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# Manual on the Quality Management System for Aeronautical Information Services

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and published under his authority**

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for Aeronautical Information Services***

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## FOREWORD

The guidance material contained in this manual has been developed to provide assistance to States in the planning and implementation of a QMS for aeronautical information management (AIM) in order to fulfill the requirement in Annex 15 — Aeronautical Information Services for States to introduce a QMS. This manual contains key elements to provide 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 9001:2008 — *QMS — Requirements* and ISO 9000:2005 — *QMS — Fundamentals and Vocabulary*.

A specimen 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 emphasized 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 organization and division of functions, and a selection of rules and procedures. The content of a quality manual for an actual State AIM would need to be adapted to reflect its respective organization, assignment of functions and established procedures in accordance with the QMS requirements.

## ACRONYMS

The acronyms used in this manual are defined as follows:

AIC	Aeronautical information circular
ADP	AIS data process
AIM	Aeronautical information management
AIP	Aeronautical information publication
AIS	Aeronautical information service(s)
ANSP	Air navigation service provider
ATM	Air traffic management
ATS	Air traffic services
ATSP	Air traffic service provider
CAA	Civil aviation authority
CRC	Cyclic redundancy check
DAL	Data assurance level
EUROCAE	European Organization for Civil Aviation Equipment
IAIP	Integrated aeronautical information package
IAF	International Accreditation Forum
ISO	International Organization for Standardization
KPI	Key performance indicator
NOF	International NOTAM office
PDCA	Plan-Do-Check-Act
PIB	Pre-flight information bulletin
QMS	QMS(s)
RNAV	Area navigation
RNP	Required navigation performance
SARPs	Standards and Recommended Practices
SDP	Static data procedures
SLA	Service level agreement
SMS	Safety management system(s)
TC	Technical committee (ISO)



# Chapter 1

## POLICIES ON QUALITY SYSTEMS FOR AERONAUTICAL INFORMATION MANAGEMENT

### 1.1 BACKGROUND

1.1.1 Quality assurance-related Standards and Recommended Practices were first introduced in ICAO Annex 15 to the Convention on International Civil Aviation — *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 by the use of 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.”

1.1.2 In Amendment 30 to Annex 15, a Recommended Practice 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 Organization for Standardization (ISO) 9000 series of quality assurance standards, and certified by an approved organization.”

### 1.2 NEED FOR QUALITY

1.2.1 Annex 15, Chapter 1 implies the necessity for a QMS when it states that “Corrupt or erroneous aeronautical information/data can potentially affect the safety of air navigation.”

1.2.2 Aeronautical information distributed by means of AIPs including charts and by NOTAM, PIBs, AICs and other products and services provided by an AIS, has an inherent and essential need to fulfill specific requirements in order 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 fulfill requirements is referred to as “quality”.

1.2.3 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 RNAV, 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 QMS

1.3.1 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 or 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.

1.3.2 The ISO 9000 series of standards and associated guidelines are based on principles which emphasize 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 organizations, general aviation, data vendors, etc.).

1.3.3 The ISO QMS approach encourages organizations 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.

1.3.4 At the core of ISO 9001 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 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, organizing, documenting, managing and improving processes, and interactions between processes.

#### **1.4 RELEVANT PROVISIONS IN ICAO ANNEXES AND DOCUMENTS**

1.4.1 Definitions for QMS were introduced in Annex 15 by Amendment 29. The SARPs related to QMS are found in Chapter 3, Section 3.2. In brief, they set out the following:

- Each Member State shall ensure that QMS are implemented and maintained encompassing all functions of an AIS. The execution of such QMS shall be made demonstrable for each function stage, when required.
- 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.
- The QMS established in accordance with 3.2.1 of Annex 15 should follow the International Organization for Standardization (ISO) 9000 series of quality assurance standards, and be certified by an approved organization.
- 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 include the necessary policies, processes and procedures to assure and verify that aeronautical data is traceable to its origin so as 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).

1.4.2 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.

1.4.3 Chapter 1 of the *Aeronautical Information Services Manual* (Doc 8126) refers to the need for a quality system and the required accuracy, resolution and integrity of aeronautical data are outlined in Chapter 2 of the *World Geodetic System — 1984 (WGS-84) Manual* (Doc 9674). The quality assurance of aeronautical data required for the quality of an instrument flight procedure is set out in *The Quality Assurance Manual for Flight Procedure Design* (Doc 9906).

## 1.5 THE DATA QUALITY PROCESS

1.5.1 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 AIP and other media derived from the AIP for end-use.

1.5.2 An aeronautical data management standard is required in order to:

- a) ensure compliance of the data quality reported to national administrations, as specified in this document;
- b) ensure that the data management processes are carried out such that the integrity of the data is not jeopardized at any point in the process;
- c) design the data collection and handling processes such that due regard is paid to the risk of error;
- d) operate multi-layer data integrity management tools that enable the detection of discrepancies against known and tested logic and the appropriate rules;
- e) ensure that data management tools are developed and managed in a controlled manner to ensure the integrity of the overall process;
- f) provide for the development of appropriate metadata to ensure that complete audit trails are available at all times.

1.5.3 In order for the required quality of service/data to be provided, a QMS is required for all organizations operating within the total aeronautical data chain.

1.5.4 Figure 1 shows the overall data process chain from origination to end-use. This manual, however, only applies to those elements of the process shown in gray, from origination through to publication. Thereafter, it is considered that the requirements published in, for example, EUROCAE 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 organize their interaction, to enable interoperability and quality service provision. Data supply chain management shall be based on a QMS and be supported by SLAs as addressed in Appendix G.

## 1.6 THE RELATIONSHIP BETWEEN QUALITY AND SAFETY

1.6.1 Quality management is a means of standardizing a process and providing the capability to meet a set of pre-defined requirements. A QMS offers the ability to formalize an organization's processes and to provide assurance that process requirements are being met. Organizations define what their quality objectives are, in most cases focused on customer/stakeholder satisfaction (e.g. ISO-9000's reference to "customer focus" in ISO 9001:2008, Clause 5.2).

1.6.2 It is possible to meet customer/stakeholder requirements while not meeting the objectives of safety. Requirements for protective systems, such as SMS, 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 SMS and QMS are highly similar. Safety management and quality management can be highly complementary and must therefore work closely together to achieve the overall organizational product or service goals of aviation safety. SMS does not require an organization to have a QMS, but if it has both, they should not conflict with one another.

**Figure 1-1. Aeronautical data chain ref. industry standards**

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## Chapter 2

### CONCEPTS AND VOCABULARY

#### 2.1 STANDARDS AND ISO

2.1.1 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 utilized, 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 Member States follow the standards stipulated in the Annexes to the Convention on International Civil Aviation in order to ensure safety, regularity and efficiency in the operation of international air navigation.

2.1.2 The ISO, established in 1947 and based in Geneva, Switzerland, prescribes procedures 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 155 countries, many of which are government organizations. The objective of ISO is to promote the development of standardization 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 THE ISO 9000 SERIES

2.2.1 The work of preparing International Standards is normally carried out through ISO specialized TCs. ISO/TC 176 — Quality management and quality assurance, the Secretariat of which is held by the Standards Council of Canada, is the ISO TC responsible for developing and maintaining a universally accepted set of quality management standards.

2.2.2 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 organizations engaged in establishing quality systems on the basis of the 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.

2.2.3 There are many reasons why a new series of the standards was published in 2000. Firstly, 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 into account developments in the field of quality and the considerable body of experience that had built up as a result of implementing ISO 9000. The users demanded a process-oriented approach and a defined route for performance improvement. The ISO 9000 series of standards, which represents a major improvement over the two earlier versions, was subsequently published in December 2000.

2.2.4 In November 2008, a new version of the ISO 9001 Standard, the ISO 9001:2008, was released. ISO 9001:2008 was developed to introduce clarifications to the existing requirements of ISO 9001:2000 and to improve compatibility with ISO 14001:2004. ISO 9001:2008 does not introduce additional requirements nor does it change the intent of the ISO 9001:2000 standard. No new requirements were introduced in ISO 9001:2008 edition but, in order to benefit from the clarifications of ISO 9001:2008, users of the former version will need to take into consideration whether

the clarifications introduced have an impact on their current interpretation of ISO 9001:2000, as changes may be necessary to their QMS.

## **2.3 WHAT IS QUALITY?**

2.3.1 The literature on quality management provides a broad range of definitions of quality. In particular, the literature notes that quality is a subjective term and that individuals and organizations 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 aeronautical information services and 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.

2.3.2 As individuals and organizations hold their own perception of what defines quality, there is obviously a need for a common understanding. ISO provides this in its definition of quality: the "degree to which a set of inherent characteristics fulfills requirements" (Clause 3.1.1 of ISO 9000:2005). "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.

2.3.3 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.

2.3.4 AIM has become one of the most valuable and important enabling services in the global ATM system. Computer-based navigation systems, RNAV, 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 organization 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 (Clause 3.2.10 of ISO 9000:2005). 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 more or less detection and that is considered a reactive downstream approach, i.e 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 (Clause 3.2.11 of ISO 9000:2005). 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

2.6.1 Quality improvement is another part of quality management that is focused on increasing the ability to fulfill quality requirements (Clause 3.2.12 of ISO 9000:2005). It is not concerned with correcting errors but concerned with doing things better to improve system efficiency and effectiveness.

2.6.2 ISO offers the PDCA cycle as a useful tool for continual improvement. The methodology applies to both high-level strategic processes and to simple operational activities. Figure 2-1 illustrates the PDCA cycle.

## 2.7 QMS

2.7.1 As defined in ISO 9000:2005, a QMS is a management system that directs and controls an organization with regard to quality (Clause 3.2.3 of ISO 9000:2005). Activities generally include the following:

- a) establishment of a quality policy and quality objectives;
- b) quality planning;
- c) quality control;
- d) quality assurance; and
- e) quality improvement.

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

*Note.— The term "customer" is frequently referred to in ISO 9000. The equivalent term used at ICAO is "user".*

## 2.8 QUANTIFYING QUALITY COSTS

2.8.1 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:

- a) **Internal failure costs.** Costs associated with defects or non-conformance found before the customer receives the product or service, for example, correcting a wrongly encoded aeronautical information when captured by automatic checking procedures.
- b) **External failure costs.** Costs associated with defects or non-conformance found after the customer receives the product or service, for example investigating complaints from a pilot for the late issuance of aeronautical information and loss of goodwill.
- c) **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 IAIP.

- d) **Prevention costs.** Costs incurred to keep failure or non-conformance and appraisal costs to a minimum, for example training staff in quality practices and procedures.

2.8.2 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 organization with simple but effective tools and skills. At the other end, quality management involves the entire organization 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 organization, 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 9000:2000 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 organizations towards improved performance. These principles are as follows:

- a) **Customer focus.** Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer requirements. ISO 9001:2008 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 and 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".
- b) **Leadership.** Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization'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 has a sound appreciation and understanding of all facets of quality management and, in particular, 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 organization and identifying this quality may be of great benefit in establishing a quality culture within a specific section of an organization or throughout the organization as a whole.
- c) **Involvement of people.** People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization'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 quality consciousness, that is, to assist in building a quality-focused culture. With the implementation of the QMS, staff needs to take on additional responsibilities such as the day-to-day consistency checks as part of the data for product quality assurance and control processes.
- d) **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, Volume 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, have to be managed as processes.

- e) **System approach to management.** Identifying, understanding and managing interrelated processes as a system contributes to the organization'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.
- f) **Continual improvement.** Continual improvement of the organization's overall performance should be a permanent objective of the organization. Specifically, the effectiveness and suitability of the QMS have to be evaluated and areas for improvement identified and rectified. Management reviews have to 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 organization to make suggestions on ways to improve the service.
- g) **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.
- h) **Mutually beneficial supplier relationships.** An organization 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 the basis of their ability to meet purchase order requirements and on their past performance.

## 2.10 THE ISO 9000 SERIES OF STANDARDS

2.10.1 The ISO 9000 series of standards has been developed on the basis of the eight quality management principles (see 2.9) with an emphasis on system effectiveness. The entire series has been reduced from more than twenty standards in the 1994 version to only four standards in the 2000 version, as follows:

- a) ISO 9000:2005 *Quality Management Systems — Fundamentals and Vocabulary*. This standard is intended to provide the fundamental background information of QMS 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 organization, suppliers, customers, statutory and regulators).
- b) ISO 9001:2008 *Quality Management Systems — Requirements*. This standard specifies requirements of a QMS where the organization 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 8 contain the required elements of the QMS. The details of the clauses and their meanings are given in Chapter 3.
- c) ISO 9004:2009 *Quality Management Systems — 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

organization 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 nor as a guide to the implementation of ISO 9001.

- d) ISO 19011:2002 — *Guidelines for Quality and/or Environmental Management Systems Auditing*. The standard provides guidance on the principles of auditing, managing audit programs, conducting QMS audits, as well as guidance on the competence of quality and management system auditors.

2.10.2 In order 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 also 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.

2.10.3 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 <http://www.iso.org>. For countries where there is no ISO member institute, the soft copy of the standards can be purchased online from the ISO website.

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**

## Chapter 3

# THE ANATOMY OF THE ISO 9001:2008 QMS

### 3.1 INTRODUCTION

3.1.1 The ISO 9001:2008 International Standard specifies the requirements for a QMS applicable to all organizations, products and services. It is the only standard in the ISO 9000:2000 family of standards that can be used for certification of the system. The AIS provider can only seek certification of the QMS after validating that every ISO 9001:2008 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 AIS for international air navigation.

*Note.— ISO 9001:2008 only defines the fundamental requirements and lays down the framework for certification. Each AIS 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 AIS 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 9001:2008 in a simple and cost-effective manner.*

3.1.2 ISO 9001:2008 also requires that a “process approach”, that is, one of the eight quality management principles, be followed when developing and maintaining an effective QMS. For an AIS provider to function effectively, it has to identify and manage numerous linked processes. To name but a few, these may include the following:

- a) the process for review of the requirements related to the products;
- b) the process for provision of such products; and
- c) 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 9001:2008

3.2.1 ISO 9001:2008 is organized into the following eight clauses:

Clause 1 — Scope;

Clause 2 — Normative reference;

Clause 3 — Terms and definitions;

Clause 4 — QMS;

Clause 5 — Management responsibility;

Clause 6 — Resource management;

Clause 7 — Product realization; and

Clause 8 — Measurement, analysis and improvement.

3.2.2 The first three clauses are introductory and set the stage for the requirements. The *shall* clauses that signify the actual requirements are stipulated in the last five clauses. The QMS described in Clause 4 encompasses the four major groups of processes, within the process-based QMS. These, which are described in Clauses 5 to 8, are as follows:

- a) management responsibility;
- b) resource management;
- c) product realization and measurement; and
- d) analysis and improvement.

### 3.3 THE PROCESS MODEL

3.3.1 Activities that receive inputs and convert them to outputs can be considered to be 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.

3.3.2 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 an AIM are often referred to as a “process approach”.

3.3.3 A more sophisticated conceptual process model recognizes the role that the customer plays in the definition of requirements as inputs. By monitoring customer satisfaction, or in some cases dissatisfaction, we are able to monitor and evaluate whether or not defined customer requirements have been met.

3.3.4 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 there is the degree of customer satisfaction with the product or service that has been provided as a result of a number of 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 in turn is a measure of 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.

3.3.5 Resources are a key component of the quality system. 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 quality system will strive for excellence, always looking for ways to do the work better through a program of continuous improvement. A quality system will continue to challenge the outputs against the customer requirements and

specifications to ensure that customer's expectations are met and exceeded. This is why all of the elements in the continuous improvement program are so important.

