemination	

Table 9-1 Commonalities and differences between SMS and QMS

<u>Acronyms</u>

AFTN	Automatic fixed telecommunication network
AIC	Aeronautical Information Circular
AIM	Aeronautical Information Management
AIP	Supplements to the AIP
SUPP	
3011	
AIP	Aeronautical Information Publication
AIRAC	Aeronautical Information rules and control
AIS	Aeronautical information services
ATM	Air traffic management
CAA	Civil aviation authorities
CRC	Cyclic Redundancy Checks
DAIO	Duty Aeronautical Information Officer
DAL	Data Assurance Levels
FIR	Flight Information Region
FMS	Flight management system
ISO	International Organisation for Standardisation
NOF	International NOTAM office
NOTAM	Notice to Airmen
PIB	Pre-flight information bulletins
QMS	Quality management system
RNAV	Required area NAVigation
RNP	Required navigation performance
SARPs	Standards and Recommended Practices
SLA	Service Level Agreements
SMS	Safety Management Systems

Appendix 1

Checklist for the Development of a QMS for AIM

ltem	PROGRAMME INITIATION					
	SENIOR MANAGEMENT					
1.	Commitment by senior management					
2.	Briefing/seminar/workshop to familiarise senior management with QMS in general and related ISO regulations and guidelines					
3.	Development of the quality policy					
4.	Development of the quality objectives					
5.	Communicate the quality policy and quality objectives to all AIM staff					
6.	Define the initial roles and responsibilities of the quality resources					
7.	Appoint quality resources					
8	Arrange for ISO training of the quality resources					

PLANNING PHASE

ltem	PROJECT IMPLEMENTATION TEAM QUALITY RESOURCES						
1.	Define roles and responsibilities of the project implementation team members						
2.	Create the project implementation team						
3.	Brief the project implementation team on the goals and purpose of the QMS, the QMS implementation project and the role of ISO						
4.	Arrange for ISO training of all team members and staff						
5.	Assign tasks with specific outcomes and deadlines to the team members						

Item	GAP ANALYSIS				
	QUALITY RESOURCES (WITH THE ASSISTANCE OF THE PROJECT IMPLEMENTATION TEAM)				
1.	List the functional groups of AIM and its organisational structure. Show how the organisational structure of each functional group relates to the others and how the AIM functional groups relate to functional groups outside AIM. (This may be represented best as a flow chart.)				
2.	List the activities performed within each functional group.				
3.	List the processes involved in each of the activities listed, the inputs and outputs of each process and the sequences of the processes. Describe where inputs are derived from outputs of previous processes and where outputs are linked to succeeding processes.				
4.	List the customer requirements (including standards and regulations) and the requirements of other functional groups in AIM. Link the processes to these requirements. Note processes that serve neither customers nor other AIM functional groups. Note where processes are still needed to meet requirements. Note where processes need to be improved or changed in order to be effective.				
5.	List the procedures used in each of the processes. Note where procedures are undocumented or non-existent.				
6.	List the roles and responsibilities of each person involved. Note the differences between actual responsibilities and those documented in the job descriptions, as well as the lack of documented responsibilities.				
7.	List the skills and competencies needed to perform the duties and responsibilities described above. Note where tasks are not carried out because of a lack of training.				
8.	List existing documentation on all of the above. This documentation maybe in many forms, such as flow charts, procedures, checklists, forms, job descriptions, manuals or style guides.				

Item	COMPLETION OF PLANNING ITEMS AND PROJECT PROPOSAL					
	QUALITY RESOURCES					
	(WITH THE ASSISTANCE OF THE PROJECT IMPLEMENTATION TEAM)					
1.	Determine the deliverables for the QMS project.					
2.	Develop a schedule of target dates					

3.	Draw up a list of resources required
4	Internal resources
5.	External resources

Item	APPROVAL OF THE IMPLEMENTATION PROJECT				
	SENIOR MANAGEMENT				
1.	Review project proposal with the quality resources				
2.	Approve the implementation project as proposed or negotiate changes.				
3.	Other costs				
4.	Complete the project proposal to senior management				

DESIGN PHASE

Item	DEVELOPMENT OF PROCEDURES AND DOCUMENTATION					
	QUALITY RESOURCES					
	(WITH THE ASSISTANCE OF THE PROJECT IMPLEMENTATION TEAM)					
1.	Create document templates for procedures, instructions, forms, checklists, job descriptions and any other documentation to be developed for the QMS.					
2.	Develop and produce all necessary procedures and documentation.					

Appendix 2

Template of a Quality Manual to be used by an AIM Organisation

The template for a project proposal in this appendix could be used as the basis for a proposal to senior management to secure approval of the QMS implementation project. It can also be used as a framework for the development of the QMS in terms of defining scope, assessing the potential benefits, outlining the programme, determining the roles and responsibilities of those involved in the development and implementation of the QMS, and for specifying deliverables, target dates and the resources needed.

PROJECT PROPOSAL IMPLEMENTATION OF A QMS FOR AERONAUTICAL INFORMATION MANAGEMENT (AIM)

[NAME OF STATE]

TABLE OF CONTENTS

- 1. Introduction
- 2. Objective
- 3. Scope
- 4. Benefits
- 5. Programme Description
 - 5.1. Planning of the QMS
 - 5.2. Design of the QMS
 - 5.3. Deployment and Testing of the QMS
 - 5.4. Final Adjustment and Internal Audit
- 6. Project Plan
- 7. Project Implentation Team
- 8. Resources
- 9. Deliverables
- 10. References

1. Introduction

ICAO Annex 15 — Aeronautical Information Services requires that States introduce a quality system to implement quality management at each functional stage performed by the aeronautical information service.

Furthermore, it is recommended in Annex 15 that the quality system conform with the International Organisation for Standardisation (ISO) 9000 series of quality assurance standards and that it be certified by an approved organisation.

2. Objective

This proposal outlines the project to implement a QMS within the AIM organisation of the State. The objectives of the project are to comply with the ICAO provisions and (add specific objectives as required).

3. Scope

The programme described will implement a QMS for all activities (or specify) performed by all functional groups (or specify) at all locations (or specify) that contribute to AIM in (State).

4. Benefits

The implementation and operation of quality measures in the form of a QMS will bring improvements in quality, efficiency, and reliability with subsequent enhancements to productivity, safety and service levels.

5. Programme Description

The programme tasks can be broken down into following four principal phases:

- 1) Planning of QMS requirements in the AIM functional groups
- 2) Design of the QMS
- 3) Deployment and testing of the QMS
- 4) Final adjustment and audit for ISO certification

Planning of the QMS

The objective of this phase is to establish, in relation to each of the AIM products and services.

- a) The activities and the organisational relationships
- b) The processes involved
- c) Tthe requirements
- d) The necessary procedures to affect the processes identified and fulfil the requirements
- e) The duties and responsibilities and the associated skills and competencies required
- f) The necessary documentation

Design of the QMS

In this phase it is necessary to:

- a) Create new procedures as required and to ensure consistency with existing ones
- b) Write all documentation
- c) Develop training plans
- d) Plan for certification by audit

The key to this phase will be developing and producing the necessary documentation.

Deployment and Testing of the QMS

As the QMS develops, the procedures need to be issued/applied and the system must be implemented in such a manner that the processes can be tested and checked for correct functioning. Discrepancies will be dealt with by corrective action and follow-up action procedures.

Final Adjustment and Internal Audit

The final phase represents the on-going working QMS which will be operated for a period of time before the internal audit. This provides an opportunity for fine tuning of the QMS elements. The timescale for this adjustment phase may extend beyond the internal audit date in order to accommodate any corrective action issues that may arise from the internal audit.

6. Project Plan

The following is a schedule of the programme, showing a proposed total implementation timescale of [number] work days.

Document type	Information	Content	Implementation	Evaluation	Revision	Work	Target
	planning	development		and review		days	dates
Quality manual							
Quality							
objectives							
Requirements							
Processes							
Procedures							
Quality records							
Instructions							
Document							
templates							
Checklists							

Forms				
Job descriptions				
etc.				
Training plan				
Audit plan				
Total number of work days				

7. Project Implementation Team

The following staff members are proposed to form the project implementation team. An assessment of the effort required of each staff member is included.

PROJECT IMPLEMENTATION TEAM				
Name	Role	Skills/Department	Estimated Effort	
		Represented	Required	
	Ovelite veces / Drei est		Mark days	
	Quality resources/Project		Work days,	
	implementation team leader		fulltime/part time, etc.	

8. Resources

Internal

The following is an estimate of the effort required for the specified tasks, the majority of which can be provided internally.

INTERNAL EFFORT		
Task Estimated effort (work days)		
Process analysis		

Procedures development	
Documentation development	
Documentation control and other records	
QMS training	
Internal auditor training	
Any other related not indicated above	

External

Some external support is recommended to assist with correct interpretation of the ISO 9000 QMS requirements and to ensure that the project implementation team is kept on track for compliance.

EXTERNAL EFFORT		
Task	Estimated effort (work days)	Cost
Interpretation of requirement		
against standard ISO 9001		
QMS awareness training		
Internal auditor training		
Pre-registration audit		
Any other related not indicated		
above		

OTHER SUPPORT COSTS			
Item	Purpose	Cost	
Software	Document control, text processing, etc.		
Hardware	Upgrading of database, networking, etc.		
ISO registration fee	Professional registration of QMS by independent agency		
Any other related not indicated above			

9. Deliverables

The project objective is to establish a QMS that meets the requirements of the ISO 9001 standard. The following are considered to be essential elements of this process:

- Quality manual
- Documented procedures
- quality records

10. References

- 1. Annex 4 Aeronautical Charts
- 2. Annex 11 Air Traffic Services
- 3. Annex 14 Aerodromes
- 4. Annex 15 Aeronautical Information Services
 - 5. Doc 8400, PANS-ABC Procedures for Air Navigation Services ICAO Abbreviations and Codes
 - 6. Doc 8126 Aeronautical Information Services Manual
 - 7. Doc 8697 Aeronautical Chart Manual
 - 8. Doc 9679 World Geodetic System 1984 (WGS-84) Manual
 - 9. Doc 9839 Quality Management System for AIS/MAP
 - 10. ISO 9001:2015 Quality Management Systems Requirements

[Include national laws and/or regulations if applicable.]

Appendix 3

Sample of Certification/Registration Audit

1. Example of Procedure for ISO9000 Series Certification

< Insert name of Organisation >		
DIRECTORATE: <insert name=""></insert>	DOC NO. <insert doc="" number=""></insert>	
SUBJECT: <insert addressed="" being="" by="" procedure="" subject:="" the=""> e·g IAIP MANAGEMENT</insert>	ISSUE: REV: DATE:	

1. RECORD OF CHANGE

NO.	DETAILS OF CHANGE	DATE
1.		
2		
۷.		

2. CIRCULATION

This procedure is issued on controlled basis to: -

Name <insert name="" office=""></insert>	Department <insert department="" name=""></insert>	No. <insert copy<br="">number></insert>

Name and Copy Number

ISSUED BY <insert aim="" head="" of="" title=""></insert>	APPROVED BY
SIGNATURE	SIGNATURE
DATE	DATE

3. CONTENTS

- 1. Purpose
- 2. Scope
- 3. Reference
- 4. Terminologies
- 5. Responsibilities
- 6. Procedure/Method
- 7. Appendices

1.0. Purpose

The purpose of this procedure is to ensure that aeronautical information/data provided is adequate, timely and is of the required quality.

2.0. Scope

This procedure covers the Management of the Integrated Aeronautical Information Package (IAIP) that includes; AIP including amendment services, Supplements to the AIP, AIC, NOTAM, Pre-flight Bulletins (PIB), checklists and list of valid NOTAM.

3.0. References

- ▼ Aeronautical information service Manual ICAO Doc 8126
- ▼ Manual standards -AIM
- Manual of AIM operations
- ▼ Civil Aviation Regulations CAP394
- ▼ ICAO abbreviation and codes- Doc 8400
- ▼ Location Indicators- Doc 7910
- ▼ Designators for Aircraft operating agencies, aeronautical authorities and services
- **→** Doc 8585
- ▼ Aircraft type designators Doc 8643
- ▼ Clearance Records

4.0. Terminologies

DATA	A COLLECTION OF FACTS FROM WHICH
	CONCLUSIONS MAY BE DRAWN
Format	The acceptable wordings page numbering or form
IAIP	Integrated aeronautical information package (AIP, including amendment services, Supplements to the AIP, AICNOTAM, Pre-flight Bulletins (PIB) including checklists and list of valid NOTAM)
Data Originators	Institutions or persons who are in possession of information essential to air navigation as listed in

	the AIS Manual of operations
NOTAM	A notice distributed by means of telecommunication containing information concerning the establishment, condition or change in any aeronautical facility, service, procedure or hazard, the timely knowledge of which is essential to personnel concerned with flight operations.
In-Charge	An officer designated as the head of an AIM unit e.g. head of NOF, AIM head of AIS Aerodrome unit, head of AIP/MAP unit.
AIM Operations Manual	An operations manual containing processes and procedures to be followed when performing AIM Functions

4.1. Abbreviations

AIM	Aeronautical Information Management
AFTN	Aeronautical Fixed Telecommunication Network
AIC	Aeronautical Information Circular
AIS	Aeronautical Information Services
AIP SUPP	Supplements to the AIP
AIP	Aeronautical Information Publication
AIRAC	Aeronautical Information rules and control
ATM	Air Traffic Management
CAAs	Civil Aviation Authorities
CRC	Cyclic Redundancy Checks
DAIO	Duty Aeronautical Information Officer
DAL	Data Assurance Levels
FIR	Flight Information Region
FMS	Flight Management System
ISO	International Organisation for Standardisation
NOF	International NOTAM office
NOTAM	Notice to Airmen
PIB	Pre-flight information bulletins
QMS	Quality Management System
RNAV	Required to support area Navigation
RNP	Required Navigation Performance
SARPs	Standards and Recommended Practices
SLA	Service Level Agreements
SMS	Safety Management Systems

5.0. Responsibilities

<Insert title of Head of AIM> shall be responsible for the implementation of this procedure

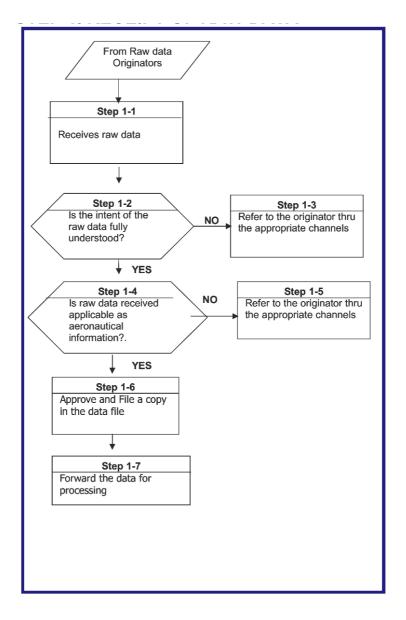
6.0. Method

6.1. Management of the Elements of IAIP

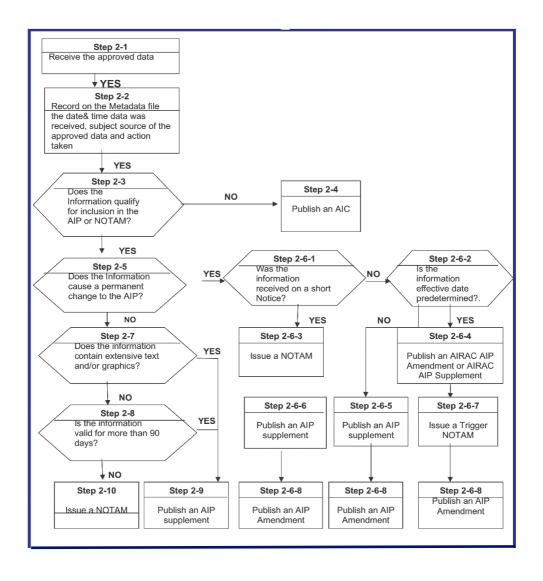
- 6.1.1. The responsible AIM shall receive data from data originators and review as per step 1 of Appendix 1 to determine its applicability. If not applicable, the in-charge shall refer the data back to the originator. If applicable, approve and forward to the Duty Aeronautical Information Officer (DAIO) for analysis and processing.
- 6.1.2. On receiving the approved data, the DAIO shall record in the Metadata file and conduct data analysis to determine the appropriate IMP element as per step 2 of Appendix 1 attached.
- 6.1.3. When processing the applicable IAIP element, DAIO shall follow processes and procedures as published in chapter of AIM operations m.
- 6.1.4. Data capture during processing of elements of IAIP shall be as detailed in Chapter of AIM operations manual.
- 6.1.5. Validation of data shall be per the processes and procedures provided in Chapter of AIM operations manual.
- 6.1.6. The publications resulting from steps 6.1.1 to 6.1.5 shall be stored in both electronic and paper form as detailed in the appropriate chapter of the AIM operations manual.
- 6.1.7. Distribution and dissemination of the publications resulting from steps 6.1.1 to 6.1.5 shall be as per appropriate chapter of AIM operations manual.