### 3.4 GENERAL REQUIREMENTS

3.4.1 The general requirements for the implementation of a QMS are to:

- a) identify the processes needed for the QMS;
- b) determine the sequence and interaction of these processes;
- c) determine criteria and methods required to ensure the effective operation and control of these processes;
- d) ensure the availability of information necessary to support the operation and monitoring of these processes; and
- e) measure, monitor and analyse these processes, and implement action necessary to achieve planned results and continual improvement.

### 3.5 MANAGEMENT RESPONSIBILITY

3.5.1 AIM Managers have a number of demonstrable responsibilities within the quality system. These responsibilities relate to:

- a) quality policy;
- b) commitment to quality;
- c) customer focus;
- d) planning;
- e) management representation; and
- f) management review.

Each of these responsibilities is addressed in further detail below.

3.5.2 A quality system 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.

#### **Quality policy**

3.5.3 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) a commitment to quality;

- b) what the quality objectives or the organization are; and
- c) how the objectives relate to customers expectations.

3.5.4 The quality policy must address these issues and ensure that it:

- a) is appropriate for the needs of the organization;
- b) includes commitment to meeting requirements and continual improvement;
- c) provides a framework for establishing and reviewing quality objectives;
- d) is communicated, understood and implemented throughout the organization; and
- e) is reviewed for continuing suitability.

3.5.5 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.

3.5.6 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.

### ***Commitment to quality***

3.5.7 AIM managers must take an active responsibility in the establishment and maintenance of a quality system. This role includes:

- a) definition and implementation of quality policy;
- b) communicating the quality policy within the organization, including the importance of meeting customer, regulatory and legal requirements;
- c) setting objectives, strategies and targets derived from the policy;
- d) position descriptions that describe the role, responsibilities and authorities for all staff;
- e) ensuring that resources are adequate;
- f) appointment and support of a management representative; and
- g) regular reviews of the effectiveness of the system.

### ***Customer focus***

3.5.8 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.

### **Planning**

3.5.9 The step that follows the publication of the quality policy is the setting of objectives, strategies and targets that will show how the organization 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.

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

- a) staff performance measurements;
- b) budgets;
- c) overall business performance measurements;
- d) asset and facility purchases;
- e) staff competencies and training requirements;
- f) other resource requirements; and
- g) the continuing improvement program.

3.5.11 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 organization 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**

### **Responsibility and authority**

3.6.1 A quality system requires responsibilities and authorities for all staff members to be defined and communicated. This means that everyone in the organization 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 organizational chart should supplement job descriptions.

### **Management representative**

3.6.2 Quality systems are required to have a management representative who looks after the quality system, and who has the responsibility and authority that includes:

- a) ensuring that processes for the QMS are established and maintained;
- b) reporting to senior management on the performance of the QMS, including needs for improvements; and

- c) promoting awareness of customer requirements throughout the organization.

### **Internal communications**

3.6.3 Internal communications is 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.

3.6.4 Effective internal communications will provide the ability to:

- a) receive information quickly and act on it;
- b) build trust among the staff;
- c) identify business opportunities; and
- d) identify opportunities for improvement.

## **3.7 RESOURCE MANAGEMENT**

### **Provision of resources**

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

- a) implement and improve the processes of the QMS; and
- b) address customer satisfaction.

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

### **Human resources**

3.7.2 Staff who is assigned responsibilities defined in the QMS must be competent on the basis of applicable education, training, skills and experience.

3.7.3 People assigned to carry out quality activities are required to be competent to do them, otherwise 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 also on skill and experience that the people possess. There is however, no requirement to have all four, only those applicable to the particular task.

3.7.4 Appropriately qualified and experienced staff in sufficient numbers is pre-requisites for an AIM organization to provide safe and timely aeronautical information.

3.7.5 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 must be technically oriented in the nature of 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 the AIM and that the AIM has an appropriate status in the parent civil or military organization.



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

3.7.7 Equally, staff responsible for the collection, collation, checking, coordination and edition information published in the IAIP must have a thorough understanding of the content, standards, format and other user requirements related to the material being published.

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

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

- a) conversant with the standard format, codes and abbreviations for NOTAM;
- b) conversant with the operational requirement for ATS, flight operations personnel, flight crews and the services responsible for pre-flight information to be kept informed of operationally significant information that may affect the safety of air navigation; and
- c) competent in the operation of the AFTN.

### ***Training, awareness and competency***

3.7.10 This part of the standard requires an organization to:

- a) determine competency needs for personnel performing activities affecting conformity to product requirements ;
- b) *where applicable* provide training to *achieve the necessary competence*;
- c) evaluate the effectiveness of the training provided;
- d) ensure that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives; and
- e) maintain appropriate records of education, experience, training and qualifications.

### ***Checking competence and training***

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

3.7.12 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.

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

- a) principles of the AIS;

- b) organization of aim;
- c) responsibilities and functions of aim:
  - ICAO documents;
  - AIM products;
  - responsibilities and limitations;
- d) the IAIP;
- e) relationships with external agencies;
- f) 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;
- g) AIM automation.

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

3.7.15 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.

**Facilities and the work environment**

3.7.16 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.

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

- a) workspace;
- b) equipment, hardware and software; and
- c) 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.— Doc 8126 provides guidance on facilities and equipment for AIS.*

3.7.18 AIM organizations are moving more and more towards automated systems to improve the efficiency, accuracy and cost effectiveness of their businesses. AIM 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 AIS.

**3.8 PRODUCT DEVELOPMENT AND REALIZATION****Product realization**

3.8.1 Product realization is the sequence of processes and sub-processes required achieving the delivery of a product. Planning of the realization processes must be consistent with the other requirements of the organization's QMS and documented in a form suitable for the organization's method of operation.

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

- a) objectives for the product, project or contract;
- b) the need to establish processes and documentation, and provide resources and facilities specific to the product;
- c) verification and validation activities, and the criteria for acceptability; and
- d) the records that are necessary to provide confidence of conformity of the processes and resulting product.

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.

3.8.3 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 the QMS are applied for a specific product, project or contract may be referred to as a quality plan.*

### **Identification of customer requirements**

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

- a) product requirements specified by the customer, including the requirements for availability, delivery and support;
- b) product requirements not specified by the customer but necessary for intended or specified use; and
- c) obligations related to product, including regulatory and legal requirements.

3.8.5 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 organization that has ownership of the information provided by AIM.

*Note.— For the purposes of these Guidelines and the ISO requirements, the Author Areas can be considered to be 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.*

### **Review of product requirements**

3.8.6 AIM 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:

- a) product requirements are defined;
- b) where the customer provides no documented statement of requirement, the customer requirements are confirmed before acceptance;
- c) contract or order requirements differing from those previously expressed (e.g. in a tender or quotation) are resolved; and
- d) the organization has the ability to meet defined requirements.

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

3.8.9 When product requirements are changed, the 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.

3.8.10 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.

### ***Customer communication***

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

- a) product information;
- b) enquiries, contracts or order handling, including amendments; and
- c) customer feedback, including customer complaints.

### ***Understanding and meeting the customer's requirements***

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

- a) written order;
- b) verbal agreement; or
- c) telephone order.

3.8.13 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.

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

3.8.15 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:

3.8.16 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.

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

3.8.18 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.

3.8.19 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

3.9.1 Many AIM provides a 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:

- a) stages of design and/or development processes;
- b) review, verification and validation activities appropriate to each design and/or development stage; and
- c) responsibilities and authorities for design and/or development activities.

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

#### ***A disciplined approach to design and/or development***

3.9.3 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:

- a) the design aims, planning how the design is to proceed, and who is to carry out the design;
- b) what is needed to be known for the design to proceed;
- c) the form of the output from the design;

and to:

- d) review, on completion of the design, whether it has achieved what was wanted (flight validation);
- e) modify the design to include changes, which may occur at any stage of the process and for any reason.

#### ***Who is going to do what?***

3.9.4 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.

#### ***Design and/or development inputs***

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

- a) functional and performance requirements;
- b) applicable regulatory and legal requirements;

- c) applicable information derived from previous similar designs, and
- d) any other requirements essential for design and/or development.

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

#### ***Does AIM have it right?***

3.9.10 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:

- a) performing alternative calculations;
- b) comparing the new design with a similar proven design (if available);
- c) undertaking tests and demonstrations e.g. flight validations; and
- d) reviewing the design stage documents before release.

AIM 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.

#### ***Does it work?***

3.9.11 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.

#### ***Control of design and/or development changes***

3.9.12 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.— Additional guidance may be found in ISO 10007 — Quality Management — Guidelines for Configuration Management.*

**Controlling changes**

3.9.13 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 modified as a result 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 actually 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.

**Product identification and traceability**

3.9.14 AIM should identify;

- a) the product by suitable means throughout production and service operations when appropriate;
- b) the status of the product with respect to measurement and monitoring requirements; and
- c) 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.

**Keeping track of what AIM is doing**

3.9.15 **Identification** is knowing what the product and/or service resulting from a particular process is, 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.

3.9.16 **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:

- a) job card entries;
- b) data checked and confirmed, data entry complete;
- c) service records, e.g. signing-off a particular work aspect;
- d) tagging;
- e) computer tracking.

3.9.17 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 telephone 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



telephone answering service would have some suitable means of identifying the status. Some of the above techniques may be also used for identification. You need to be aware that the requirements for traceability may result in additional paperwork and costs, so you have to be aware of the balance between really needing to know and superfluous information. An example of a checklist is shown on Table 3-1.

**Table 3-1. Example of a checklist**

<i>Action</i>	<i>Reg. No.</i>	<i>Status</i>	
		<i>Completed</i>	<i>Yet to be done</i>
Change details registered	WP16/00	(DS)	
Data checked and verified		(DS)	
Data entry		(CS)	
Entered on charts		(CH)	
Airspace handbook			x
AIP book			x
Document checks complete			x
Chart checks complete			x
Publications to printer			x
Publications to dispatch			x

3.9.18 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) the AIM adopt(s) as being most suited to its business should be described, e.g. in its work instructions, so that everybody knows how it works.

### ***Customer property***

3.9.19 AIM must exercise care with customer property while it is under the organization's control or being used by the organization. The organization 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.*

### ***Looking after what the customer gives you***

3.9.20 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:

- a) instruments provided by the customer for measurement purposes;
- b) training room provided by the customer;
- c) special hardware of software; and
- d) special paper for specific products.

While documented procedures are not required for this aspect, the organization 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.

### ***Looking after the product and/or service***

3.9.21 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, and also applies to the constituent parts of a product. This part of the Standard means that none of these activities is allowed to affect the quality of the product and/or service being provided. It is up to the AIM to determine how AIM will ensure that this is the case. Depending on the nature of AIM business, some or all of 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 a number of 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:

- a) ***Handling.*** This might be the use of computers and/or a filing system, job-cards, or work-packages to control work in progress.
- b) ***Storage/preservation.*** Use of computer systems to store work in progress, and off-site or other back-up arrangements.
- c) ***Packaging/delivery.*** Use of mailing tubes or electronic transfer of data to deliver charting products to a printer for reproduction.

3.9.22 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. The 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 "use-by-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.

### ***Stock control***

3.9.23 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.

### **Control of measuring and monitoring devices**

3.9.24 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 CRCs. 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:

- a) 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;
- b) be safeguarded from adjustments that would invalidate the calibration;
- c) be protected from damage and deterioration during handling, maintenance and storage;
- d) have the results of their calibration recorded; and
- e) have the validity of previous results re-assessed if they are subsequently found to be out of calibration, and corrective action taken.

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

*Note.— See ISO 10012 for additional guidance.*

### **Having confidence in the equipment used to check your work**

3.9.25 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 emphasized 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 or not it is still capable of meeting the accuracy required for the measurements made with it. "Periodically" can mean on a time basis (monthly, annually) or a usage basis (before each use or after a 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 recognized 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 take into account 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 has to be capable of measuring to a much closer tolerance 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:

- a) make sure it is looked after, regularly calibrated and adjusted as needed;
- b) describe how this will be done so that records are available which show calibration is traceable to national standards; and
- c) make sure it is possible to identify which equipment has been calibrated and that it is suitable for use, e.g. label the equipment.

3.9.26 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 minimize 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:

- a) ideally, the organization should be endorsed as a calibrating service by a suitable certifying body;
- b) the organization should issue a certificate of calibration, which states the uncertainty of measurement. (This is another way of stating how accurately the instrument can measure);
- c) the certificate should indicate that the organization can trace your calibration back to a national or international standard.

3.9.27 AIM is free to use an organization 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 confidence in your inspection and test 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 in light of experience. In addition to calibrating equipment, records need to be kept to show:

- a) 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); and
- b) 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.
- c) 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.

### ***Measurement and monitoring of products***

3.9.28 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 realization 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.

### ***Checking things are right***

3.9.29 This part of the Standards requires that you establish how you intend to check and monitor both 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:

- a) measuring dimensions;
- b) proof-reading publications;
- c) matching colours; and
- d) looking at things and deciding if they are what were asked for.

3.9.30 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.

3.9.31 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 has to 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.

3.9.32 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.

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

- a) a quality plan;
- b) a sampling plan;
- c) an inspection and test plan;
- d) a procedure;
- e) an instruction; and
- f) the customer's order.

3.9.34 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**

#### ***Control of non-conformity***

3.10.1 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 organization shall take appropriate action regarding the consequences of the non-conformity.

3.10.2 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.

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

- a) investigation to find out the extent of the problem;
- b) segregation and quarantine of the remaining ink supply from that consignment;
- c) segregation and quarantine of affected maps and charts awaiting delivery; and
- d) 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.

### ***Analysis of data***

3.10.4 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, the AIM must analyse data to provide information on:

- a) customer satisfaction and/or dissatisfaction;
- b) conformance to customer requirements;
- c) characteristics of processes, product and their trends; and
- d) suppliers.

### ***Do the measurements reveal any trends?***

3.10.5 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.

### ***Planning for continual improvement***

3.10.6 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.

### ***What improvements does AIM plan to make?***

3.10.7 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 a number of tools and inputs that AIM can use to both plan and actually implement improvement.

#### ***Corrective action***

3.10.8 AIM must take corrective action to eliminate the cause of non-conformities in order 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:

- a) identifying non-conformities (including customer complaints);
- b) determining the causes of non-conformity;
- c) evaluating the need for actions to ensure that non-conformities do not recur;
- d) determining and implementing the corrective action needed; and
- e) recording results of action taken reviewing of corrective action taken.

#### ***Preventive action***

3.10.9 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:

- a) identifying potential non-conformities and their causes;
- b) determining and ensuring the implementation of preventive action needed;
- c) recording results of action taken; and
- d) reviewing of preventive action taken.

#### ***Fixing the causes of problems***

3.10.10 Both corrective and preventive action can 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 particular 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 these potential causes. The documented procedures for both corrective and preventive actions should define the responsibilities and authorities for these activities.



**Fixing the cause of known problems**

3.10.11 There is a difference between carrying out corrective action and fixing a non-conformity. Fixing a 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 non-conformity occurred and making sure that the problem does not occur again. The need for corrective action could be indicated by a number of factors, some of which could be:

- a) customer complaints;
- b) non-conformances;
- c) rework or repairs; and
- d) audit reports.

3.10.12 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.

**Fixing the cause of potential problems**

3.10.13 AIM 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:

- a) difficulties with suppliers;
- b) in-process problems, rework rates, wastage levels;
- c) final inspection failures; and
- d) customer complaints and customer surveys.

Other sources might include market surveys, audit reports and quality records.

3.10.14 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. As a result 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:

- a) identifying possible situations where product damage may occur and implementing practices to prevent it from happening;
- b) feedback from personnel may indicate a more efficient process; and
- c) re-assessment of suppliers to overcome potential supply problems.

3.10.15 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.

#### **Customer satisfaction**

3.10.16 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?**

3.10.17 This is an important new aspect to the 2000 version of ISO 9001. 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**

3.10.18 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**

3.10.19 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**

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

- a) telephone calls made periodically or after delivery of product and/or service;
- b) questionnaires and surveys;
- c) using a market research company; and
- d) focus groups/conferences.