Appendix 1: Data Handling Procedures

Step 1 Receipt of Raw Data



Step 2 - Data Analysis



2. Diagnostic Audit of AIS Quality System

2.1 Purpose of the audit:

- ▼ Develop a statement describing the fundamental (essential) nonconformities or absence of work undertaken by the organisation's quality system elements, or the management system. Also describe if it includes initiated quality system elements that are convergent or compatible with requirements that are specified in ISO 9001 standard.
- Ascertain if a quality system elements were initiated and their efficiency from the organisation's purpose point of view.
- Tenable audited organisation to improve their existing quality system.
- ▼ Determine and confirm fulfilment of quality requirements that are result of related regulations.
- To state if the procedures, documents and other information referring to quality are well known, available, clear (intelligible, understandable) and in use by the organisation's staff.
- To state if the documents and other information describing the organisation quality system adopted are able to achieve (attain) planned quality goals (aims, purpose, objectives).

A diagnostic audit doesn't replace the part of supervision or inspection activities are directed to process control or product acceptance (of maintenance or service). The audit will estimate if the organisation is meeting criteria required by the organisation quality system as necessary to achieve quality goals. The quality audit go beyond (enlarge) the scope of activities referred the quality system of the organisation only those which are necessary to determine if the audited unit is meeting their quality goals and those defined in Annex 15.

Requirements should refer to:

- The goals and the scope of audit
- Identification of persons responsible for the for material connected with the scope of audit
- ▼ Identification of relative documents
- Date and place of audit
- ▼ Identification of divisions that are or may be included in the audit
- ▼ Beginning time and the length of audit duration
- ▼ Meeting's timetable
- ▼ Confidentiality
- ▼ Audit report distribution index

It has been presented, adjusted as required, and agreed to by representatives of the organisation.

Because of the audit safety aspects, which are essential for AIS, the below mentioned non-conformity criteria are also mentioned. The requirements described in ISO 10011-1, 10011-2, 10011-3 standards are consciously limited.

Nonconformity of the first grade (critical) – system nonconformity present or in the process description a nonconformity that has got direct, negative influence for air safety; for example false data published in AIP or in NOTAM, lack of information, improper graphic symbol used in the chart.

- Nonconformity of the second grade (important) obvious nonconformity, but having no direct, negative influence for the interpretation of published data; for instance lack of information about the level of access to the published instructions.
- Nonconformity of the third grade (minor, insignificant) nonconformity, that has no or very small influence on safety; for instance spelling or punctuation errors in the instruction which has no influence for explicit (unmistakable) understanding of the record.

During the audit, the auditor performs initial estimation of the identified nonconformity and presents it to the lead auditor. Nonconformity of the first grade requires immediate action on the part of the responsible individual for the process where the nonconformity was detected. Nonconformity of the second grade should be removed as soon as possible. Nonconformity of the third grade is the information's nature nonconformity (notice).

DIAGNOSTIC AUDIT SCHEDULE

	Audited Organisation (Auditee):	Organisation's Man	ager:
	Opening Meeting Date:	Closing Meeting D	ate:
Leading Auditor (Audit Team Leader): (if applicable)		Audit Team:	
Date	Audit Progress	Place of Audit	Responsible Person (organisation's side)
	 a. Initial meeting b. Introduction of the Audit team c. Presentation of audit goals, audit scomethodology d. Develop questionnaire of supervision e. Presentation of questionnaire of superorganisation's representatives f. Complete the diagnostic audit of the using the requirements included in the PN-ISO 9001:2015, • PN-ISO 10011-1, 2, 3:1994 (auxity) g. Prepare the audit report h. Present the results of the audit to the of the organisation i. Acceptance of corrective action propapplicable). j. Establish a meeting date where the ecorrective action, if applicable, will be 	organisation, ne; liary) management losal (if	

Auditor	Organisation's representative
Name (legibly written)	Name (legibly written)

AIS INTERNAL DIAGNOSTIC AUDIT

Item	Subject	QuestionsS	Ans	wer
			Yes	No
i	ii	iii	iv	٧
1	ACTIVITY PRINCIPLES: LEGAL AND FORMAL	Does the AIS management and personnel know the legal and formal basis of AIS activity: a. ICAO Annex 15 – Air Information Service b. Air Information Service Instruction IL-15 c. Operational Instruction Preparation - ICAO Doc. 9376. d. Air Training Centres institution and leading manual – ICAO Doc. 9401. e. Aerodromes Certification Manual – ICAO Doc. 9774 AN/966.		
2.		 Has the organisation adequately established; a. An organisational structure b. A model of requirements, referring to employee position description and responsibilities c. Management responsibilities and planning d. How authority is delegated; e. How delegation of a task responsibility is handed over task and assumed; including procedures and appropriate times f. Levels and criteria of access to data g. Information flow procedures h. Principles of internal communication and have they been published and distributed i. The levels of operational, technical and organisational decision delegation j. Substitution system of responsibilities for ongoing projects k. Responsibility levels on projects 		
3.	SUPERVISION PROCEDURES IN AIS	Has the organisation adequately established a; a. Validated main and auxiliary processes for the supervisory system b. Valid mandatory documentation oversight system c. Process for supervisory monitoring d. Supervisory process checklists		

		e. Methodology and practice of supervision the
		entering and the evidence of corrective action
4.	AIS STAFF	Has the organisation established / defined on the
٦.	AISSTAIT	adequate way :
		adequate way .
		a. qStaff composition adequately to the needs and
		requirements
		b. Conditions, that employees have to fulfill – in
		accordance (compliance) with stands
		requirements
		c. Main and accessory (auxiliary) processes leaders
		d. Qualifications (including minimum requirements) -
		in accordance (compliance) with stands
		requirements including :
		oThe way of obtaining
		oThe way of confirmation
		oThe way of evidencing
		oThe way of renewal
		oThe way of actualisation
		The way of invalidation/suspension
5.	AIS WORK	Has the organisation adequately established or
-	ENVIRONMENT	defined;
		a. An overall AIS work environment?
		B. An AIS work environment in the divisions that are
		involved with AIS processes?
		c. Who the customer is and what are the
		categories/kinds of customers?
6.	PLANNING IN AIS	Has the organisation adequately established or
		defined:
		a. An AIS work plan
		b. An AIS work environment for the divisions that
		are involved with AIS planning processes?
		c. A system of plans for responding to customer
		requirements
		d. Planned fixing (pointing out, stating, naming)
		measurable quality objectives with reference to
		ISO 9001:2015 standard
		e. Quality objectives with reference to ISO
		9001:2015 standard
		f. Customer requirements resulting from standards,
		regulations, recommended practice and specifics
		of customer

		a Validated management procedures on main and	
		g. Validated management procedures on main and auxiliary processes at the appropriate decision level, with data access at the same time h. A vertical and horisontal information flow and a way of planning that doesn't slow down, garble, or disturb execution of the process	
7.	METHODS OF AIS PROCESS QUALIFICATION	Has the organisation adequately established or defined:	
		 a. A conscious need for a process approach when referring to quality management for AIS; B. The way of understanding validated processes – main and auxiliary; c. Processes (validated) - main d. Support processes – auxiliary e. Other processes (not defined) - refers to process identification Fd. Quality system management as a special nature validated process 	
8.	EVIDENCE OF AIS QUALIFIED PROCESSES • technical • operational • organisational	Has the organisation adequately established or defined: a. Main, validated process specification and map b. Specification of documents that describe main processes; c. Evidence of standardisation in main processes d. Proper administration of original documents, that describe main processes	
9.	EVIDENCE OF AIS AUXILIARY PROCESSES	Has the organisation adequately established or defined: a. Auxiliary processes specification and map b. Specification of documents that describe auxiliary processes c. Evidence of standardisation for auxiliary processes d. Proper administration of original documents, that describe auxiliary processes	
10.	REALISATION CONDITIONS OF MAIN PROCESSES IN AIS	Has the organisation adequately established or defined (keep hold if reasonable): a. Stability, repeatability, adequacy of processes; b. information about processes course (run, progress)	