All of these have merits and disadvantages. For a small AIM organization, 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 do. 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 simple. Choose the questions very carefully. Ensure that they are clear. Why not test it out on a trusted friend before AIM sends it out?

3.10.21 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***

3.10.22 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. In reality, 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.

### ***Internal audit***

3.10.23 CAAs should conduct periodic internal audits to determine whether the QMS:

- a) conforms to the requirements of the International Standard; and
- b) has been effectively implemented and maintained.

3.10.24 CAAs should plan the audit program 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 the responsibilities and requirements for conducting audits, ensuring their independence, recording results and reporting to management. AIM Management must take timely corrective action on deficiencies found during the audit. Follow-up actions shall include the verification of implementation of corrective action and the reporting of verification results.

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

*Note.— See ISO 10011 for additional guidance.*

### ***What is the internal audit?***

3.10.26 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:

- a) reading the documented procedures;
- b) reading relevant process control documents;
- c) observing processes being carried out;
- d) talking to the people carrying out the processes; and
- e) 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.

3.10.27 For a well organized 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.

3.10.28 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:

- a) writing or revising a documented procedure or a process control document;
- b) redesigning a form to incorporate more information; and
- c) arranging for employee retraining.

3.10.29 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 any particular aspect should be audited, the following factors may be considered:

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

3.10.30 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 vice-versa. This can provide benefits in developing an understanding of each other's problems.

3.10.31 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.

3.10.32 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.

3.10.33 Effective use of internal quality audits is an area that AIM may use to minimize the ongoing costs of certification/registration. If the auditor from the certification/registration body can see that internal quality audits are being used to effectively monitor and control the QMS, the auditor does not need to spend as much time verifying the QMS operation. Again it must be emphasized that what the auditor will be seeking is objective evidence with respect to internal quality audits.

**Figure 3-1. Simplistic process**

**Figure 3-2. Conceptual model of the “process approach”**

**Figure 3-3. An example of traceability**



# Chapter 4

## QMS DOCUMENTATION

### 4.1 STRUCTURE OF QMS DOCUMENTATION

4.1.1 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 organization, 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

4.1.2 Level 1 documentation defines the principles and approaches of the AIS provider to quality-related issues. It consists of the quality manual, the quality policy and objectives of the organization.

4.1.3 Level 2 documentation consists of procedures by which the AIS provider manages the QMS. Note that while ISO 9001:2008 explicitly requires a minimum of six documented procedures respectively on the following:

- a) control of documents;
- b) control of records;
- c) internal audit ;
- d) control of non-conforming product;
- e) corrective action; and
- f) preventive action.

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

4.1.4 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.

4.1.5 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.

4.1.6 In essence, the QMS documentation usually includes the following:

- a) quality policy and objectives (explicit requirement);
- b) quality manual (explicit requirement);
- c) documented procedures (explicit requirement);
- d) work instructions/operational procedures (implicitly required by Clause 4.2.1 of ISO 9001:2008);

- e) external documents which can include specifications, statutory and regulatory requirements, standards, codes, etc. ICAO Annex 15 and Doc 8126, Regional Air Navigation Plans and States' AIPs also fall under this category (implicitly required by Clause 4.2.1 of ISO 9001:2008);
- f) forms and records (explicit requirement); and
- g) quality plans, usually used in complex projects, products, processes or contracts (not a mandatory requirement in ISO 9001:2008).

4.1.7 ISO 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” (Clause 3.7.5 of ISO 9000:2000). It is an output of the process for planning of product realization (Clause 7.1 of ISO 9001:2008) 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 AIS providers to decide if quality plans should be prepared for their products. There are no requirements from ISO 9001:2008.

4.1.8 While ISO 9001:2008 explicitly requires a minimum of six documented procedures, the AIS provider may need to document additional processes to ensure the effective operation and control of such processes. For example, although not explicitly required by ISO 9001:2008, it would be useful to have a documented procedure for the management review (Clause 5.6 of ISO 9001:2008) process, taking into account the importance of this process to the effective operation of the QMS and the complexity and possibility of deviation from the requirement.

4.1.9 Work instructions and operational 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 AIS providers, extensive work instructions and operational procedures should naturally be expected for the realization of products and services. Whenever appropriate, reference to the relevant external documents are containing the product requirements.

4.1.10 It has to 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.

4.1.11 Forms and records provide evidence of what the AIS provider has performed and, therefore, would indicate whether or 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**

4.2.1 Documentation for a QMS must include:

- a) documented procedures (see the section that follows for a description of Documented Procedures); and

- b) documents required by the organization to ensure the effective operation and control of its processes.

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

- a) size and type of the organization;
- b) complexity and interaction of the processes; and
- c) competence of personnel.

### 4.3 DOCUMENTATION

4.3.1 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.

4.3.2 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.

4.3.3 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.

4.3.4 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 standardize the work of developing documentation.

### 4.4 DOCUMENTED PROCEDURES

4.4.1 ISO requirements for a quality system call for 6 QMS procedures to be in place. These are mandatory written procedures that describe how the organization performs the activities described in each of the six QMS procedures described below:

- a) control of documents;
- b) control of records;
- c) internal audit;
- d) control of non-conforming product
- e) corrective action; and
- f) preventive action.



4.4.2 Documented procedures should indicate who does what, where and when they do it, why they do it, and how. It is up to the organization itself to decide the level of detail that is included in the documented procedures. Largely, this will depend on:

- a) methods used;
- b) skills needed;
- c) training; and
- d) extent of supervision required.

4.4.3 Documented procedures should not contain what you would like to happen in the organization, 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

4.5.1 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) authorized 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

*Note 1.— Appendix A contains a template of a quality manual to be used by an AIM organization.*

*Note 2.— Appendix B contains samples of quality manuals.*

4.6.1 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:

- a) the scope of the QMS;
- b) the documented procedures or a suitable reference; and
- c) a description of the sequence and interaction of the processes included in the QMS.

4.6.2 The quality manual is the “map” for the organization, and where the following items would be found:

- a) the quality policy;
- b) the activities of the business
- c) how the documentation works and where people might look to find information about how to do things;
- d) a definition of any terms having a unique meaning to your business; and

- e) statements of responsibility and authority.

4.6.3 The quality manual should also include information about the AIM and its activities, about the manual itself and where to find information and guidance, a description of the organizational structure and statements of responsibilities and authorities, and, if appropriate, a glossary and appendices for supportive data.

4.6.4 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.

4.6.5 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 complete and correct.

#### 4.7 CONTROL OF DOCUMENTS

4.7.1 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:

- a) approve documents for adequacy prior to issue;
- b) review and update documents as necessary and re-approve documents;
- c) ensure that changes and the current revision status of documents are identified;
- d) ensure that relevant versions of applicable documents are available at points of use;
- e) ensure that documents remain legible and readily identifiable;
- f) ensure that documents of external origin are identified and their distribution controlled; and
- g) prevent the unintended use of obsolete documents and apply suitable identification to them if they are retained for any purpose.

4.7.2 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. A number of computing software packages makes 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.

4.7.3 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**

4.8.1 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**

4.9.1 Each controlled document has an owner. This is the person or persons authorized 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**

4.10.1 Documents may be issued as controlled or uncontrolled copies. Controlled copies are those issued to particular 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.

4.10.2 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 RECORDS**

4.11.1 Records exist in all organizations. 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.

4.11.2 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.

4.11.3 Each quality system document must include definitions of the quality records to be produced and kept.

4.11.4 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".

4.11.5 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.

4.11.6 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*

- a) document change request form;
- b) controlled documents master list;

*Human resources records*

- c) training;
- d) education;

*Process and product review records*

- e) non-conformance reports;
- f) management review results;
- g) status of corrective actions;
- h) requirements and changes to requirements;
- i) minutes of meetings;
- j) audit reports;

*Miscellaneous quality records*

- k) files on customers and suppliers; and
- l) records of resources and goods received.

4.11.7 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 minimized.

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

4.11.9 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:

- a) What is received before a procedure starts;
- b) What is produced to show intermediary steps have been completed; and
- c) What is produced to show a procedure has been completed.

4.11.10 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.

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

- a) What the record is;
- b) Who is responsible for its filing;
- c) How long the record is required to be kept;
- d) Where the record will be kept; and
- e) Who is responsible for the record's disposal.

A tabular layout, an example of which is given in Table 4-1, may be useful to present the information required:

**Table 4-1. Example of tracking of quality records**

<i>Record</i>	<i>Responsibility</i>	<i>Minimum Retention Period</i>	<i>Location</i>
What the record is	Who is responsible for its filing.  Who is responsible for its eventual disposition.	The minimum time the record must be retained for.	Where the record is kept

4.11.12 In some ways, by default, the person deemed responsible for the record's filing is also responsible for and authorized 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.

4.11.13 In summary, the records management process ensures that all quality records are identified and controlled, in order 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 Table 4-1.

**Table 4-2. Example of record management process**

<i>Stage</i>	<i>Description</i>	<i>Explanation</i>
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 authorized to dispose of the record.

**Figure 4-1 Hierarchy of QMS documentation**


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## Chapter 5

# AUDITING PROCESSES

### 5.1 AUDIT OBJECTIVES

5.1.1 ISO defines an audit as a “systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled” (Clause 3.9.1 of ISO9000:2005). The term “audit criteria”, according to the same standard, refers to a “set of policies, procedures or requirements” used as a reference (Clause 3.9.3). In effect, they are those materials contained in the QMS documentation. The policies and procedures are developed by the AIS provider and the requirements may originate from ISO 9001:2008, users, regulatory and legislative bodies and the AIS provider itself. During the audit, the certification body/registrar will try to verify if the AIS provider is doing what it says it will do (according to the QMS documentation) and to confirm if the QMS is effectively implemented.

5.1.2 While the obvious reason for the AIS 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 realized.

5.1.3 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 to:

- a) confirm conformance of the QMS with ISO 9001:2008;
- b) confirm that the QMS has been properly implemented and maintained;
- c) confirm the commitment and ability of management to review the QMS for continuing suitability, adequacy and effectiveness, and for continual improvement; and
- d) identify opportunities to further improve the QMS.

### 5.2 AUDIT TYPES

5.2.1 A first-party audit refers to an internal audit conducted by, or on behalf of, the AIS provider for compliance with the associated requirement of ISO 9001:2008 (see Chapter 3, Clause 8.2.2) 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 AIS provider and the QMS for the next visit of the certification body/registrar.

5.2.2 A second-party audit refers to an audit conducted by an interested party, such as a user of the AIS provider or ICAO. The AIS provider may be audited by a user for the purpose of awarding a service contract, or evaluating the performance of the AIS provider.

5.2.3 A third-party audit refers to an audit conducted by an external, independent auditing organization, 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 AIS 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.

5.2.4 Second- and third-party audits are collectively known as “external audits”.

### **5.3 PROCESS AUDITING APPROACH**

5.3.1 ISO 9000:2000 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 9000:2000 audit emphasizes the practice of process auditing that identifies the inputs and outputs of the subject process and determines if the process is capable of delivering the desired output consistently. In general, the auditors will look at the following aspects of the process being audited:

- a) inputs and outputs of the subject process;
- b) process activities;
- c) process ownership;
- d) quality objectives;
- e) continual improvement of the process;
- f) interrelation and interaction with other processes; and
- g) the risks to the process.

5.3.2 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 AIS provider is meticulous in following the published procedures and in controlling the process. This is why the procedures should be designed and maintained as simple as possible while still ensuring consistency of the outputs.

### **5.4 CERTIFICATION/REGISTRATION AUDIT**

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

5.4.2 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 AIS provider, and one or more auditors depending on the size and scope of the QMS being audited. Technical experts, in particular 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.



5.4.3 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 AIS provider, applicable statutory and 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”.

5.4.4 The second phase of 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 AIS provider and observing their work. They will sometimes ask to inspect certain documents, samples of products or the records maintained by the AIS provider.

5.4.5 At the end of the last audit day, the auditors will conduct a closed meeting and report their findings to the management of the AIS provider. The auditors should advise of any non-conformity identified in the QMS during the audit. All such non-conformities must be corrected within a certain time period as agreed between the certification body/registrar and the AIS provider. The certification audit can be halted and require immediate corrective action if a major non-conformity is found at this point. minor non-conformities can be addressed at 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 of different non-conformities and the corrective action process is provided in Chapter 6.

5.4.6 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 AIS provider especially if it has not had the assistance of consultants or experienced ISO 9000 auditors in the implementation process of the QMS.

5.4.7 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 AIS provider with 20 employees.

5.4.8 The various steps of the certification/ registration audit are summarized in Figure 5-1. Appendix D contains a sample of a certification/registration audit.

## 5.5 SURVEILLANCE

5.5.1 Certification/registration is only the beginning. After certification/registration, the 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 pay particular attention to the effectiveness of the QMS with regard to achieving the organization’s objectives, changes and improvements implemented to the QMS since the last visit, areas that have generated non-conformities and results of the corrective actions taken by the AIS provider. The minimum frequency of surveillance audits is once every 12 months, but some certification bodies/registrars will audit once every 6 months.

5.5.2 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 organization 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.

**Figure 5-1 Steps of certification/registration audit**



## Chapter 6

# NON-CONFORMANCE REPORTS AND CORRECTIVE ACTION

### 6.1 MEANING OF CERTIFICATION AND REGISTRATION

#### *Starting out*

6.1.1 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 have the opportunity to 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?*

6.1.2 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*

6.1.3 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.

6.1.2 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.

6.1.3 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.

6.1.4 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.

6.1.5 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.

6.1.6 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.

6.1.7 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 rectified by the next surveillance audit, which under these circumstances may seem to come round very quickly.

## 6.2 CONTROL OF NON-CONFORMING PRODUCT

6.2.1 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.

6.2.2 Data or information presented to AIM for publication in the IAIP that does not conform to the specified requirements for a particular AIS product must be marked (e.g. stamped or hand endorsed) as non conforming by AIS provider.

6.2.3 The AIS provider is responsible for advising the originator that the material submitted does not conform.

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

**Table 6-1. The steps for control of non-conforming products**

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

## 6.3 CORRECTIVE ACTION AND ERROR ANALYSIS

6.3.1 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:

- a) 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;
- b) 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;
- c) issue of an AIP amendment at next available amendment; and
- d) correct at next scheduled issue of page or chart.

6.3.2 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:

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

6.3.3 Attention should be given to whether or not an occurrence has actually created or had the potential to create a hazard. In the event that 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

6.4.1 This instruction describes the procedures to be used when an error is detected in a component of the IAIP. The steps for error tracking are shown in Table 6-2.

**Table 6-2. The steps for error tracking**

<i>Step</i>	<i>Action</i>	<i>Responsibility</i>
1.	Confirm the error and raise an ETF(Error Tracking Form)	<insert>
2.	Register the ETF	<insert>
3.	Analyse the safety aspects associated with the error and determine if NOTAM or other action is appropriate	<insert>
4.	Initiate corrective action as a NOTAM or AIP SUP and process through the NOTAM officer/NOF	<insert>
5.	Attach a copy of the NOTAM request/Draft AIP SUP to this form	<insert>
6.	Analyse the cause of the error	<insert>
7.	Discuss the error with the officer responsible	<insert>
8.	Determine remedial action	<insert>

9.	Brief AIM Manager as necessary	<insert>
10.	Initiate change action when required	
11.	Amend or establish procedures as required to strengthen processes	<insert>
12.	Sign-off the ETF when completed	<insert>
13.	Forward the completed form to <insert> for filing	<insert>

### **Error analysis**

6.4.2 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*

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

- a) where the published information could compromise aircraft clearance from terrain, e.g. incorrect instrument approach minima;
- b) where there is an error in navigational or route information, e.g. incorrect track; and
- c) any error in the depiction or publication of airspace information, e.g. incorrect vertical limits.