	1		
		c. Process compactness at the beginning and at the	
		end of process	
		d A methodology of validated process	
		e. The way of obtaining data	
		f. Times of reaction, both own and receiver's	
		(customer's)	
		g. Data filtration" procedures at each stage of	
		executing the process	
		h. Permissible modification ranges of information;	
		i. Data transit, including cross-ref. Matrixes,	
		j. Process/system doubling (multiplication)	
		k. Non-failure operations procedures	
		I. Process synchronisation in stable and dynamic	
		unstable conditions	
		m. Updating of procedures in accordance with	
		specific regulations requirements, sarp's and	
		customer requirements	
11.	UNTYPICAL	Has the organisation adequately established or defined	
	CONDITIONS	procedures to respond to:	
	(STATES)		
		a. Nonprocedural events	
		b. Unstable states	
		c. Critical states	
		d. Special or unique cases	
		e. Threat (imminence) map	
12	CRITICAL	Does the organisation adequately take into	
	(SENSORY)	consideration, define and/or bring into practice;	
	ANALYSIS		
	AIR	a. A simulation process before actual initiation	
	INFORMATION	b. A supervision model sampling system	
	SYSTEM	c. Of staff awareness of the process management in	
		ais. This is referring to process identification and	
		existence of their mutual dependence;	
		d. Determination of risk for work on the basic	
		processes	
		e. Adequate end ergonomics of information (ais	
		product) analysis with reference to pilots'	
		expectations and other receivers of information	
		(customers)	
		f. Repair response time. This is in reference to	
		rebuilding the api information system and its	
		ability to reconstitute to readiness for work after	
		damage	
		g. Automatic system test procedures after one of its	

components (element) are damage h. Procedures for proceeding after a nonconforming service indication

		i. Methods of data compiling and customers
		satisfaction grade analysis
		Satisfaction grade analysis
13.	AIS TOOLING	Has the organisation adequately defined/render
		accessible for use:
		a. An AIS division tooling
		B. Tooling with reference to reliability and
		ergonomics to AIS tasks?
		c An internal communication system
14.	AIS (SUPPLIERS)	Has the organisation adequately identified and/or
	PROVIDERS	defined:
		a. Purchase processes
		B. Qualifying and acknowledgement of supplier
		system
		c. A complete register of qualified suppliers
		c. The rules of care for customer's and supplier's
		property
		e. The process for continuous monitoring and the
		evidence provided by suppliers product quality
		rule
		f. Measures taken in the event of statement
		mistakes for product (s) provided by suppliers
		g. Products and services received from providers
		are meeting the methodological identification
		according to icao, eurocontrol, aviation
		regulations (law) requirements. Are they
		identified as meeting the ais service quality point
		of view
		h. If there is a project (plan) of audit and periodic
		evaluation of providers product's quality
		i. If the range of providers quality audit include
		required topical areas
15	AIS QUALITY	a. Is there a quality system established in the
13	SYSTEM	organisation
	- GENERALLY	b. Is there a defined scope (or area) of quality
		system
		c. Is there a quality policy defined in the
		organisation
		d. Is there a evidenced of a quality policy
		declaration; (Does evidence of a Quality Policy
		Declaration exist)
		e. Is there a quality resource authority or a
		managing director for quality affairs appointed
		f. Is there a person established in the organisation
		i. is there a person established in the organisation

	who is responsible for quality documentation	
	supervision	
	·	
g.	Does the organisational Quality Manual exist	
h.	Are there organisational documents describing	
	quality system – documents which conform to,	
	are compatible with, and/or in accordance with)	
	PN-EN ISO 9001:2015 standards	
i.	Are there procedures in the organisation for	
	quality system inspections	
j.	Has the organisation established who is	
	responsible (answers) for working out, actual	
	distribution of the quality manual and other	
	quality documents	
k.	Have procedures for the documents (including	
	quality ones) been explicitly defined; currency,	
	distribution and original management status	
	Are the documents, that have been completed	
	(including quality ones) in accordance with the	
	organisation's internal procedures and their	
	status, including suitable limitations subject to	
	data confidence or appropriate data level of	
	access,	
m.	Has the organisation defined who supervises	
	records management for AIS publications;	
n.	Is it defined and are there procedures on how	
	one should proceed with out-of-date or	
	inadequate documents	
0.	Has the organisation defined management	
	responsibilities for the below quality	
	requirements:	
	Management commitment	
	Customer focus and compliance with	
	adequate regulations requirements	
	o Quality policy	
	o Responsibility, authorisation (competence),	
	and communication	
	Management representation	
	o Management review	
	o Provision of resources	
p.	Is there a stabile product/service (in AIS –	
	information) or an actual planning model in the	
	organisation	
q.	Are inputs complementary and output data	
	identified, verified and authorised with respect	

to aviation safety (in consideration of AIS tasks)

- r. Is the product updating process;
 - Stabile from initial handling (transformation), transmission, coordination and adequate time for modifications time
 - Adequate to meet regulatory and customer requirements
 - Compatible on income and outcome,
 - Repeatable (reproducible)
- s. For simulation, do production processes have a positive effect on air traffic safety
- t. Are the staff tasks during product production (AIS information) clearly understood, determined, realised and supervised in stable and nonprocedural conditions
- u. Is there a storage/archives keeping system of AIS information (AIS product)
- v. Are AIS products able to identify, who is interested in the products
- Are the products (AIS information) able to identify, according to ICAO, Eurocontrol, and other appropriate aviation law regulations requirements, who are identified as receivers
- x. Are internal quality audits carried out in the organisation
- y. Is there an organisational quality audits plan
- z. Do the quality audits range include required thematic (topical) area (space)
- aa. Are there internal quality auditors in the organisation (first side)
- bb. Are there second side quality auditors in the organistion
- cc. Are audit conclusions the subject of analysis by the management board
- dd. Are there a corrective or preventive actions carried out as a result of completed (realised) audits
- ee. Does a product quality continuous monitoring principle exist in the organisation
- ff. Are monitoring and/or product tests designed
- gg. Are there product measurement, analysis and improvement criteria
- hh. Is there a formally ratified (approved) and prescribed nonconforming product (AIS information) supervision system
- ii. Are there defined activities that are undertaken for the product (AIS information) creation process or mistakes in product statements

		::	la thanna a magalicat confela di Sancaratana	
		jj.	Is there a product unblocking system (information flow continuity in real time) in	
			special cases	
		kk.	Is there criteria that allow to unblock product (as	
		KK.	above) together with definition of levels of	
			access, responsibility and evidence of such	
			activities	
		II.	Is there a permanent product creation	
			improvement model	
16.	AIS QUALITY	a.	Is AIS information published in the name of the	
	SYSTEM		State	
	A CCORDING TO	b.	Do accumulated and published air information	
	ACCORDING TO IL –15		originate from other countries government	
	INSTRUCTION		offices or other available sources	
	REQUIREMENTS	c.	Is the air information received from above	
			mentioned sources checked before	
			dissemination	
		d.	Is there a method for customers to report that	
			information hasn't been verified in the case or	
			not checked?	
		e.	Is air information accessibility assured in the	
			places it is required, including air operations	
			staff, flight planning staff, and flight information	
			service personnel	
		f.	Does the air information office receive and/or	
			prepare and publish information in the AIP	
		g.	Is air information service's quality management	
		Ĭ	ensured, where it is necessary;	
		h.	Are requirements for skills and knowledge of AIS	
			staff on every work position defined and is the	
			staff properly trained	
		i.	Is an office designated to ensure that AIS staff	
			has the proper skills and competence for the	
			carrying out the explicit functions required and	
			do the records provide that evidence of skills	
			and competences, and are those records stored	
			according to prescribed rules	
		j.	Is initial and periodic verified staff verification	
		٠,	performed properly?	
		k.	Is it possible to conduct a study of air	
			information at every stage of the process,	
			starting from the information sources through all	
			stages of the publication process and out-of-	
			date information withdrawal	
		l.	Does the AIS information demonstrate attributes	
		۱.	Does the Alb information demonstrate attributes	