#### *Major*

6.4.2.2 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*

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

- a) any “typographical” error, where the information published is correct in context and content but could contain spelling or grammatical errors; and
- b) errors where there are no operational impacts.

### **Preventive action**

6.4.3 Good error analysis should identify where necessary the preventive action required to ensure the error does not re-occur. The steps for preventive action are shown in Table 6-3.

**Table 6-3. The steps for preventive action**

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

## 6.5 CHANGE PROCEDURES

6.5.1 Staff are encouraged to suggest changes that will improve the quality system. To facilitate this process, suggestions may be made in the format of Figure 6-1.

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

6.5.3 An example of change procedure action is shown in Table 6-4.

<b>AIM Quality System — Staff Suggestion</b>		
<b>No.</b>	<b>To:</b> <Insert who the suggestions are directed to (e.g. Manager AIM)>	<b>From:</b>
<b>Details:</b>		
<b>Action taken:</b>	<b>Originator advised:</b>	<b>Date:</b>

**Figure 6-1. Example of a suggestion form**

**Table 6-4 Example of change procedure action**

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

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## Chapter 7

### STEPS TO CERTIFICATION AND OTHER PRACTICAL ISSUES

#### 7.1 RESPONSIBILITY FOR INITIATING A QMS

7.1.1 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 organization 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 that the CAA can require or mandate individual line office to establish a QMS.

7.1.2 The AIM in any organization will have been operating with a certain level of quality management in order to have been providing, 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 organization 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.

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

7.1.4 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.

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

- a) learn about ISO;
- b) formulate a quality policy and establish the quality objectives of the AIM;
- c) convey the quality policy and quality objectives to the entire AIM organization;
- d) define the roles and responsibilities of the quality manager;
- e) appoint a quality manager;
- f) arrange for ISO training of the quality manager; and
- g) arrange ISO training of the staff.

7.1.6 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 their organization's performance. Detailed information is found in ISO 9000:2005 — QMS — Fundamentals and vocabulary, ISO 9001:2008 — QMS — Requirements and ISO 9004:2000 — QMS — Guidelines for performance improvements. Supporting information for those not already familiar with the ISO 9000 QMS standards is provided on the ISO Web site [www.iso.org](http://www.iso.org).

7.1.7 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.

7.1.8 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 at 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.

7.1.9 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.

7.1.10 While there will be more involvement by some staff than by others in the QMS implementation project, all staff must eventually be engaged in and guided by the quality policy and quality objectives in order for the QMS to succeed. It should be emphasized that implementing a QMS is an opportunity to improve the way the AIM carries out its work and that, to achieve this, each person has an important contribution to make.

## **7.2 QMS IMPLEMENTATION PROJECT**

### **7.2.1 Introduction**

This section 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. Appendix E of this manual contains samples of templates and planning QMS implementation into AIM.

### **7.2.2 Phase 1 — Planning**

#### **Overview**

7.2.2.1 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 manager may require the assistance of a project implementation team. Project implementation team.

7.2.2.2 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.

7.2.2.3 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.

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

### **Gap analysis**

7.2.2.5 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:

- a) **Organizational perspective.** List the functional groups of AIM and its organizational structure. Show how the organizational 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.)
- b) **Products and services, and customers.** List the products and services provided by AIM. List the customers for the products and services provided.
- c) **Activities.** List the activities performed within each functional group and link them to the products and services provided.
- d) **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.
- e) **Customer requirements.** 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.
- f) **Procedures.** List the procedures used in each of the processes. Note where procedures required to ensure quality are undocumented or non-existent.

- g) **Duties and responsibilities.** List the duties and responsibilities of each person involved in processes. Link responsibilities to processes. Note the differences between actual responsibilities and those documented in the job descriptions, as well as the lack of documented responsibilities.
- h) **Skills and competencies.** 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.
- i) **Infrastructure.** List the workspace, hardware, software and equipment required to effectively carry out activities. Note where a lack of infrastructure is adversely affecting activities.
- j) **Documentation.** List existing documentation on all of the above. 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 of the above.

7.2.2.6 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:

- a) how a job is initiated;
- b) how the work gets started;
- c) who monitors the progress;
- d) how the work is processed and controlled;
- e) what documentation is used to support the task;
- f) what are the skills and competencies needed to perform the task;
- g) what hardware, software and other equipment and materials are used to perform the task;
- h) who decides when the work is finished;
- i) how delivery is made;
- j) what follow up action is needed and who does it; and
- k) what records are kept and who keeps them.

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

- a) Has AIM identified its products and services?
- b) Have all the requirements for each of these products and services been determined?
- c) Do processes and procedures exist for effectively meeting these requirements?
- d) In addition to the processes required to meet requirements for AIM products and services (including those that may be outsourced), do the following QMS processes exist for:
  - 1) control of documents, including records;

- 2) control of resources;
  - 3) communication (internal and external);
  - 4) planning;
  - 5) training;
  - 6) monitoring and measurement of process performance and quality;
  - 7) dealing with non-conformities;
  - 8) continual improvement of process performance and of the QMS, including corrective and preventive actions;
  - 9) management review of the QMS;
  - 10) internal audit of the QMS;
- e) Are all these processes and the interconnections between these processes identified and documented?
  - f) 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?
  - g) Are the resources needed to achieve effective outcomes of the processes defined?
  - h) Is there a quality manual for AIM?

7.2.2.8 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. It is possible to discover exclusions to the standard during this process.

### **Deliverables**

7.2.2.9 The items of documentation identified during the gap analysis as requiring development in order 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:

- a) documented statements of quality objectives and quality requirements;
- b) documented procedures;
- c) quality records; and
- d) documents needed to ensure the effective planning, operation and control of processes, such as:
  - 1) document templates;
  - 2) instructions;

- 3) checklists; or
- 4) forms.

### **Target dates**

7.2.2.10 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.

7.2.2.11 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*

7.2.2.12 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*

7.2.2.13 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*

7.2.2.14 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**

7.2.2.15 Implementing a QMS may require extra-budgetary funding for training or for the hiring of consultants and a rearranging of work priorities. In order for senior management to make proper decisions about these matters, a project proposal should be prepared by the quality manager. 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 objective, scope and benefits of QMS implementation.

7.2.2.16 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.

7.2.2.17 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.

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

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

### 7.2.3 Phase 2 — Design

#### **Overview**

7.2.3.1 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.

7.2.3.2 The principle tasks in the design phase are to:

- a) create new procedures where required, ensuring consistency with existing ones;
- b) document the QMS;
- c) develop training plans;
- d) develop a plan for certification of the QMS by audit.

7.2.3.3 Existing procedures and documentation should be incorporated in the QMS whenever possible. The task of writing procedures and developing checklists may be best undertaken by personnel directly involved in the process concerned.

#### **Processes and procedures**

7.2.3.4 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 organization that delivers products or services. These processes relate to:

- a) document control (including control of quality records);
- b) control of outsourced processes;
- c) design and development;
- d) provision of resources;
- e) product realization;
- f) communication;
- g) training;
- h) purchasing;
- i) non-conformance;
- j) corrective and preventive action;
- k) monitoring, measurement and analysis of products and processes;
- l) management review; and
- m) programme management.

7.2.3.5 Documented procedures should adhere to a consistent structure. This will facilitate standardization in the development and 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***

7.2.3.6 AIM is required the control of documents accordingly to actions as described in 4.7.1.

#### ***Document master list***

7.2.3.7 Each document is managed by the manner as described in 4.5.1.

#### ***Control of records***

7.2.3.8 Procedures similar to those required for documents are required for control of quality records. ISO 9001:2008 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 information may be included in the record itself, as in the example in Figure 7-1.



Record name	Reference number	Responsibility	Location	Minimum retention period

**Figure 7-1. Control of records**

7.2.3.9 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***

7.2.3.10 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.

### ***Provision of resources***

7.2.3.11 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 both 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.

### ***Product realization***

7.2.3.12 The procedures necessary for the product realization process are first to determine customer requirements, and second to review requirements. Customer requirements to be determined include:

- a) requirements for delivery and post-delivery activities;
- b) requirements not stated by the customer but necessary for specified or intended use, where known;
- c) statutory and regulatory requirements;
- d) any additional requirements determined by the organization (including the quality objectives and requirements).

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

7.2.3.14 Procedures for the review of requirements must ensure that:

- a) product requirements are defined;

- b) contract or order requirements differing from those previously expressed are resolved; and
- c) AIM has the ability to meet the defined requirements.

### **Communication**

7.2.3.15 Procedures must be developed to ensure effective communication within the AIM and with customers.

7.2.3.16 Within AIM procedures must exist to inform about changes in:

- a) policy;
- b) requirements; and
- c) procedures.

7.2.3.17 Procedures are necessary to allow for feedback and communication from personnel to management regarding opportunities for improvement.

7.2.3.18 Procedures must also exist to inform customers of product information.

7.2.3.19 Essential to the QMS is a system of communication that effectively uses feedback and from customers. Procedures must be in place for dealing with:

- a) enquiries;
- b) complaints; and
- c) surveys;

### **Purchasing**

7.2.3.20 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:

- a) documented procedures for ensuring purchased products meet requirements;
- b) the evaluation, selection and reviewing of contractors;
- c) clear definitions of requirements of contractors; and
- d) procedures for verifying and allowing customer verification of contractor operation at the contractor's premises.

7.2.3.21 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 realization processes and their output. Examples of products or services that AIM might purchase are:

- a) hardware;

- b) software;
- c) aeronautical data;
- d) cartographic services.
- e) distribution services.

7.2.3.22 The organization 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, measurement and analysis**

7.2.3.23 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.

7.2.3.24 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 CRCs. 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.

7.2.3.25 Measuring and monitoring devices must be used and controlled to ensure that measurement capability is consistent with the measurement requirements. (See 3.9.13)

7.2.3.26 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 realization process.

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

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

7.2.3.29 This Standards requires that AIM establishes how AIM intends to check and monitor both 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:

- a) measuring dimensions;
- b) proof-reading publications;
- c) matching colours; and
- d) looking at things and deciding if they are what were asked for.

7.2.3.30 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.

7.2.3.31 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.

7.2.3.32 Somebody has to 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.

7.2.3.33 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.

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

- a) a quality plan;
- b) a sampling plan;
- c) an inspection and test plan;
- d) a procedure;
- e) an instruction; and
- f) the customer's order.

7.2.3.35 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.

7.2.3.36 The QMS should be capable of identifying the job and including a procedure to recall the job if the item subsequently proves defective. It 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.

7.2.3.37 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**

7.2.3.38 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.

7.2.3.39 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 organization shall take appropriate action regarding the consequences of the non-conformity.

7.2.3.40 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:

- a) investigation to find out the extent of the problem;
- b) segregation and quarantine of the remaining ink supply from that consignment;
- c) segregation and quarantine of affected maps and charts awaiting delivery; and
- d) recall of those maps and charts likely to be similarly affected, and that could affect safety.

### **Management review**

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

- a) results of audits;
- b) customer feedback;
- c) process performance and product conformity;
- d) status of preventive and corrective actions;
- e) follow-up actions from previous management reviews;
- f) changes that could affect the QMS; and
- g) recommendations for improvement.

### **Programme management**

7.2.3.42 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**

7.2.3.43 Certain of the ISO 9001 requirements may relate to activities and processes that are not performed by AIM. In such cases, ISO 9001 allows for "exclusions", provided that such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements. Specifically, allowances for exclusions are made only for ISO 9001 requirements related to product realization. In terms of ISO 9001 compliance, no exclusions are permitted to the general QMS requirements, nor those related to management responsibility, resource management, and measurement, analysis and improvement. All exclusions must be documented and explained in the quality manual.

**Documentation**

7.2.3.44 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.

7.2.3.45 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.

7.2.3.46 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.

7.2.3.47 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 standardize the work of developing documentation.

**Quality manual**

7.2.3.48 The quality manual is the principal document of 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 9001:2008, provides continuity of the QMS, and can be used for QMS training of personnel.

*Note.— The details of a quality manual is provided in Chapter 4.*

**Training plans**

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

7.2.3.50 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.

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

**Planning for the audit process**

7.2.3.52 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.

7.2.3.53 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.

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

## 7.2.4 Phase 3 — Deployment and testing

### **Overview**

7.2.4.1 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**

7.2.4.2 QMS training should be provided to the entire workforce of the AIS provider or section seeking ISO 9000 certification. It is an integral part of the QMS. The training should include the following:

- a) basic awareness training for all staff to increase their awareness about the QMS;
- b) documentation writing for staff who are responsible for the preparation of documentation required by ISO 9001; and
- c) internal auditor training for staff selected to conduct the internal audits.

### **QMS documentation**

7.2.4.3 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 year 2000 version of ISO 9001 (ISO 9001:2008) are found in Chapter 4.

### **Management review meeting**

7.2.4.4 Deal with discrepancies by determining action required, implementing non-conformance procedures and corrective action and follow-up procedures.

### **Internal audit**

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

## **7.2.5 Phase 4 — Certification**

### **Overview**

7.2.5.1 Annex 15 includes a recommendation that the QMS put in place be certified by an approved organization. Certification in accordance with ISO 9001:2008 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 9001:2008 — QMS— Requirements are used to assess the effectiveness a QMS in meeting regulatory, customer and an organization's own requirements. However, these standards are not intended to impose a particular system of documentation or a specific structure for the QMS.

7.2.5.2 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**

7.2.5.3 Certification begins with an application to a certification organization. The certification organization may request the AIM provide information on its activities, services and products/verification of the QMS.

7.2.5.4 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.

7.2.5.5 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**

7.2.5.6 Once certification is granted, the certification organization 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.

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## Chapter 8

# THE DATA QUALITY PROCESS

### 8.1 INTRODUCTION

8.1.1 As introduced in 1.5.4, the data process consists of a series of complex functions within a sequential flow, particularly from data origination through to the publication of the AIP and other media derived from the AIP for end-use.

8.1.2 The objective of this manual 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.

8.1.3 The following figure depicts the concept of the aeronautical data chain with its five main functions performed by various actors at distinct organizational levels. Those functions are: data origination, publication, application integration, end-use and transmission.

8.1.4 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.

8.1.5 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

8.2.1 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 regularized process.

8.2.2 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 organizations 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.

8.2.3 The outputs of the process will be products 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 using its integrated geospatial data).

### 8.3 ORGANIZATIONS IN THE SUPPLY CHAIN

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

- a) surveyors;
- b) requesting authorities — CAAs, ANSPs, ATSPs, aerodrome/airport authorities and, possibly, equipment suppliers (such as those developing terrain awareness warning systems) that require surveys of, and survey information for, aeronautical facilities (navaids, aerodromes, obstacles, etc.);
- c) originating authorities — organizations responsible for creating facilities related to other ATM facilities. These organizations may perform procedure or airspace design, airspace planning etc. and create facilities such as ATS routes or instrument flight procedures;
- d) publishing authorities — usually States' AIS that issue aeronautical information; and
- e) users.

#### 8.4 THE GENERIC DATA PROCESS

8.4.1 The generic data process may be best described by way of the diagram in Figure 8-2 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.

#### 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:

- a) data/information is provided by defined/approved/certified, ISO9001:2008, ISO accredited companies in accordance with legal and regulatory requirements;
- b) data/information is held in electronic media, preferably through use of standard worksheets which are used throughout the process;
- c) 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 CRC value be calculated. This activity is usually referred to as CRC wrapping;
- d) data/information being transferred electronically is encrypted to provide further protection to its integrity;
- e) data/information is checked/verified by the responsible organization (aerodrome authority, ANSP, CAA etc.) if provided by a subcontractor e.g. a surveyor;
- f) data/information is transferred electronically to AIS;
- g) AIS verifies completeness and integrity of data; and

- h) AIS processes the data to publication using electronic media.

### **Data origination**

8.5.2 Data origination addresses the functions performed by requesting authorities, originating authorities, surveyors and any other third party organizations supplying aeronautical data to such authorities.

Those functions are:

- a) surveyed data:
  - 1) geodetic datum specification and use;
  - 2) establishment of aerodrome survey control networks;
  - 3) recommended procedures for achieving minimum data requirements;
  - 4) documentation of survey control stations;
  - 5) production of survey reports;
  - 6) ongoing maintenance of data;
  - 7) data management and quality assurance;
  - 8) document configuration management; and
- b) calculated and derived data (originating authority activities):
  - 1) geodetic datum specification and use;
  - 2) airspace design;
  - 3) instrument flight procedure design;
  - 4) audit;
  - 5) data management and quality assurance;
  - 6) document configuration management.

### **Data publication**

8.5.3 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:

- a) document management:
  - 1) quality assurance;

- 2) data management;
  - 3) document processing requirements;
  - 4) document modification;
  - 5) document configuration management.
- b) document publication tool;
  - c) guidance for specific publication types.

## 8.6 AERONAUTICAL DATA PROCESSING MODEL

8.6.1 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 organization performs the aeronautical data transmission function.

8.6.2 There are four phases of the aeronautical data preparation function link, i.e. assemble, translate, select and format, while the transmission functional link consist of two phases; receive and distribute.

8.6.3 Figure 8-4 highlights the AIM processes, the aeronautical data preparation and transmission functional links.

8.6.4 Figure 8-5 depicts an aeronautical data processing model related to data flows from preparation to transmission (distribution).

## 8.7 HOW TO CONNECT AND ENHANCE QUALITY AS DATA TRAVELS ALONG THE KEY STEPS

8.7.1 This chapter triggers two important conclusions for the implementation of an AIS/AIM QMS system:

- a) the process applied needs to be identified, documented and understood; and
- b) the “glue” between the key process steps shall be provided/supported by SLAs (see Appendix G).

## 8.8 MEASUREMENT OF INTEGRITY

*The integrity of data*

8.8.1 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 authorized amendment. This integrity must be maintained throughout the data process from origin to application.

8.8.2 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  $1 \times 10^{-8}$  means that an undetected corruption can be expected in no more than one data item in every 100 000 000 data items processed.

8.8.3 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.

8.8.4 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. Thus the integrity of a point at threshold used for landing needs a higher integrity than one used for guidance in cruise.

8.8.5 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 Annex 15 which states:

“3.2.10 Contracting States shall ensure that the integrity of aeronautical data is maintained throughout the data process from survey/origin to distribution to the next intended user. 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  $1 \times 10^{-8}$ : 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  $1 \times 10^{-5}$ : 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  $1 \times 10^{-3}$ : 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.

...

3.2.12 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.”

8.8.6 The value for critical data was derived from the required maximum level of accidents from all causes in  $10^7$  approaches. For that purpose was taken the results of flight tests in the final approach segment data block as defined in Annex 14. As data errors can be one of the causes of these accidents the same value was adopted for the required data integrity.

8.8.7 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.

**How integrity is measured**

8.8.8 An integrity level of  $1 \times 10^{-8}$  means that the acceptable rate of loss of integrity is one 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), 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.

8.8.9 Taking the data item and assuming that it is the latitude/longitude of a NAVAID, held in the traditional form of "N dd mm ss/E ddd mm ss", 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 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.

8.8.10 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 expected 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.

8.8.11 If there were one hundred coordinates 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  $1 \times 10^{-8}$  integrity.

8.8.12 The sums used in this calculation are shown below:

- critical points: 100
- characters per point: 22
- bits per character: 7
- bits per point:  $22 \times 7 = 154$
- bits for all critical points:  $154 \times 100 = 15\,400$
- access per day: 4
- bits subject to transactions/day:  $4 \times 15\,400 = 61\,600$
- days per year: 365
- bits subject to transactions/year:  $365 \times 61\,600 = 22\,484\,000$
- number of years for  $1 \times 10^{-8}$ :  $100\,000\,000 / 22\,484\,000 = 4.45$  years

8.8.13 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 the European Region**

8.8.14 EUROCONTROL has been developing the specification for DALs 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.

8.8.15 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 Annex 15 data integrity requirements and the effectiveness in achieving the requisite data quality will be realized by compliance to the objectives:

- a) DAL 1 for critical data items;
- b) DAL 2 for essential data items; and
- c) DAL 3 for routine data items.

8.8.16 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 independence is required than for objectives at DAL 3. Independence is the functional separation between the person, department or organization performing the primary activity, and the person, department or organization verifying or validating the activity output.

8.8.17 The DAL objectives are split into several sections:

- a) evidence requirements;
- b) dataset;
- c) data interchange;
- d) data quality aspects;
- e) consistency, timeliness and personal performance;
- f) tools and software requirements;
- g) data protection;
- h) quality management, safety and security requirements;
- i) conformity or suitability for use of constituents;
- j) verification of systems; and
- k) additional requirements.

8.8.19 Table 8-1 contains 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 this cases a D for a person within a separate group or department and an P for a person within the same group or department).

**Table 8-1. Extract of a data interchange section**

<i>Objective reference</i>	<i>Objective</i>	<i>DAL 1</i>	<i>DAL 2</i>	<i>DAL 3</i>	<i>Guide reference</i>
DAL-DI-10	Whenever data is transmitted from one user to the next, processes shall be established to protect the data during the transfer.	○	○	○	
DAL-DI-020	For data transmitted by electronic means, the 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 data transmitted by paper means, the integrity of the data may be protected by including the associated CRCs	○	○		
DAL-DI-030	The applied CRCs shall be robust enough to protect the data from corruption over transfer from one user to the next	● D	● P	○	
DAL-DI-040	For data received by electronic means, the integrity of the data shall be confirmed by checking the CRC.	○	○	○	
DAL-DI-050	On receipt of data, it shall be verified that the received data is from an authorized and approved source.	○	○	○	
DAL-DI-060	The means for determining authorisation of data shall be appropriate to the method of data transfer.	○	○		
DAL-DI-070	Documentation shall be maintained that identifies all the suppliers of data used by the organization and the approval status of data.	○	○		
DAL-DI-080	Data that cannot be authenticated shall not be used.	○			
DAL-DI-090	After receiving data but before use data reasonableness checks shall be performed.	● P	● P	○	
DAL-DI-100	For data received by means other than electronic and/or where manual entry of the data is required, the entered data shall be checked against the source data.	● D	● D	○	
DAL-DI-110	If errors are discovered in the received data, the data supplier shall be informed immediately.	○	○	○	

8.8.20 It is now recognized 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.



8.8.21 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.

8.8.22 Annex 15, 3.2.12 recognizes the application of CRCs as a means 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.

### ***How integrity of a process is measured***

8.8.23 Having in consideration the recognized 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.

**Figure 8-1. Aeronautical data chain**

**Figure 8-2. Generic process diagram**

**Figure 8-3. AIM related processes**

**Figure 8-4. Aeronautical data processing model**

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## Chapter 9

### SMS AND QMS

#### 9.1 INTRODUCTION TO SMS

9.1.1 Safety management system is a systematic approach of managing safety, including the necessary organizational structures, accountabilities, policies and procedures.

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

#### 9.2 RELATIONSHIP BETWEEN SMS AND QMS

9.2.1 Both SMS and QMS achieve the overall organization goals, and in particular, the organization’s safety goals through a management system, (i.e., policies, objectives, organizational structure, procedures, monitoring and the improvements of organizational management.)

9.2.2 A QMS provides basic assurance for the management of quality by means of a process method-PDCA (2.6.1 refers). The SMS provides further assurance for operation quality by identifying , preventing and controlling the safety hazards existing in an operation.

9.2.3 QMS cannot, by itself, as proposed by quality dogma, “assure safety”. Because a QMS does not contain the function of identifying (and therefore controlling) safety risks which are inevitable during operations complying with QMS, it cannot positively prevent accidents beforehand and assure safety. It is the integration of SMS into QMS that enhances the possibility of achieving safety goals significantly.

9.2.4 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 organization’s safety goals.

9.2.5 QMS provides a structured and standardized approach for processes and procedures, enabling the SMS to identify hazards and keep safety risks under control. The relationship therefore allows the SMS to operate as planned and make improvements when a deviation occurred.

#### 9.3 INTEGRATION PRINCIPLE AND METHOD OF QMS AND SMS

9.3.1 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 and improvement, consequently, the management goals will be upgraded from "stable quality" to "assured safety".

***QMS as the basis of SMS***

9.3.2 The implementation of a QMS can greatly reduce the potential problems and risks in operations. Without a 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.

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

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## Appendix A

### CHECKLIST FOR THE DEVELOPMENT OF A QMS FOR AIM

#### 1. PROGRAMME INITIATION

<i>Item</i>	<i>Senior management</i>
1.	Commitment by senior management
2.	Briefing/seminar/workshop to familiarize 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 manager
7.	Appoint a quality manager
8.	Arrange for ISO training of the quality manager

#### 2. PLANNING PHASE

##### 2.1 Project implementation team

<i>Item</i>	<i>Quality manager</i>
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

## 2.2 Gap analysis

<i>Item</i>	<i>Quality manager (with the assistance of the project implementation team)</i>
1.	List the functional groups of AIM and its organizational structure. Show how the organizational 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.

## 2.3 Completion of planning items and project proposal

<i>Item</i>	<i>Quality manager (with the assistance of the project implementation team)</i>
1.	Determine the deliverables for the QMS project.
2.	Develop a schedule of target dates
3.	Draw up a list of resources required
	Internal resources
	External resources
	Other costs
4.	Complete the project proposal to senior management

**2.3 Approval of the implementation project**

<i>Item</i>	<i>Senior management</i>
1.	Review project proposal with the quality manager
2.	Approve the implementation project as proposed or negotiate changes.
3.	Commit the resources necessary to carry out the implementation project as approved.

**3. DESIGN PHASE****3.1 Development of procedures and documentation**

<i>Item</i>	<i>Quality manager (with the assistance of the project implementation team)</i>
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.

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## **Appendix B**

### **TEMPLATE OF A QUALITY MANUAL TO BE USED BY AN AIM ORGANIZATION**

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 (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 SERVICES  
(AIS)**

**NAME OF STATE**



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## 1. INTRODUCTION

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

Furthermore, it is recommended in Annex 15 that the quality system be in conformity with the International Organization for Standardization (ISO) 9000 series of quality assurance standards and that it be certified by an approved organization.

## 2. OBJECTIVE

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

## 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 organizational relationships;
- b) the processes involved;
- c) the requirements;

- d) the necessary procedures to effect the processes identified and fulfill the requirements;
- e) the duties and responsibilities and the associated skills and competencies required; and
- 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; and
- 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.

<i>Document type</i>	<i>Information planning</i>	<i>Content development</i>	<i>Implementation</i>	<i>Evaluation and review</i>	<i>Revision</i>	<i>Work days</i>	<i>Target dates</i>
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.

<i>Project implementation team</i>			
<i>Name</i>	<i>Role</i>	<i>Skills/department represented</i>	<i>Estimated effort required</i>
	Quality manager/ Project implementation team leader		Work days, 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.

<i>Internal effort</i>	
<i>Task</i>	<i>Estimated effort (work days)</i>
Process analysis	
Procedures development	
Documentation development	
Documentation control and other records	
QMS training	
Internal auditor training	
etc.	

**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.

<i>External effort</i>		
<i>Task</i>	<i>Estimated effort (work days)</i>	<i>Cost</i>
Interpretation of requirement against standard ISO 9001:2008		
QMS awareness training		
Internal auditor training		
Pre-registration audit		
etc.		

**Other support costs**

<i>Other support costs</i>		
<i>Item</i>	<i>Purpose</i>	<i>Cost</i>
Software	Document control, text processing, etc.	
Hardware	Upgrading of database, networking, etc.	
ISO registration fee	Professional registration of QMS by independent agency	
etc.		

**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
- etc.

**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 xxxx — *Manual on the Quality Management System for Aeronautical Information Services*
10. ISO 9001:2008 — *QMS — Requirements*

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

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## **Appendix C**

### **SAMPLES OF QUALITY MANUAL**

*(To be developed.)*

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## Appendix D

### SAMPLE OF A CERTIFICATION/REGISTRATION AUDIT

#### 1. EXAMPLE OF PROCEDURE FOR ISO 9000 SERIES CERTIFICATION

< Insert name of Organization >	
DIRECTORATE:<Insert name>	DOC NO. <Insert Doc number>
SUBJECT: <Insert the subject: being addressed by the procedure> e.g. IAIP MANAGEMENT	ISSUE: REV: DATE:

#### Record of change

NO.	DETAILS OF CHANGE	DATE
1		
2		

#### Circulation

This procedure is issued on controlled basis to:

NAME <Insert Office name>	DEPARTMENT <Insert department name>	NO. <Insert copy number>

#### Name and copy number

ISSUED BY <insert title of Head of AIM>	APPROVED BY
SIGNATURE	SIGNATURE
DATE	DATE

## 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 IAIP that includes:

- AIP including amendment services;
- supplements to the AIP;
- AIC;
- NOTAM;
- 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 (CAP 394)*

*Procedures for Air Navigation Services — ICAO Abbreviation and Codes* (ICAO PANS-ABC, Doc 8400)

*Location Indicators* (ICAO Doc 7910)

*Designators for Aircraft Operating Agencies, Aeronautical Authorities and Services* (ICAO Doc 8585)

*Aircraft Type Designators* (ICAO Doc 8643)

Clearance records

#### 4.0 Terminology

**Data.** A collection of facts from which conclusions may be drawn.

**Format.** The acceptable wordings page numbering or form.

**Integrated aeronautical information package (IAIP).** AIP including amendment services, supplements to the AIP, AIC, NOTAM, pre-flight bulletins (PIBs) 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 AIM.** An officer designated as the head of an AIM unit (e.g. head of NOF, head of AIS aerodrome unit or head of AIP/MAP unit).

**AIM Manual of Operations.** An operations manual containing processes and procedures to be AIM followed when performing AIM functions.

#### 4.1 Abbreviations

AIC	Aeronautical information circular
NOTAM	Notice(s) to Airmen
AIP	Aeronautical information publication
AIP SUPP	Supplements to the AIP
NOF	International NOTAM office
AIRAC	Aeronautical information rules and control
FIR	Flight information region
DAIO	Duty aeronautical information officer

#### 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 in-charge 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 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.

6.1.3 When processing the applicable IAIP element, DAIO shall follow processes and procedures as published in Chapter..... of the *Manual of AIM Operations*.

6.1.4 Data capture during processing of elements of IAIP shall be as detailed in Chapter..... of the *Manual of AIM Operations*.

6.1.5 Validation of data shall be as per the processes and procedures provided in Chapter..... of the *Manual of AIM Operations*.

6.1.6 The publications resulting from 6.1.1 to 6.1.5 shall be stored in both electronic and paper form as detailed in Chapter..... of the *Manual of AIM Operations*.

6.1.7 Distribution and dissemination of the publications resulting from 6.1.1 to 6.1.5 shall be as detailed in Chapter..... of the *Manual of AIM Operations*.

**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:

- a) statement of existence of fundamental (essential) non-conformities/absence of undertaken work organization system elements, management system – also if it includes initiated quality system elements, that are convergent or compatible (conformable) with requirements that are specified in ISO 9001:2000 standard;
- b) ascertaining of initiated yet quality system elements efficacy from the organization's purpose point of view;
- c) enable audited organization to improve existing quality system;
- d) quality requirements fulfillment confirmation, requirements that are result of relative regulations.
- e) to state do the procedures, documents and other information referring quality are well known, available, clear (intelligible, comprehensible) and in use by organization's staff.
- f) to state do the documents and other information describing adopted in the organization quality system are proper to achieve (attain) planned quality goals (aims, purpose, objectives).

2.2 Diagnostic audit does not play the part of "supervision" or "inspection", activities directed to process controlling or product acceptance (of maintenance or service).