- of precision of differentiation and compactness (cohesion)
- m. Does the information dissemination system work with proper lead time
- n. Does precision of published air data perform the criterion of 95 percent level of probability
- Can a differentiation be noted of the three kinds of positioning data: measured points, localisation of radio navigation aids and points calculated when using other known measuring points
- p. Is air data conciseness ensured throughout the whole the range of processing
- q. Is the level of compactness $1x10^{-8}$ for critical data, $1x10^{-5}$ for important data and $1x10^{-3}$ for usual data
- r. During digital air data storage or export, is the data protected by redundant control cycles (courses, series, rounds, periods)(32 or 24-bit algorithm)
- s. Do adequate AIS divisions check the material, that is a part of AIP, in accordance with ICAO document 8126 before its delivery
- t. Are possible nonconformities noticed, verified, and recorded
- Does the organisation comply to recommended methods stated in WGS – Doc. 9674, RTCA DO 201A, for air information compiling, processing and publishing;
- Has the organisation assigned an office to where all AIP inputs from foreign countries would be directed
- w. Does AIS organise NOTAM publication and receipt?
- x. For the above mentioned documents, does the International NOTAM Office publish the register of the countries with which it performed exchanges?
- y. Does the suitable NOTAM information exist and is it available in a dedicated register?
- z. Are AIS products protected by law?
- aa. Are the appropriate sections of the AIP published in English and the local language, as appropriate?

	bb.	Are the names of localities published in the	
		appropriate languages;	
	cc.	Are the units of measurement used in the	
		published air information documents compatible	
		with ICAO convention's tables?	
	dd.	Are published geographical coordinates	
		consistent with WGS-84 geodetic reference	
		system;	
	ee.	Are reference coordinates whose calculation	
		precision doesn't comply with appropriate	
		regulations annotated with an asterisk (pip)?	
	ff.	Are the abbreviations used in AIS publications in	
		accordance with ICAO recommendations?	
	gg.	Does the AIS take human factors into	
		consideration during AIS information	
		transformation and distribution process;	
	hh.	Are the forms used for information storage,	
		processing, dispatch, and publication, adequate	
		and explicitly meant for their application;	
17.	a. [Does the organisation's supervision ensure	
	(competence, qualifications, and licence,	
	á	appropriate certifications and valid records of AIS	
	9	staff in a systematic way?	
	b. [Does the technical staff work full time	
	C. A	Are the organisation's staff theory and practice	
	9	skills regularly checked within organisation's own	
	t	training and supervision structure	
	d. I	s the organisation's staff evaluated to see if they	
	á	are knowledgeable and skilled on atypical issues, if	
	á	applicable?	
	е. [Does the organisation provide specialised training	
	f	for personnel and supervisory staff to maintain	
	F	oroficiency, knowledge, and skills for those in AIS	
	t	that work on an international aviation net	
	f. [Does the organisation properly validate, by	
	á	aviation authorities, common AIS staff training or	
	6	equivalent programmes	
	g. [Does the organisation have separate training and	
	9	supervision programmes	
	h. [Does the organisation have personnel knowledge	
	á	and skills check documents authorised by	
	á	appropriate aviation authorities	
		appropriate aviation authorities Has the staff been trained in quality programme	

			issues and quality training?	
		j.	Is the training postured to project modifying	
			requirements and needs in quality	
		k.	Has the organisation's staff been trained for	
			atypical events, threats, nonprocedural situations	
			which may arise with tasks accomplished by AIS	
		l.	Has the staff been trained in labour legislation, fire	
			protection and firefighting, and safety;	
		m.	Has the organisation's staff been informed or	
			trained in accident preventive measures	
		n.	Is the organisation's technical staff able to use	
			procedural records or other proper AIS	
		ο.	Have the criteria and minima of staff language	
			qualifications been defined and published for	
			organisation's personnel who require foreign	
			language knowledge in the essential range for	
			safe and fluent AIS tasks achievement?	
18.	AIS BUDGET	a.	Has the organisation's budget established on the	
			way to ensure necessary for fluent AIS work (in	
			stabile and nonprocedural conditions, also in the	
			cases of fate work disturbances) outlays	
		b.	Have funds been designated for required	
			international relations and domestic training, its	
			documentation and professional references	
			purchase, and documentation translation	
		c.	Have funds been provided for technical-	
			organisational progress in AIS	

NONCONFORMITIES REPORT

Worked out by:	Agreed: Quality	Organisation's
	Representative	Representative
signature	signature	signature

DIAGNOSTIC AUDIT REPORT

	Audit range / area (space)	Nonconformities amount
1.	ACTIVITY PRINCIPLES: LEGAL AND FORMAL	
2.	WORK ORGANISATION IN AIS	
3.	SUPERVISION PROCEDURES IN AIS	
4.	AIS STAFF	
5.	AIS WORK ENVIRONMENT	
6.	PLANNING IN AIS	
7.	METHODS OF AIS PROCESS QUALIFICATION	
8.	EVIDENCE OF AIS QUALIFIED PROCESSES	
	technical, operational, organisational	
9.	EVIDENCE OF AIS AUXILIARY PROCESSES	
10.	REALISATION CONDITIONS OF MAIN PROCESSES IN AIS	
11.	ATYPICAL CONDITIONS (STATES)	
12.	CRITICAL (CENSORIOUS) ANALYSIS	
	AIR INFORMATION SYSTEM	

13	AIS TOOLING	
14.	AIS (SUPPLIERS) PROVIDERS	
15.	AIS QUALITY SYSTEM - GENERALLY	
16.	AIS QUALITY SYSTEM ACCORDING TO IL -15	
	INSTRUCTION REQUIREMENTS	
17.	AIS TRAINING	
18.	AIS BUDGET	

Samples of Templates and Planning QMS Implementation into AIM

1. Quality Management in AIM in the Asia Pacific region

The approach in this example consists of three stages:

- a) Considering what happens in AIM;
- b) Implementing a QMS
- c) Improving the QMS

a. Considering what happens in AIM	Step 1	Consider the business of AIM, i.e. the different flows of work through the organisation and list them.
	Step 2	With this list in mind, decide if there are any ISO 9001 requirements that cannot be met.
b. Implementing a QMS	Step 3	Get people involved in writing down what their jobs cover.
	Step 4	Collate this in sequences relevant to the list of main business activities collected in Step 1.
	Step 5	Identify where the standards and this list of main business activities link together.
	Step 6	Apply the standard and the QMS.
	Step 7	Keep the QMS simple and functional, i.e. relevant to the business operations.
c. Improving the QMS	Step 8	Consider the feedback of information from the QMS to lead to improvements in ideas and activities
	Step 9	Monitor and measure the changes so that everybody is aware of the gains made by the system.

1.2 The stages and their associated steps have been outlined above; the next table provides an amplification of the details.

Consider what your main business activities are and list them Step 1 Those elements described in Annex 15 form the main business activities of AIM. Receive and/or originate Collate or assemble Edit Format ▼ Publish/store Distribute Aeronautical information/data Step 2 With this list of main business activities, determine if any of the activities require you to do design work Design means taking raw ideas or concepts and either through design drawing, computer design or academic thought process developing a product and/or service design or project plan to suit the needs of your customer. Generally for AIM, design work will manifest itself through the design of instrument procedures. If you determine that you do not design, and the products and/or services are done against tried and previously developed standards or specifications, you may be able to claim a "permissible exclusion". To achieve the next step, you need to keep the list of main business activities firmly in mind. It may help at this stage to produce these activities in the form of a flow chart to assist in the development of a QMS. The purpose of setting activities out in this way is to identify: ▼ The different components of AIM and decide if they all fit together, or if changes are required to make the whole process work better Where and if the elements of the standard are covered Step 3 Get people involved by writing down what their jobs cover Now is the time to get everyone concerned involved in writing down how they carry out the parts of the AIM activities they are responsible for, stating: ▼ Who is responsible for performing and checking activities ▼ Where the activity takes place

When it will happen

What happens, that is, how the activity is performed

Some important points you will need to think about are:

- ✓ As the job is being carried out by a specialist, you will only need to reference the type of person and the qualifications
- If, the work is done by non-specialist staff, or there are specific in-house requirements, more detail may be required
- ▼ The sequence of the activities may still need to be defined, for example:
 - How a job is initiated
 - How does the work get started?
 - ▼ Who monitors the progress?
 - → How is the work processed and inspected?
 - ▼ Who decides when the work is finished?