2.3 One took estimation criterion that is result of fact, quality system, that shall be initiated (entered) inside organization will be extended (enlarged) as much, as it is necessary to achieve quality goals.

2.4 Quality audit does not lead to widen (enlarge) the scope of activities referring quality in excess of these, that are necessary for quality goals and are defined in Annex 15.

2.5 Requirements that refer to:

- the goals and the scope of audit;
- identification of persons responsible for the sphere connected with the scope of audit;
- identification of relative documents;
- date and place of audit's realization;
- identification of divisions that are included in audit, that come within audit;
- beginning time and the time of audit duration (length of time)|
- meeting's timetable;
- confidentiality; and
- audit rapport distribution index;

have been introduced to and agreed (adjusted) with representatives of organization.

2.6 Because of safety aspect, which is essential for AIS, additionally in audit documents one introduces below mentioned qualification criteria for non-conformities. This way one limits, consciously, the requirements that are described in ISO 10011-1, 10011-2, 10011-3 standards.

- a) non-conformity of the first grade (critical) — system non-conformity present in process description or non-conformity that has got direct, negative influence for air safety (e.g. false data published in AIP or in NOTAM, lack of information or improper graphic symbol used in the chart);
- b) non-conformity of the second grade ( important ) — obvious non-conformity, but having no direct, negative influence for the interpretation of published data (e.g. lack of information about the level of access to the published instructions;
- c) non-conformity of the third grade ( minor, insignificant ) — non-conformity, that has no or very small influence for safety (e.g. orthographic mistake in the instruction, having no influence for explicit (unmistakable) understanding of the record).

2.7 During the audit, auditor performs initial estimation of identified non-conformity and agrees this estimation with leading auditor. Non-conformity of the first grade requires immediate reaction of the personnel who is responsible for the process, which non-conformity was detected in. Non-conformity of the second grade should be removed as soon as possible. Non-conformity of the third grade is the information's nature non-conformity( notice).



**3. DIAGNOSTIC AUDIT SCHEDULE**

Audited organization (Auditee):	Organization's manager:
Opening meeting date:	Closing meeting date:
Leading auditor (audit team leader): ( if applicable	Audit team:

Date	Audit progress	Place of audit	Responsible person (organization)
	<ol style="list-style-type: none"> <li>1) Initiation meeting.</li> <li>2) Audit team presentation.</li> <li>3) Presentation of audit goals, audit sphere and methodology.</li> <li>4) Working up questionnaire of supervision.</li> <li>5) Presentation of questionnaire of supervision to organization's representatives.</li> <li>6) Realization of diagnostic audit in the organization, making use of requirements included in the standards:                             <ul style="list-style-type: none"> <li>— PN-ISO 9001:2000; and</li> <li>— PN-ISO 10011-1,2,3:1994 (auxiliary).</li> </ul> </li> <li>7) Working up the outcome of audit.</li> <li>8) Presentation the results of audit to the management of organization.</li> <li>9) Acceptance of corrective action proposal (if applicable).</li> <li>10) Determination of the date of meeting, which purpose is stating of initiation effects end effectiveness of undertaken corrective action (if applicable).</li> </ol>		

Auditor ..... Organization's representative .....

## 4. AIS INTERNAL DIAGNOSTIC AUDIT

Item	Subject	Questions	Answers	
			Yes	No
1.	ACTIVITY PRINCIPLES: LEGAL AND FORMAL	<p>Does the management and personnel of AIS know legal and formal basis of AIS activity? Is it:</p> <p>a) ICAO Annex 15 — <i>Aeronautical Information Services</i>;</p> <p>b) <i>Air Information Service Instruction IL-15</i>;</p> <p>c) ICAO Doc 9376 — <i>Preparation of an Operations Manual</i>;</p> <p>d) ICAO Doc 9401 — <i>Manual on Establishment and Operation of Aviation Training Centres</i>;</p> <p>e) ICAO Doc 9774 — <i>Manual on Certification of Aerodromes</i>.</p>		
2.		<p>Has the organization established in an adequate way:</p> <p>a) organization's structure;</p> <p>b) model of requirements, that refer to employee on her/his stand;</p> <p>c) the way of managing/planning;</p> <p>d) the way of competence and responsibility granting;</p> <p>e) the way of taking (assuming)/handing over tasks, procedures and the times of adaptation;</p> <p>f) levels and criterions of access to data;</p> <p>g) information flow;</p> <p>h) principles of internal communication (Have they been published?);</p> <p>i) the levels of operational, technical and organizational decision giving;</p> <p>j) substitution system on continuous work stands; and</p> <p>k) responsibility levels on the stands.</p>		

Item	Subject	Questions	Answers	
			Yes	No
3.	SUPERVISION PROCEDURES	<p>Has the organization established in an adequate way:</p> <ul style="list-style-type: none"> <li>a) main and accessory (auxiliary) processes (validated)supervision system;</li> <li>b) valid (obligatory) documentation supervision system;</li> <li>c) process supervision monitoring map;</li> <li>d) supervising processes checklists; and</li> <li>e) methodology and practice of supervision the entering and the evidence of corrective action.</li> </ul>		
4.	AIS STAFF	<p>Has the organization established/defined in an adequate way:</p> <ul style="list-style-type: none"> <li>a) staff composition adequately to the needs and requirements;</li> <li>b) conditions, that employees have to fulfil in accordance (compliance) with stands requirements;</li> <li>c) main and accessory (auxiliary) processes leaders; and</li> <li>d) qualifications (including minimum requirements) in accordance (compliance) with stands requirements including : <ul style="list-style-type: none"> <li>1) the way of obtaining;</li> <li>2) the way of confirmation;</li> <li>3) the way of evidencing;</li> <li>4) the way of renewal;</li> <li>5) the way of actualization; and</li> <li>6) the way of invalidation/suspension.</li> </ul> </li> </ul>		
5.	AIS WORK ENVIRONMENT	<p>Has the organization established/defined in an adequate way:</p> <ul style="list-style-type: none"> <li>a) work environment in AIS;</li> <li>b) work environment in the divisions that cooperate with AIS; and</li> <li>c) who is the customer and what are the categories/kinds of customers.</li> </ul>		

Item	Subject	Questions	Answers	
			Yes	No
6.	PLANNING IN AIS	<p>Has the organization established/defined In an adequate way:</p> <ul style="list-style-type: none"> <li>a) work planning in AIS;</li> <li>b) work planning in divisions that cooperate with AIS;</li> <li>c) planned system of turning the requirements to the customer;</li> <li>d) planned fixing (pointing out, stating, naming) measurable quality objectives in the meaning of ISO 9001:2001 standard;</li> <li>e) quality objectives in the meaning of ISO 9001:2000 standard;</li> <li>f) customer requirements (resulted from standards, regulations, recommended practice and specifics of customer);</li> <li>g) management of processes (validated), main and accessory (auxiliary) processes on the adequate decision level, with data access at the same time; and</li> <li>h) vertical and horizontal way of information flow and the way of planning that does not slow down, does not garble and does not disturb process realization.</li> </ul>		
7.	METHODS OF AIS PROCESS	<p>Has the organization established/defined in an adequate way:</p> <ul style="list-style-type: none"> <li>a) the need for consciousness of process approach referring to quality management for AIS needs;</li> <li>b) the way of understanding of validated processes (main and auxiliary);</li> <li>c) processes (validated ) main;</li> <li>d) support processes (auxiliary;</li> <li>e) another not defined processes ( refers to process identification); and</li> <li>f) quality system management as a special nature validated process.</li> </ul>		

Item	Subject	Questions	Answers	
			Yes	No
8.	EVIDENCE OF AIS QUALIFIED PROCESSES: TECHNICAL, OPERATIONAL AND ORGANIZATIONAL	<p>Has the organization established/defined in an adequate way:</p> <ul style="list-style-type: none"> <li>a) main, validated processes specification and map;</li> <li>b) specification of documents that describe main processes;</li> <li>c) main processes evidence standardisation; and</li> <li>d) administration of original documents that describe main processes.</li> </ul>		
9.	EVIDENCE OF AIS AUXILIARY PROCESSES	<p>Has the organization established/defined in an adequate way:</p> <ul style="list-style-type: none"> <li>a) auxiliary processes specification and map;</li> <li>b) specification of documents that describe auxiliary processes;</li> <li>c) auxiliary processes evidence standardisation;</li> <li>d) administration of original documents that describe auxiliary processes.</li> </ul>		
10.	REALIZATION CONDITIONS OF MAIN PROCESSES IN AIS	<p>Has the organization established/defined (keep hold if reasonable) in an adequate way:</p> <ul style="list-style-type: none"> <li>a) stability, repeatability, adequacy of processes;</li> <li>b) information about processes course (run, progress);</li> <li>c) process compactness on the beginning and on the end of process;</li> <li>d) methodology of validated process realization;</li> <li>e) the way of data gaining;</li> <li>f) times of reaction, both own and receiver's (customer's);</li> <li>g) „data filtration” processes in each stage of process realization;</li> <li>h) permissible information modification ranges;</li> <li>i) data transit , including cross-reff. matrixes;</li> <li>j) process/system double ting (multiplication);</li> <li>k) non-failure operation procedures;</li> </ul>		

Item	Subject	Questions	Answers	
			Yes	No
		l) process synchronization in stable and dynamic unstable in time conditions; and  m) procedures actualization in accordance with specific regulations requirements, SARPs and customer requirements.		
11.	UNUSUAL CONDITIONS (STATES)	Has the organization established/defined in an adequate way:  a) non-procedural events;  b) unstable states;  c) critical states;  d) special or unique cases;  e) threat (imminence) map;  f) occurrences of misfortune event series or states; and  g) occurrences of so-called "unfavourable events wave self extinguishing".		
12.	CRITICAL (CENSORIOUS) ANALYSIS AIR INFORMATION SYSTEM	Does the organization take into consideration, define and/or bring into practice in an adequate way:  a) process simulation before initiation;  b) sampling as a system supervision model;  c) staff consciousness estimation that refers process management in AIS, in the meaning of process identification and existence of their mutual dependence;  d) risk estimation of basic processes work;  e) adequacy and ergonomics of information (ais product) analysis in the aspect of pilots expectations and other information receivers (customers);  f) time of repair, it means "restarting of API informatics system" and its answer about readiness to work after damage;  g) automatic action of system test procedures after one of its component (element) damage;		

Item	Subject	Questions	Answers	
			Yes	No
		<p>h) the way of proceeding after non-conforming service indication;</p> <p>g) methods of data gleaning (compiling) and customers satisfaction grade analysis.</p>		
13.	AIS TOOLING	<p>Has the organization defined/rendered accessible for use in an adequate way:</p> <p>a) AIS division tooling (Is the tooling adequate in the meaning of reliability and ergonomics to AIS tasks?); and</p> <p>b) Internal communication system.</p>		
14.	AIS (SUPPLIERS) PROVIDERS	<p>Has the organization identified and/or defined in an adequate way:</p> <p>a) purchase processes;</p> <p>b) qualifying and acknowledgement of supplier system;</p> <p>c) qualified supplier total (full) register;</p> <p>d) the rules of care for customer's and supplier's property;</p> <p>e) continuous monitoring and evidence of provided by purveyors product quality rule;</p> <p>f) activities undertaken in the case of mistakes statement in the process of product(s) providing by purveyors;</p> <p>g) products received from providers in the meaning of methodological identification according to ICAO, EUROCONTROL, aviation regulations (law) requirements, are they identified by AIS from the influence on rendered by AIS service quality point of view;</p> <p>h) is there a project (plan) of audit and periodic valuation of providers product's quality;</p> <p>i) does the range of providers quality audit include required topical areas.</p>		
15.	AIS QUALITY SYSTEM: GENERAL	<p>15.1) Is there a quality system established in the organization?</p> <p>15.2) Is there defined a scope (or area ) of quality system?</p>		

Item	Subject	Questions	Answers	
			Yes	No
		15.3) Is there so-called quality policy defined in the organization?		
		15.4) Is there a evidenced quality policy declaration? (Does evidenced quality policy declaration exist?)		
		15.5) Is there a quality manager or managing director's plenipotentiary for quality affairs appointed?		
		15.6) Is there established in the organization a person, who is responsible for quality documentation supervision?		
		15.7) Does organization's quality manual exist? Is there existing quality manual?		
		15.8) Are there existing in the organization other describing quality system documents (documents conformable to, compatible with, in accordance with) that correspond to PN-EN ISO 9001:2000 standard?		
		15.9) Are there existing in the organization quality system inspection procedures?		
		15.10) Has it been established in the organization, who is responsible (answers) for working out, actualization and distribution of quality manual and other quality documents?		
		15.11) Have the documents (including quality ones) got explicitly defined: actualization, distribution and originals management status?		
		15.12) Do the documents, that has been filled in (including quality ones) in accordance to organization's internal prescriptions and their status, include suitable limitations subsequent to data confidence or data level of access?		
		15.13) Has it been defined in the organization, who supervises records in AIS publications?		
		15.14) Is it defined (is there a procedure) how one should proceed with out-of-date and inadequate documents?		
		15.15) Has it been defined in the organization the responsibility of management that refers to the following quality requirements:		



Item	Subject	Questions	Answers	
			Yes	No
		<ul style="list-style-type: none"> <li>a) management commitment;</li> <li>b) customer focus and compliance with adequate regulations requirements;</li> <li>c) quality policy;</li> <li>d) responsibility, authorization (competence), and communication;</li> <li>e) management representative;</li> <li>f) management review;</li> <li>g) provision of resources?</li> </ul> <p>15.16) Is there a stable product (in AIS information) realization planning model in the organization?</p> <p>15.17) Are input, complementary and output data identified, verified and authorized in respect of aviation safety (in the bearing of AIS tasks)?</p> <p>15.18) Product realization process, is it:</p> <ul style="list-style-type: none"> <li>a) stable during reception, processing (transformation) transmission, complementation and modification time;</li> <li>b) foreseeable, repeatable (reproducible);</li> <li>c) adequate to regulation's and customer's requirements</li> <li>d) compact on income and outcome?</li> </ul> <p>15.19) Does product realization process on simulation stage not bring imminences in the bearing of air traffic safety?</p> <p>15.20) Staff task during product realization (AIS information), are they univocally determined, realized and supervised in stable and nonprocedural conditions?</p> <p>15.21) Is there storage/archives keeping system of AIS information (AIS product)?</p>		

Item	Subject	Questions	Answers	
			Yes	No
		15.22) Are AIS products able to identify for all the people, who are interested in this products?		
		15.23) Are the products (AIS information) able to identify according to ICAO, EUROCONTROL, aviation law regulations requirements, are they able to identify for receivers;		
		15.24) Are internal quality audits carried out in the organization?		
		15.25) Is there an organization's quality audits plan?		
		15.26) Does quality audits range include required thematic (topical) area (space)?		
		15.27) Are there internal quality auditors in the organization (first side)?		
		15.28) Are there second side quality auditors in the organization?		
		15.29) Audit conclusions, are they the subject of analysis of managing board?		
		15.30) Are there a corrective and preventive actions carried on in the bearing of executed (realized) audits?		
		15.31) Does product quality continuous monitoring principle exist in the organization?		
		15.32) Are monitoring and/or product tests designed?		
		15.33) Are there product measurement , analysis and improvement criterions?		
		15.34) Is there formally ratified (approved) and described non-conforming product (AIS information) supervision system?		
		15.35) Have been defined activities, that are undertaken in the case of product (AIS information) creation process or product attendance mistakes statement?		
		15.36) Is there product unblocking system ( information flow continuity in real time?		

Item	Subject	Questions	Answers	
			Yes	No
16.	AIS QUALITY SYSTEM ACCORDING TO IL-15 INSTRUCTION REQUIREMENTS	<p>16.1) Are AIS information published in the name of State;?</p> <p>16.2) Do accumulated and published air information originate from other countries government offices or other available sources?</p> <p>16.3) Air information received from above mentioned sources, are they checked before propagation (dissemination)?</p> <p>16.4) Is there a reservation for customer that information haven't been verified in the case that a.m. information are not checked?</p> <p>16.5) Is there air information accessibility assured in the places it is required, among others air operation staff, flight planning staff, flight information service?</p> <p>16.6) Does air information office receive and/or prepare and publish information in the AIP?</p> <p>16.7) Is air information service's quality management ensured, where it is necessary?</p> <p>16.8) Skills and knowledge of AIS staff on every work stand, are they defined, is the staff properly trained?</p> <p>16.9) Is it defined the organ (office), which ensures that AIS staff has got proper skills and competence for compactly explicit functions realization and the records ,that evidence a.m. skills and competences, are stored according to determined rules;?</p> <p>16.10) Is staff verification going on designed way and has got function of initial (introductory)and periodically verification?</p> <p>16.11) Is there a possibility to make a thorough study of air information at every stage of information processing, starting at the information sources through all the stages to publication system and out-of-date information withdrawal?</p> <p>16.12) Precision, differentiation and compactness (cohesion) – are they AIS information attributes?</p> <p>16.13) Does information propagation system work with proper advance (lead)?</p>		

Item	Subject	Questions	Answers	
			Yes	No
		16.14) Does precision of published air data perform the criterion of 95% level of probability?		
		16.15) Does one differentiate three kinds of positioning data: measured points, localization of radio navigation aids and points calculated by using other, known measuring points?		
		16.16) Is air data compactness in whole the range of processing ensured?		
		16.17) Is the level of compactness $1 \times 10^{-8}$ for critical data, $1 \times 10^{-5}$ for important data and $1 \times 10^{-3}$ for usual data?		
		16.18) During digital air data storage or export, Is the data protected by redundant control cycles (courses, series, rounds, periods)(32 or 24-bit algorithm)?		
		16.19) Do adequate AIS divisions check the material, that is a part of AIP, according to ICAO Doc 8126 regulations before this material delivery (transmission) [delivery of this material?]?		
		16.20) Are possibly noticed non-conformities evidenced and recorded?		
		16.21) Does the organization apply to recommended methods, that are enfolded in WGS – Doc. 9674, RTCA DO 201A, of air information compiling, processing and publishing?		
		16.22) Has the organization assigned an office, where all the AIP pieces from foreign countries would be directed to?		
		16.23) Do AIS organize NOTAM publication and receipt?		
		16.24) Has it been published the register of the countries, that International NOTAM Office exchanges above mentioned documents with?		
		16.25) Does it exist and is it available, the adequate (suitable) NOTAM information dedication places register?		
		16.26) Are AIS products protected by the law?		

Item	Subject	Questions	Answers	
			Yes	No
		<p>16.27) Are pieces of AIP published in Polish and English?</p> <p>16.28) Are the names of places (localities) in Poland published in full form in above mentioned language versions?</p> <p>16.29) The measure units, that are in use in published air information, are they compatible with ICAO convention's tables?</p> <p>16.30) Are published geographical co-ordinates consistent with WGS-84 geodetic reference system?</p> <p>16.31) Are reference coordinates, that calculation precision doesn't perform suitable regulations, signed with asterisk (pip)?</p> <p>16.32) Are the abbreviations, that are in use in AIS publications, in accordance with ICAO recommendations?</p> <p>16.33) Does AIS take so called human factor influence into consideration during AIS information transformation and distribution process?</p> <p>16.34) Are applied forms, used for information storage, processing, dispatch and publication, adequate and explicitly dedicated in the meaning of application nature?</p>		
17.	ACHIEVEMENT (REALIZATION)	<p>17.1 Does organization supervise, in a methodical (systematic) way, competence (authorization), qualifications and licence, premises and practice annotations validity of AIS staff?</p> <p>17.2 Do employed technical staff work full time?</p> <p>17.3 Does one check organization's staff theory and practice skills regularly checked within the organization's own training and supervision structure?</p> <p>17.4 Does one check organization's staff untypical knowledge and skills (if applicable)?</p>		

Item	Subject	Questions	Answers	
			Yes	No
		17.5 Does the organization ensure specialist training for personnel and supervising staff for continuous actualization of knowledge and skills taking into consideration that AIS works in an international aviation net?		
		17.6 Has the organization got properly (suitably) authorized ( by aviation authorities for example) commonly available AIS staff training programs (or equivalent programs)?		
		17.7 Has the organization got separate (it's own, internal) training and supervision programs?		
		17.8 Has the organization got authorized by aviation authority personnel knowledge and skills check documents form (pattern)?		
		17.9 Has the staff been trained in quality problems (issues), quality training?		
		17.10 Is the training projected in the bearing of modifying requirements and needs?		
		17.11 Has the organizations staff been trained in the bearing of untypical events, threat (imminence), nonprocedural situations relevant to (connected with) tasks accomplishing by AIS?		
		17.12 Has the staff been trained in the bearing of labour legislation, fire protection and fighting, safety?		
		17.13 Is organization's staff informed or trained up to date in scope of accident preventive treatment (flight safety)?		
		17.14 Is organization's technical staff able to use (employ) procedural documentation or other proper (suitable, fit) for AIS documentation, that is published in foreign language (in the referring range)?		
		17.15 Has it been defined and published for organizations purpose the criteria and minima of staff language qualifications connected with foreign language procedure knowledge in the essential (imperative) range for safe and fluent AIS tasks?		

Item	Subject	Questions	Answers	
			Yes	No
18.	AIS BUDGET	18.1 Has it been established organization's budget on the way to ensure necessary for fluent AIS work (in stable and non-procedural conditions, also in the cases of fate work disturbances) outlays?		
		18.2 Has it been provided the funds for relations, international and domestic training, required documentation and professional references purchase, documentation translation (if necessary)?		
		18.3 Has it been provided the funds for technical-organizational progress in AIS?		

**5. NON-CONFORMITIES REPORT**

<i>Worked out by</i>	<i>Agreed: quality manager</i>	<i>Organization's representative</i>
..... signature	..... signature	..... signature

**6. DIAGNOSTIC AUDIT REPORT**

<i>Item</i>	<i>Audit range/area (space)</i>	<i>Non-conformities amount</i>
1.	Activity principles: legal and formal	
2.	Work organization 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, organizational	
9.	Evidence of AIS auxiliary processes	
10.	Realization conditions of main processes in AIS	
11.	Untypical conditions (states)	
12.	Critical (censorious) analysis: air information system	
13.	AIS tooling	
14.	AIS (suppliers) providers	
15.	AIS quality system: general	
16.	AIS quality system according to IL-5 instruction requirements	
17.	AIS training	
18.	AIS budget	



## Appendix E

### SAMPLES OF TEMPLATES AND PLANNING QMS IMPLEMENTATION INTO AIM

#### 1. ASIA/PACIFIC REGION

1.1 The approach in this example consists of three stages:

- a) considering what happens in AIM;
- b) implementing a QMS; and
- c) improving the QMS.

CONSIDERING WHAT HAPPENS IN AIM	Step 1	Consider the business of AIM, i.e. the different flows of work through the organization and list them.
	Step 2	With this list in mind, decide if there are any “permissible exclusions” (refer to Standards Guidelines for details) that apply to the AIM. Remember that any exclusion will need to be justified in the Quality Manual.
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>i.e.</i> relevant to the business operations.
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 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.

<i>Step 1</i>	<i>Consider what your main business activities are and list them</i>
	<p>Those elements described in Annex 15 form the main business activities of AIM:</p> <ul style="list-style-type: none"> <li>— receive and/or originate;</li> <li>— collate or assemble;</li> <li>— edit;</li> <li>— format;</li> <li>— publish/store; and</li> <li>— distribute</li> </ul> <p>aeronautical information/data</p>
<i>Step 2</i>	<i>With this list of main business activities, determine if any of the activities require you to do design work</i>
	<p>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.</p> <p>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.</p> <p>The purpose of setting activities out in this way is to identify:</p> <ul style="list-style-type: none"> <li>— the different components of the AIM and decide if they all fit together, or if changes are required to make the whole process work better; and</li> <li>— where and if the elements of the standard are covered.</li> </ul>
<i>Step 3</i>	<i>Get people involved by writing down what their jobs cover</i>
	<p>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:</p> <ul style="list-style-type: none"> <li>— who is responsible for performing and checking activities;</li> <li>— where the activity takes place;</li> <li>— when it will happen; and</li> <li>— what happens, that is, how the activity is performed.</li> </ul> <p>Some important points you will need to think about are:</p> <ul style="list-style-type: none"> <li>— As the job is being carried out by a specialist, you will only need to reference the type of person and the qualifications?</li> </ul>

	<ul style="list-style-type: none"> <li>— If, the work is done by non-specialist staff, or there are specific in-house requirements, more detail may be required?</li> <li>— The sequence of the activities may still need to be defined, for example:             <ul style="list-style-type: none"> <li>a) how a job is initiated;</li> <li>b) how the work gets started;</li> <li>c) who monitors the progress;</li> <li>d) how the work is processed and inspected;</li> <li>e) who decides when the work is finished;</li> <li>f) how delivery is made;</li> <li>g) what follow up action is needed and who does it; and</li> <li>h) what records are kept and who keeps them.</li> </ul> </li> </ul> <p>If your organization 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.</p> <p>Most important: Keep written documentation simple.</p>
<p><i>Step 4</i></p>	<p><i>Collate this in sequences relevant to the list of business activities (Step 1)</i></p>
	<p>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:</p> <ul style="list-style-type: none"> <li>— look at what has been written;</li> <li>— satisfy yourself that it all fits together; and</li> <li>— deal with any gaps or inconsistencies.</li> </ul> <p>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.</p> <p>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.</p>

Step 5	<i>Identify where the standards and this list of your business activities link together</i>
	<p>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:</p> <ul style="list-style-type: none"> <li>— the requirements of the standard; and</li> <li>— the process control requirements.</li> </ul> <p>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 the aim.</p> <p>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.</p>
Step 6	<i>Apply the standard and the QMS</i>
	<p>If you continue to involve others in your organization, 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:</p> <ul style="list-style-type: none"> <li>— Do 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.</li> <li>— 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.</li> <li>— Remember, keep a record when: <ul style="list-style-type: none"> <li>a) a problem arises;</li> <li>b) a good suggestion is raised; or</li> <li>c) a customer or employee expresses a need for action.</li> </ul> </li> <li>— To implement the QMS, everybody needs to 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.</li> <li>— 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.</li> </ul>

<i>Step 7</i>	<i>Keep the QMS simple, functional and relevant to the business operations</i>
	<p>The following points are worth noting:</p> <ul style="list-style-type: none"> <li>— The purpose of implementing a QMS is to ensure that the business activities of the aim are operating in a controlled manner and the people responsible for the various activities know and understand their roles and responsibilities.</li> <li>— 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.</li> <li>— Documentation should be in a format that is easily used in the organization. For example: <ul style="list-style-type: none"> <li>a) if computers are available, it may be easier to have a computerised system, rather than a paper system; and</li> <li>b) where there may be language or other differences in the workforce, it may be necessary to use pictures or several translations of the documents.</li> </ul> </li> <li>— 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.</li> </ul>
<i>Step 8</i>	<i>Consider the feedback of information from the QMS to lead to improvement in ideas and activities</i>
	<p>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.</p> <p>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.</p> <p>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.</p>
<i>Step 9</i>	<i>Monitor and measure the changes so you know what you have gained</i>
	<p>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.</p> <p>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.</p>

## 2. EUROPEAN 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 unit, the aim being to register for compliance against the ISO 9002 standard.

### 2.2 Document structure

<i>Content</i>	<i>Purpose</i>
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 quality assurance 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

2.3.1 By following the document in sequential order the essential elements of the implementation process will be addressed.

2.3.2 The approach overview serves two purposes:

- a) provides a breakdown of the main tasks; and
- b) can be used as a primary checklist.

2.3.3 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).

2.3.4 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.

2.3.5 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.

2.3.6 The final section contains a number of example documents from QMS. Again these items can be modified by the user by using the accompanying electronic files.

## 2.4 Electronic version of this document

2.4.1 This document is also provided in electronic form on an accompanying diskette:

File name: Planning Outline for QA Implementation.doc

File name: Generic AIS QA Project.mpp

### **Hidden Text**

2.4.2 The text highlighted in blue italics within the electronic document is "hidden" text. Be aware that the visibility of the hidden text will be dependent on the tools menu default setting in the configuration of MS Word on the PC being used to read the file. There are two options:

- a) to see hidden text on the screen use the following MS WORD menu selection: tools, options, view and tick the appropriate box; or
- b) to include hidden text in the printed document use the following MS WORD menu selection: tools, options.

2.4.3 Guidance and further explanatory comments have been added to many of the points in the planning document. These comments have been formatted as "hidden text " so that the document can be printed as a template of checklists without the explanatory material, if necessary.

### **Document navigation**

2.4.4 External links within the document provide additional functionality in accessing the supporting project plan file which the user can tailor to the requirement. These links and other internal navigation links are identified by red italics and have also been formatted as hidden text.

*Note.— In order to preserve embedded external links within this document when copying the "Planning outline for QA implementation" file to another directory, ensure that the following files are also copied to the same location: Generic AIS QA Project.mpp (Project plan Gantt chart requires MS PROJECT 98) and Inventory State Procedures.doc*

**2.5 Approach overview**

<i>Phase</i>	<i>Initial planning checklist</i>	<i>Check item</i>	<i>Sections</i>
PREPARATION	Establish project team, target dates and resources		
	Produce a high level proposal for management support.		
	Management decision to implement ISO 9002		
PLANNING	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 accompanying generic project plan Gantt chart ().			

**2.6 Preparation**

A basic plan is needed which provides a first appraisal of the current organization requirement, resources available and other resources needed. Use the following checklist to research information and then complete the proposal template in Section....



<i>Item</i>	<i>Programme initiation</i>	<i>Check Item</i>
1.	<p>Management support</p> <p>Who? It is recommended that the highest level of support be looked for.</p>	
2.	<p>Internal resources and budget</p> <p>The introduction of a quality system should not create new employment posts to be filled but may increase work responsibilities. Support for external consultancy will, however, be needed and budgetary provision required.</p>	
3.	<p>External support/effort needed</p> <p>Recommended in order to assist with correct interpretation and to ensure the internal team is kept on track for compliance. Consider the initial quality and internal auditor training.</p>	
4.	<p>Target date to be met for registration</p> <p>Defines a timescale for planning purposed, provides goals in the form of milestones for the project team and can also assist in continuing interest and support from senior management.</p>	
5.	<p>Scope</p> <p>1. Activity: Complexities of seeking registration with some operation s may not be apparent until analysis of the full requirement is made.'</p> <p>2. Location: In deciding the scope of the implementation, consideration must be given to those aspects of the operation that are not confined to one location.</p>	
6.	<p>Project leader and team</p> <p>Careful consideration needs to be given to the responsibility for coordination of the implementation. Define skills required including motivation for the programme and ability for good communication and relationship with all levels. Note that the project team assigned at this stage need not imply a fixed decision on responsibilities within the quality system. These roles have yet to be defined (e.g. the quality management representative at this stage may not necessarily continue with the role once the quality system has been implemented.</p>	
7.	<p>Resources</p> <p>Estimates of the time required by existing personnel should be made before estimating effort and costs of external support.</p>	
8.	<p>Contact with registration organizations</p> <p>It is not necessary at this stage to make a formal agreement regarding registration, however, information re costs and schedules for the registration assessment is needed for planning purposes.</p>	
9.	<p>Complete and submit QA Implementation Proposal</p>	
10	<p>Programme launch</p>	

**2.7 Planning quality assurance requirement phase****2.7.1 Determine department organization structure, roles and responsibilities**

<i>Item</i>	<i>Management organization structure</i>	<i>Check Item</i>
1.	<p>Prepare organizational perspective</p> <p>Although the quality system may only be confined to one unit or department of a larger organization, the relationship of the unit to the whole is of benefit to understanding certain processes and identifying responsibilities which may lie outside of the unit.</p>	
2.	<p>Unit structure</p> <p>Specific working/business groups probably already exist but need to be clearly defined in their roles and responsibilities. Identify inputs and outputs. Note that areas of responsibility may be more clearly defined by considering <i>what is not</i> the responsibility of a group in a particular functional area.</p>	
3.	<p>Personnel responsibilities</p> <p>Allocation of individual responsibilities in a working group including the value of all levels communicating non conformances and or potential improvements</p>	

**2.7.2 Determine documentation requirements and control processes (ref Documentation planning tool).**

<i>Item</i>	<i>Quality system documentation</i>	<i>Check Item</i>
1	Quality policy	
2.	Management organization	
3.	<p>Quality manual</p> <p>Decide on D.M.S.</p>	
4.	<p>Training records</p> <p>Quality training and skills training as relevant to the department services</p>	
5.	<p>Forms</p> <p>Complaint forms, check sheets, corrective actions</p>	
6.	<p>Document control process</p> <p>(ref. Example)</p>	

2.7.3 Identify procedures Requires preparation and assessment of the current operation to measure compliance of existing methods.)