 - ▼ What follow up action is needed and who does it?
 - What records are kept and who keeps them?

If your organisation already has its details written down as operating or work instructions, your job is already half done. Do not rewrite what is already documented, make a note of the name and title of the document so it can be controlled and if necessary referenced in other QMS documentation at a later date.

▼ Most important - Keep written documentation simple

Step 4 Collate this in sequences relevant to the list of busness activities

Once everyone has written down (or collected previously written) work instructions relevant to their part of the activity or particular job responsibilities, you as manager should take time out with someone else from the business to look at:

- ▼ What has been written
- Satisfy yourself that it all fits together
- Deal with any gaps or inconsistencies

By appointing someone to assist you, you have basically appointed a management representative or if you are doing most of this yourself as manager, you have assumed the role of management representative. You have now addressed one of the first requirements of the standard.

By collating all these documents, you now have a procedures manual (which is another requirement of the standard). You should adopt a consistent style for these documents which you and your people are comfortable with. This may provide an

opportunity to review and improve the procedures themselves. Step 5 Identify where the standards and this list of your business activities link together The management representative needs to go through the documents you have written with a copy of the standard beside you and determine if you have met: The requirements of the standard ▼ The process control requirements If you identify an area of the standard you have not addressed you will need to consider how you will cover that particular requirement. You may need to add some detail to one of the existing procedures to ensure the requirement is met. It may require some additional documentation, but be careful, make sure it is relevant to the work of AIM. You may have to use external documents in your business activities. Some examples are dealers' manuals, maintenance manuals and installation manuals. It is not necessary to rewrite these to include them in your QMS. All that is needed is to make an appropriate reference to the process control document in your manual. Step 6 Apply the standard and the QMS If you continue to involve others in your organisation, they are more likely to grow with the QMS and have input. The QMS will then reflect reality rather than become irrelevant paperwork. The following points should be noted: To not create unnecessary paperwork, forms, and the like. Look at what is currently done and write your procedures to show how the job is done, not how you wish it was done or should be done. Only create a form if it is going to capture a critical activity or is going to help someone. A signature on or an extension to an existing form may suffice. ▼ Remember, keep a record when: a problem arises a good suggestion is raised To implement the QMS, everybody needs to be have access to the documentation that relates to their activities. They need to be given some insight into how the QMS works and why, for example, document control ensures that they have the latest copies of information relevant to their jobs and can rely on making decisions based on up-to-date information. Everybody needs to be trained to understand how to keep the QMS up-to-date themselves, if changes take place in areas they are responsible for. Everybody needs to know how to make changes to the QMS as well as noting problems and putting

forward ideas for improvement. Remember that you need to approve any changes before they are put in place.

Step 7 Keep the QMS simple, functional and relevant to the business operations

The following points are worth noting:

- The purpose of implementing a QMS is to ensure that the business activities of AIM are operating in a controlled manner and the people responsible for the various activities know and understand their roles and responsibilities.
- QMS documentation should be a ready reference point to identify how, when, where and sometimes why a job should be done, or an activity managed. For that reason, the wording should be simple and in the language used in the workplace on a daily basis
- Documentation should be in a format that is easily used in the organisation. For example:
 - if computers are available, it may be easier to have a computerised system, rather than a paper system;
 - where there may be language or other differences in the workforce, it may be necessary to use pictures or several translations of the documents.
- Documentation should reflect what is currently happening in the business. During the audit process, questions will be asked and objective evidence sought, to show that personnel are using and understanding the QMS. The objective evidence is provided by the documentation.

IMPROVING THE QMS

An effective QMS uses feedback loops to improve how you go about doing things, which in turn should lead to an improvement in product and/or service quality.

Step 8 Consider the feedback of information from the QMS to lead the improvent of ideas and activities

Improvements may be simple and easily achieved in the initial stages but may become more challenging once the obvious opportunities for improvement have been taken. It is worthwhile persevering with a systematic approach to quality improvement, since the benefits can be considerable.

Normally, improvements are adopted over a period of time as money and resources become available. A realistic approach and steady progress will build confidence and maintain enthusiasm

By noting areas of concern from corrective action activities (Step 6), you will gather

	data, or note trends that you can look at and consider for improvement.
Step 9	Monitor and measure the changes so you know what you have gained
	It is important to remember to measure your progress. One-way of doing this is to monitor mistakes and their cost. This gives you the opportunity to identify areas where cost savings may be made.
	Noting how long or how many resources are spent on an activity or service delivery may also obtain measurements. This should always be recorded on any activity that has been chosen for improvement, prior to commencement and compared again at the end, even though the activity may be small and simple.

2. QA Implementation Planning Template for Europe Region

2.1. Introduction - This document presents an outline of issues that should be considered in the preparation of a plan to implement a Quality Assurance system within an AIS/AIM unit. The AIM should be to register for compliance against the ISO 9001 standard.

2.2. Document Structure

Content	Purpose
Overview of the planning approach	Provides an initial checklist of principal issues to be addressed
	in chronological order
Implementation Plan Checklists	Checklist of items consistent with the generic project plan
Implementation Plan Proposal template	A template of a high level proposal to initiate a project to
	implement QA within an AIS department.
Useful Tools	Example forms providing support to appropriate elements of
	the implementation plan. e.g. process analysis form
Sample Quality System Elements	Example document contents

2.3. How to use this document

- By following the document in sequential order the essential elements of the implementation process will be addressed.
- ▼ The approach overview serves two purposes:
 - provides a breakdown of the main tasks
 - can be used as a primary checklist
- For the preparation phase, a template has been provided to create a high level proposal that, can be used to initiate the programme (by submitting to senior management for commitment to the project)
- The template is followed by a series of checklists that are consistent with the generic project plan provided in the USEFUL TOOLS section. These checklists identify the tasks to be undertaken during the implementation programme and can be useful in monitoring project progress.
- The generic project plan is one of the Useful Tools and is available as an electronic MS Project file for the user to adapt according to local requirements.
- ▼ The final section contains a number of example documents from QMSs.

2.5. Approach Overview

	INITIAL PLANNING CHECKLIST	
PHASE		Check Item
PREPARATION	Establish project team, target dates and resources	
	Produce a high level proposal for management support.	
	Management decision to implement ISO 9001	
PLANNING - QA Requirement Phase	Review current processes and evaluate against requirement of standard	
	From the assessment develop a plan and schedule for development and implementation for each of the elements of the quality system.	
DESIGN	High level design followed by the development and documentation of the unit processes.	
TEST	Deployment of processes with associated training and briefing sessions	
	Preliminary audit programme to validate effectiveness of the quality system against the Standard	
REGISTRATION	Operation and fine tuning of the quality system and registration assessment.	
POST REGISTRATION	Once the quality system is implemented and operational, continue to identify and establish suitable aspects within the working quality system that can be used as measures to monitor the system performance and assist with identifying improvement.	

The shaded area above refers to those phases described on the generic project plan Gantt chart.

2.6. Preparation Phase

A basic plan is needed which provides a first appraisal of the current organisation requirement, resources available and other resources needed.

Use the following checklist to research information and then complete the proposal template.

	PROGRAMME INITIATION				
Item		Check Item			
1.	Management Support.				
2.	Internal resources and budget.				

3.	External support / effort needed?	
4.	Target date to be met for registration	
5.	Scope 1. Activity - C 2. Location -	
6.	Project Leader and team	
7.	Resources	
8.	Contact with registration organisations	
9.	Complete and submit QA Implementation Proposal	
10.	Programme launch	

2.7. Planning – QA Requirement Phase

2.7.1 Determine department organisation structure, roles and responsibilities

MANAGEMENT ORGANISATION STRUCTURE		
Item		Check Item
1	Prepare organisational perspective	
2	Unit structure	
3	Personnel responsibilities	

2.7.2. Determine documentation requirements and control processes

QUALITY SYSTEM DOCUMENTATION		
Item		Check Item
1.	Quality Policy	
2.	Management Organisation	
3.	Quality Manual	
4.	Training Records	
5.	Forms.	
6.	Document control process	

2.7.3. Identify Procedures

IDENTIFY PROCEDURES		
Item		Check
		ltem
1.	Process mapping	
	Project team understanding. Identify current practices in each functional area	
	and map their relationships; (a) with each other, (b) to other organisational	
	units and (c) to the Standard. It is useful to use flowcharts to demonstrate	
	relationships.	
2.	Gap assessment	
	Perform a comparative analysis to understand how current practice differs	
	from the requirements to meet the Standard or to improve practice.	
3.	Procedures list	
	From analysis list those procedures needed to meet requirements of the	
	Standard and operation.	
	For a model production process refer to SDP procedures.	
4.	Compare proposed procedures with training requirements	
	Check for duplication of procedures with existing training instructions which	
	cover the same function.	
5.	Prepare procedure development plan	
	Identify those procedures on the list to be derived and documented from	
	existing records and those that need to be developed as new.	

2.7.4. System awareness programme

QUALITY AWARENESS TRAINING		
ltem		Check Item
1.	Generating quality awareness Whole department briefing on basic quality. Consideration should be given to the size of the group. It may be advisable to conduct separate courses.	
2.	System deployment briefing Once the quality system has been designed and documented it needs to be explained to the working units. This is best done in small groups concentrating on those aspects relevant to their functional area.	
3.	Reviews and repeats Consider the need to repeat the briefings at appropriate times to reinforce or clarify aspects of the deployment of the Quality System. Opportunity can also be given to present reviews of the system that have taken place.	

2.8. Design Phase

2.8.1. Develop procedures

PROCESS PROCEDURE DEVELOPMENT		
Item		Check Item
1.	Procedure structure Consistency is needed in the approach to detailing each procedure.	
2.	Amend existing procedures Modify existing procedures according to analysis.	
3.	Develop new procedures Documented procedures needed were identified in the gap assessment.	
4.	Identify quality measures Establish suitable aspects within the working quality system that can be used as measures to monitor the system performance and assist with identifying improvement. E.g. response times to information requests.	

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2.8.2. Training Plan

TRAINING PLAN	٦

Item		Check Item
1.	Develop procedures for identifying training	
	Evaluate experience of staff e.g. such as for prerequisite qualification for	
	specialised tasks.	
	Identify the individual training needs of staff at defined intervals e.g. by job	
	appraisal or performance reviews.	
2.	Develop procedures for providing training	
	Consider internal or external training as appropriate to fulfill current job	
	requirements	
	Consider training or briefings required for suppliers.	
3.	Develop procedures for keeping training records	
	Establish and maintain training plans and records.	
4.	Create a training record form or template	
5.	Establish a training plan for each job profile	
6.	Quality training plan	

2.8.3. Internal Auditing

INTERNAL AUDITS		
Item		Check Item
1.	Develop procedures	
2.	Selection of internal auditors	
	Consider working relationship in order to ensure cooperation.	
3.	Internal auditor training	
4.	Create documentation	
	Checklist, non conformity report templates, audit history	
5.	Internal audit plan	
	Consider the timing and frequency of internal audits. In the initial stages higher	
	frequency may be necessary in order to fine tune the system and to provide on	
	the job training for the internal auditors. Take into account the timing of external	
	registration audits.	
6.	Establish reviews	
	At management and work group level.	
	Management review agenda	

2.8.4. Corrective and preventive action

CORRECTIVE and PREVENTIVE ACTION		
Item		Check Item
1.	Develop procedures: 1.Integrate with non conformance reports and management review results 2.Analyse reports, determining action required and implementing corrective action 3.Verification of effective action by internal audit	
2.	Create forms required e.g. change request for corrective and preventive actions or changes to the Quality System.	
3.	Create log to monitor status of actions Note status of non conformances and appropriate actions is an agenda item on the management review.	

2.8.5. Document control

CONTROL OF QUALITY RECORDS		
Item		Check Item
1.	Develop procedures Issues of formatting, review, approval, implementation, and change processes Ref: Example document management requirements	
2.	Create document change request form Establish consistency through use of agreed style for documents.	
3.	Establish controlled documents master list. List all documents within the Quality System including quality records	
4.	Document control awareness Monitor effective document control through the internal audit process. Educate and inform users through briefing sessions or information updates	

2.9. Test Phase

QS DEPLOYMENT and VALIDATION		
ltem		Check Item
1.	Brief staff and inform of start date	
2.	Issue and implement procedures	
3.	Conduct internal audits to plan	
4.	Establish corrective and preventative action reporting	
5.	Develop service level agreements Provides a method of defining and controlling relationships between internal organisations. Ref: Example criteria	
6.	Conduct internal audit of management system	
7.	Registration ISO audit process	

2.10. Registration Phase

ISO AUDIT PROCESS		
ltem		Check Item
1.	Operate and fine tune the declared management system.	
2.	Pre-assessment	
3.	Corrective action arising from pre assessment	
4.	Registration ISO assessment	
5.	Post assessment corrective action plan	

Quality Audit Tool

1. Objective and Purpose

The objective of the Quality Audit Tool is to provide the States with a standardised means for assessing the conformance of their quality processes with internationally recognised ISO Standards. The Quality Audit Tool integrates the ISO 9001 requirements.

This release operates on the basis of the AuditZone software (AuditZone v2.x - ISO) which is an application that has been designed to support auditing activities.

It is a multi-platform tool and is provided free-of-charge to States for their use only. The Quality Audit Tool is intended to be applied both by service providers and by Regulators.

2. Main Features

- Embedded database
- Flexible and extensible object model
- ▼ Easy to maintain: data and application layers are separated (easier maintenance
- Easy auditing with Audit Worksheet
- User designed checklists i.e. expansion of audit criteria
- Recording of audit findings through Audit Zone Explorer and Audit Worksheet
- XML based (object) export-import
- Organisation via Audit Programmes including audit tasks and executions
- ▼ Logging/ tracing of non-conformities, actions etc.
- Recording of audit notes, opportunities, and observations
- ✓ Integrated contact management
- Root Cause Analysis
- ▼ Template based reporting. Further reports can be created and customised by users
- Quantitative (scorecard; response distribution by requirement type) and qualitative (by criticality and type) reporting features
- Tool can be exploited for further audits after customisation e.g. processes or documents

3. Technical aspects - Installation

The software 'az2x_h2' integrates the database. Therefore, when using this version no installation of other database software (MySQL or similar) is required. The database is embedded. Read the 'readme' file and the Installation Guide before proceeding to Installation.

The required files are:

Installation Guide

- Quick start Guide
- User Guide
- Administration Guide (to support customisation)
- ▼ The application files TBD

Note: EUROCONTROl operates another version which can be deployed to audit the AIP structure and the CHAIN process criteria. This version is available from EUROCONTROL upon request.

Service Level Agreements

1. Background references of ICAO Annexes

[Annex 15] 3.1.1.2 Each Contracting State shall take all necessary measures to ensure that the aeronautical information/data it provides relating to its own territory, as well as areas in which the State is responsible for air traffic services outside its territory, is adequate, of required quality and timely. This shall include arrangements for the timely provision of required information/data to the aeronautical information service by each of the State services associated with aircraft operations.

[Annex 14] 2.13.1 To ensure that aeronautical information services units obtain information to enable them to provide up-to-date pre-flight information and to meet the need for in-flight information, <u>arrangements shall be made</u> between aeronautical information services and aerodrome authorities responsible for aerodrome services to report to the responsible aeronautical information services unit, with a minimum of delay.

To address certain requirements for QMS and to particularly address the issue of supply chain management a series of documents were developed in Europe in support of a clear need for a more formal arrangement for the provision of source information to the Aeronautical Information Services (AIS). Such approach is best served through the utilisation of Service Level Agreements (SLA).

Therefore, a comprehensive 'SLA package' has been developed to support the establishment of agreements between data providers (originators) and Aeronautical Information Services possibly under the umbrella of a Regulator.

2. What is a Service Level Agreement?

An Service Level Agreement (SLA) is a (negotiated) contract between a service provider and its customers that defines the services provided, the indicators associated with these services, acceptable and unacceptable service levels, liabilities on the part of the service provider and the customer, and actions to be taken in specific circumstances.

This SLA guidance material, although applicable in many instances throughout the aeronautical data chain, is specifically intended to address the interface between the various data originators and a State AIS.

3. Benefits of a SLA

Aa SLA provides a number of benefits, some of which are as follows:

- Better communication. It facilitates two-way communication between a service provider and its customers. The parties involved come together in order to understand each other's needs, priorities and concerns and to gain an insight into the problems which may be faced to fulfil their obligations.
- Guards against 'expectation creep'. It is not uncommon for one party's expectations of another to be higher than that which may be considered reasonable. Discussing these expectations and the resource commitments necessary to meet them is one activity undertaken. As a result, it helps identify service levels that are considered acceptable by each party.
- Mutually agreed standard. It sets an agreed standard against which performance may be measured. It defines the boundaries of the service provision and clarifies responsibilities. The communication process helps to minimise the conflicts between the parties and provide a means for conflict resolution.
- A process for gauging service effectiveness. As the SLA defines standards against which the service may be measured and evaluated, it provides the basis for performing an assessment of the effectiveness of the service.
- Customisable package which can be tailored to the specific needs, operational/ institutional environment and types of actors involved.

4. A SLA guidance package developed by EUROCONTROL provides the following elements:

- ✓ SLA Guidelines: The introduction to SLA introducing the concept, providing guidance on its elements and the underlying key process and providing a generic template.
- Originator index: A Microsoft Excel spreadsheet that reflects the structure of the AIP (as defined in ICAO Annex 15). It is intended to be used to assist in the identification of the supplier of each data item in the AIP, the approver and the criticality of the data (as defined in ICAO Annex 15).
- ▼ Key Performance Indicators (KPI): A list of selected KPIs which relate to the performance of exchanging aeronautical information between a Data Originator and an Aeronautical Information Service Provider (AISP).
- SLA template: A template document which provides the basic structure of an SLA, some example text and placeholders for the negotiated agreement to be captured.
- ▼ SLA Checklist.
- ▼ SLA Pilot Implementation Lessons Learned (CHAIN): Providing specific lessons learned to aid further implementation and to increase awareness of good practices and potential risks.

Note: These documents are available from EUROCONTROL.

Static Data Procedures

1. Introduction

Of direct relevance to the quality management of aeronautical data is the AIS Data Process (ADP) and its associated Static Data Procedures (SDP).

The ADP and SDP were developed and applied by European States to drive the implementation of ISO 9001 Quality Management Systems in AIS. They establish a set of harmonised guidelines representing 'best' AIS practices for receipt, storage and publications of AIS Static Data. ADP and SDP also supported the development and implementation of the European AIS Database (EAD) and are now integral part of the EAD service provision.

These documents provide the generic process and supporting procedures covering the activities of a State AIS. Whilst they are not designed for immediate implementation within a State, they provide a description of current best practices which can easily be tailored to meet the needs of a State.

There are two main reasons for a State to implement the Static Data Procedures in its local procedures, namely:

- To ensure harmonisation, consistency and a common understanding based on the AIS Data Process
- To comply with the ICAO requirement to establish a quality management process according Annex 15, para 3.2.1.

2. The AIS Data Process

The AIS Data Process (ADP) describes WHAT actions are carried out to produce the Annex 15 Integrated Aeronautical Information Package. The ADP provides the key document to the Static Data Procedures. It provides a high-level view of all activities carried out during the processing of static data.

This information is primarily presented through use of a series of flow diagrams, boxes representing the steps which must be taken – inputs, outputs, activities or decisions. Supporting text is provided for each step that explains the rationale behind the box. Each step is allocated a unique number that may be used to identify it and provides a reference to the actual Static Data Procedure that provides a more detailed description of the processing required.

The AIS Data Process covers all activities from the receipt of data within the AIS to its publication. The activities associated with the AIS Data Process may be represented as below.

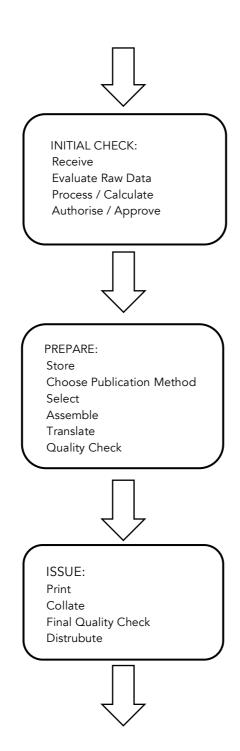


Figure 1 AIS Date Process

3. Static Data Procedures (SDP)

The SDP relate to the AIS Data Process and detail how these actions are undertaken and traced. There are 22 SDPs defined as part of a complete package. SDP/C provides all information that is common to the set of procedures. An understanding of this document is essential before the remaining procedures (SDP0-19) can be fully understood. SDP/G provides information on how to customise and implement the SDP.

4. List of SDPs

Note: These documents are available from EUROCONTROL.

- ▼ SDP/C Concept, Index and Glossary
- ▼ SDP/G Guidelines for the Implementation of the SDPs
- ▼ SDP0 Procedure for the Provision of Originated Data to the AIS
- SDP1 Receipt of Raw Data at the AIS
- SDP2 Initial Assessment of Raw Data
- ▼ SDP3 Evaluation of Static Data
- SDP4 Approval of Static Data
- ▼ SDP5 Storage of Approved Data
- ▼ SDP6 Receipt of Newly Registered Information
- SDP7 Assessment of Information for Publication
- SDP8 Assessment of Information for Notification by AIRAC
- ▼ SDP9 Preparation of an AIP Amendment
- SDP10- Preparation of an AIP Supplement
- ▼ SDP11- Assessment of Extensive Text/Graphic
- SDP12 Preparation of an AIC
- ▼ SDP13 Issue of Information
- ▼ SDP14 Preparation of a NOTAM Summary
- ▼ SDP15 Maintenance of AIS Static Data
- ▼ SDP16 Use of a Log Sheet
- SDP17- Performing a Quality Check
- ▼ SDP18 Undertaking Translation
- ▼ SDP19 Contacting Appropriate Authorities

5. Initial Steps for the Implementation of SDP

When a State is first considering implementing the SDP, a number of aspects should be taken into account. As the SDP exist as the basis for development, the State will not be required to head straight into procedure development; instead the existing working practices must be assessed.

The following approach is proposed:

- Read the AIS Data Process
- Gain a basic understanding of the SDP methodology by reading SDP/C 'SDP Concept, Index and Glossary'
- Identify role allocations
- ▼ Work through the ADP and associated SDPs against your current working practices
- ▼ Produce a compliance table
- Customise the procedures as necessary by applying SDP/G
- Create new procedures as required

The Differences Between ISO 9001 2008 and 2015 Editions

All ISO standards are reviewed every five years to establish if a revision is required to keep it current and relevant for the marketplace. ISO 9001:2015 is designed to respond to the latest trends and be compatible with other management systems such as ISO 14001.

It is not the intention of this Annex to provide an academic ISO 9001 consultancy study, but make AIM management teams aware of the most significant recent changes that may affect their QMS:

Quality Manual

A Quality Manual is no longer a specific requirement. However, in an AIM QMS, a Quality Manual remains relevant as a repository for policy-level requirements, and as a link to other levels in the QMS hierarchy.

Management Representative

The appointment of quality resources, to maintain the QMS and report findings to management team colleagues, is no longer a specific requirement. However, regulatory authorities are likely to have more confidence where an individual of suitable authority and accountability is assigned as a quality resource.

Risk-based thinking

While implicit in previous editions of the Standard, the requirement to identify and mitigate risk is now explicit. It is up to each AIM management team to determine how this is to be achieved, e.g. recording risk in audits, discussing risk in management reviews, or developing risk management procedures.

Change Management

The management of change was never explicit in previous editions of the Standard. The revised Standard requires that changes to the QMS have to be planned.

Exclusions

Some of the ISO 9001 requirements may relate to activities and processes that are not performed by AIM, (e.g. calibration). Previous editions of the ISO 9001 standard accommodated exclusions. The 2015 edition does not accommodate exclusions. Any rationale for not complying with ISO 9001 requirements must be clearly justified within the appropriate policy-level document within the QMS.

Performance Evaluation

While implicit in the previous edition, the 2015 edition requires organisations to determine what needs to be monitored and measured.