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

2.7.4 System awareness programme

<i>Item</i>	<i>Quality awareness training</i>	<i>Check Item</i>
1.	<p>Generating quality awareness</p> <p>Whole department briefing on basic quality. Consideration should be given to the size of the group. It may be advisable to conduct separate courses.</p>	
2.	<p>System deployment briefing</p> <p>Once the quality system has been designed and documented it needs to be explained to the working units. This is best effected in small groups concentrating on those aspects relevant to their functional area.</p>	
3.	<p>Reviews and repeats</p> <p>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.</p>	

**2.8 Design phase**

## 2.8.1 Develop procedures

<i>Item</i>	<i>Process procedure development</i>	<i>Check Item</i>
1.	Procedure structure  Consistency is needed in the approach to detailing each procedure. (Example structure)	
2.	Amend existing procedures  Modify existing procedures according to analysis in ...	
3.	Develop new procedures  Documented procedures needed were identified in the gap assessment in 0....	
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).	

## 2.8.2 Training plan

<i>Item</i>	<i>Training plan</i>	<i>Check Item</i>
1.	Develop procedures for identifying training  Evaluate experience of staff e.g. such as for prerequisite qualification for specialized 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 (ref: Elements identified in 2.7.4)	

## 2.8.3 Internal auditing

<i>Item</i>	<i>Internal audits</i>	<i>Check Item</i>
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. (Ref. Example management review agenda)	

## 2.8.4 Corrective and preventive action

<i>Item</i>	<i>Corrective and preventive action</i>	<i>Check Item</i>
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

<i>Item</i>	<i>Control of quality records</i>	<i>Check Item</i>
1.	Develop procedures  Issues of formatting, review, approval, implementation, and change processes (ref: Example document management requirements). <b>Error! Reference source not found.</b>	
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

<i>Item</i>	<i>Quality system s deployment and validation</i>	<i>Check Item</i>
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**

<i>Item</i>	<i>ISO audit process</i>	<i>Check Item</i>
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	

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# Appendix F

## QUALITY AUDIT TOOL

### 1. OBJECTIVE AND PURPOSE

1.1 The objective of the Quality Audit Tool is to provide the States with a standardized means for assessing the conformance of their quality processes with internationally recognized ISO standards. The Quality Audit Tool integrates the ISO 9001:2008 requirements.

1.2 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.

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

### 2. MAIN FEATURES

2.1 The main features include the following:

- 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;
- organization 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 customized by users);



- quantitative (scorecard; response distribution by requirement type) and qualitative (by criticality and type) reporting features; and
- tool can be exploited for further audits after customisation (e.g. processes or documents).

### 3. TECHNICAL ASPECTS — INSTALLATION

3.1 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.

3.2 Files are provided on the Manual CD:

- *Installation Guide*;
- *Quick Start Guide*;
- *User Guide*
- *Administration Guide* (to support customization); and
- application files (to be developed).

*Note.— EUROCONTROL operates another version which can be deployed to audit the AIP structure and the CHAIN process criteria. This version is available on request.*

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## Appendix G

### SERVICE LEVEL AGREEMENTS

#### 1. BACKGROUND REF 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, arrangements shall be made 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...”

1.1 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 AIS. Such approach is best served through the utilization of SLAs.

1.2 Therefore, a comprehensive “SLA package” has been developed to support the establishment of agreements between data providers (originators) and AIS possibly under the umbrella of a regulator.

#### 2. WHAT IS AN SLA?

2.1 An 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.

2.2 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

An 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 fulfill 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 minimize 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.

**Customizable.** A package which can be tailored to the specific needs, operational/institutional environment and types of actors involved.

#### 4. ELEMENTS

The SLA guidance package (CD) 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 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 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 AIS 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 provided on the CD that accompanies this manual.*

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## Appendix H

# THE AIS DATA PROCESS (ADP) AND STATIC DATA PROCEDURES (SDPs)

### 1. INTRODUCTION

1.1 Of direct relevance to the quality management of aeronautical data is the ADP and its associated SDP.

1.2 The ADP and SDP were developed and applied by European States to drive the implementation of ISO 9001:2008 QMS in AIS. They established a set of harmonized guidelines representing AIS best practices for receipt, storage and publication of AIS static data. ADP and SDP also supported the development and implementation of the European AIS Database and are now integral part of the European AIS Database service provision.

1.3 These documents provide the generic process and supporting procedures covering the activities of a State AIS. While 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.

1.4 There are two main reasons for a State to implement SDPs in its local procedures, namely to:

- a) ensure harmonization, consistency and a common understanding based on the ADP; and
- b) comply with the ICAO requirement to establish a quality management process in Annex 15, 3.2.1.

### 2. THE ADP

2.1 The ADP describes which actions are carried out to produce the IAIP. The ADP provides the key document to the SDPs. 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 charts, representing the steps to be taken (i.e, inputs, outputs, activities or decisions). Supporting text is provided for each step that explains its rationale. Each step is allocated a unique number that may be used to identify it and provides a reference to the actual SDP that provides a more detailed description of the processing required.

2.2 The ADP covers all activities from the receipt of data within the AIS to its publication. The activities associated with the ADP is outlined in Figure H-1.

### 3. SDPs

3.1 SDPs relate to the ADP and detail how these actions are undertaken and traced. There are twenty-two 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 (SDP 0-19) can be fully understood. SDP/G provides information on how to customize and implement the SDP.

#### 4. LIST OF SDPs

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

*Note.— These documents are provided on the CD that accompanies this manual.*

#### 5. INITIAL STEPS FOR THE IMPLEMENTATION OF SDPs

5.1 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.

5.2 The following approach is proposed:

- a) read the ADP;
- b) gain a basic understanding of the SDP methodology by reading SDP/C;
- c) identify role allocations;
- d) work through the ADP and associated SDPs against your current working practices;
- e) produce a compliance table;
- f) customize the procedures as necessary by applying SDP/G; and
- g) create new procedures as required.

**Figure H-1. The AIS data process**



# Appendix I

## DIFFERENCES BETWEEN ISO 9001:2000 AND 2008

### 1. ISO-IAF JOINT PLAN

1.1 According to a joint announcement by the ISO and the IAF, the two organizations have agreed to an implementation plan for a smooth migration to ISO 9001:2008

- Certification of conformity to ISO 9001:2008 will only be issued after publication of ISO 9001:2008 (issued 15 November 2008) and after a routine surveillance audit or re-certification audit against ISO 9001:2008.
- One year after publication of ISO 9001:2008, all certifications issued (new certifications and re-certifications) must be to ISO 9001:2008.
- Two years after publication of ISO 9001:2008, existing ISO 9001:2000 certifications will not be valid.

1.2 This plan is possible, because ISO and IAF agreed that ISO 9001:2008 introduces no new requirements. The revised quality standard only introduces clarifications to the ISO 9001:2000 requirements, as well as changes to improve consistency with ISO 14001:2004, the environmental standard.

### 2. ISO 9001:2008 DIFFERENCES

2.1 The differences between ISO 9001:2008 and ISO 9001:2000 are described below. Deleted ISO 9001:2000 text is indicated by strikethroughs. New ISO 9001:2008 text is underlined.

2.2 Most of the text in ISO 9001:2000 has not been affected by ISO 9001:2008. Text from the standard is shown in here in boxes in italics.

#### 2.1 ISO 9001:2008 — Introduction

##### 0.1 General

2.1.1 In the Introduction, ISO 9001:2008 adds “organizational environment”, “change” and “risk” to the list of factors that influence the design and implementation of a QMS. The other changes to this text are minor revisions to the other factors, as well as the use of a bulleted list.

*The design and implementation of an organization's QMS is influenced by*

- *its organizational environment, change in that environment, and the risks associated with that environment,*
- *its varying needs,*
- *its particular objectives,*
- *the products it provides provided,*
- *the processes it employs employed, and*
- *its the size and organizational structure of the organization.*

2.1.2 Later in Section 0.1, ISO 9001:2008 changes "regulatory" to "statutory and regulatory" and clarifies that the customer, statutory, and regulatory requirements are those applicable to the product.

*This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory, and regulatory requirements applicable to the product, and the organization's own requirements.*

## **0.2 Process approach**

2.1.3 In the Process Approach section, ISO 9001:2008 switches from having to "identify" linked activities to "determine" linked activities. The section clarifies that a process can be an activity or set of activities.

*For an organization to function effectively, it has to ~~identify~~ determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process.*

2.1.4 Also in this section, the definition of the Process Approach has been clarified by adding "to produce the desired outcome" to the text below:

*The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".*

## **0.3 Relationship with ISO 9004**

2.1.5 The planned revision to ISO 9004:2000 is expected in 2009 with extensive changes, including a new clause structure that no longer matches that of ISO 9001.

2.1.6 As a result, ISO 9001:2008 no longer refers to the two standards as having, "similar structures in order to assist their application as a consistent pair." The title of the revamped ISO 9004 is expected to be "*Managing for the Sustained Success of an Organization — A Quality Management Approach*."

*~~The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of~~ are QMS standards which have been designed to complement each other, but can also be used independently. ~~Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.~~*



2.1.7 ISO 9001:2008 adds a Note about the upcoming revision to ISO 9004.

*NOTE: At the time of the publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory, or contractual use.*

#### 0.4 Compatibility with other management systems

2.1.8 The change at this section is to refer to ISO 14001:2004 instead of ISO 14001:1996, and to refer to the appendix that compares the clauses of ISO 9001:2008 to the clauses of ISO 14001:2004.

*This International Standard has been aligned with ISO 14001:1996 in order. During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.*

## 2.2 ISO 9001:2008 — Scope

### 1. Scope, 1.1 General

2.2.1 This section still explains that ISO 9001 specifies requirements for a QMS. It refers to the product as meeting customer and applicable "regulatory" requirements, as well as, enhancing customer satisfaction by assuring conformity to customer and applicable "regulatory" requirements. ISO 9001:2008 has expanded the uses of "regulatory" to "statutory and regulatory".

- a) *needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and*
- b) *aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.*

2.2.2 The note in the General Section used to say the term "product" applied only to the product intended for, or required by, a customer. ISO 9001:2008 has expanded product to include any intended output resulting from the product realization processes.

*NOTE 1: In this International Standard, the term "product" only applies only to*  
*- ~~a~~ the product intended for, or required by, a customer,*  
*- any intended output resulting from the product realization processes.*

2.2.3 A second note has been added to explain that "statutory and regulatory" requirements can be expressed as "legal" requirements.

*NOTE 2: Statutory and regulatory requirements can be expressed as legal requirements.*

## 1.2 Application

2.2.4 ISO 9001:2000 stated that a requirement exclusion cannot affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements. ISO 9001:2008 replaces "regulatory" with "statutory and regulatory".

*Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.*

## 2.3 ISO 9001:2008 — Normative reference

### 2. Normative reference

2.3.1 Although the text at this section has been significantly reduced (the deleted text is not shown), the key change is to refer to ISO 9000:2005 instead of the old ISO 9000:2000.

*The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.*

*ISO 9000:~~2000~~2005, QMS — Fundamentals and vocabulary*

## 2.4 ISO 9001:2008 — Terms and Definitions

### 3. Terms and definitions

2.4.1 The change in this section was to no longer explain the supply chain terms, including that "supplier" replaced "subcontractor" and "organization" replaced "supplier". The explanation was needed for the transition from ISO 9001:1994 to ISO 9001:2000, but not now. The only text remaining is shown below:

*For the purposes of this document International Standard, the terms and definitions given in ISO 9000 apply.*

*Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".*

## 2.5 ISO 9001:2008 — Clause 4

### 4. QMS, 4.1 General requirements

2.5.1 In 4.1, General Requirements, sub-clause (a), the word "Identify" has been replaced with "determine". Although similar, the words "identify" and "determine" have slightly different meanings. To identify is to recognize or establish something as being a particular thing. To determine is to apply reason and reach a decision. To determine the processes implies more analysis and judgment than merely identifying them.

a) ~~Identify~~ Determine the processes needed for the QMS and their application throughout the organization (see 1.2),

2.5.2 Processes are monitored, but may not need to be measured. Therefore, the requirement change above indicates processes are only measured where applicable.

e) monitor, measure where applicable, and analyze these processes, and...

2.5.3 Later in clause 4.1, regarding outsourcing:

Where an organization chooses to outsource any process that affects product conformity with to requirements, the organization shall ensure control over such processes. ~~Control of such~~ The type and extent of control to be applied to these outsourced processes shall be ~~identified~~ defined within the QMS.

2.5.4 This addition clarifies that specific controls are to be defined and applied, not just identified. See the new Note 3 below for an explanation of the type and extent of controls for an outsourced process.

2.5.5 The current Note under clause 4.1 has been expanded and two new Notes have been added:

NOTE 1: Processes needed for the QMS referred to above should include processes for management activities, provision of resources, product realization, and measurement, ~~analysis, and improvement.~~

2.5.6 The text above expands from "measurement" to "measurement, analysis, and improvement" to match the title for clause 8. And, by deleting "should", it clearly states that these processes are included.

2.5.7 The new Note below provides an explanation of what is considered an outsourced process.

NOTE 2: An outsourced process is a process that the organization needs for its QMS and which the organization chooses to have performed by an external party.

2.5.8 The new Note below identifies the factors influencing the control of an outsourced process.

NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory, and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements.

b) the degree to which the control for the process is shared;

c) the capability of achieving the necessary control through the application of clause 7.4.

2.5.9 Outsourcing a process to another organization typically involves the purchase of those services. As a result, the requirements of clause 7.4, including the controls mentioned in 7.4.1, apply equally to the supplier selected to perform the outsourced process.

**4.2 Documentation requirements, 4.2.1 General**

2.5.10 The changes in this section are basically just a restructuring of the sub-clauses c), d), and e).

- c) *documented procedures and records required by this International Standard, and*
- d) *documents, including records, ~~needed~~ determined by the organization to be necessary to ensure the effective planning, operation and control of its processes. ~~and~~*
- e) ~~*records required by this International Standard (see 4.2.4).*~~

2.5.11 Adding "records" to sub-clause c) allowed sub-clause e) to be dropped. Sub-clause d) has been expanded to include the necessary records.

Two sentences were added to the first Note of Clause 4.2.1.

*A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.*

2.5.12 An example for the first sentence would be satisfying the requirements for documented procedures in 8.5.2, Corrective Action, and 8.5.3, Preventive Action, through one combined Corrective and Preventive Action procedure. An example for the second sentence would be splitting the required procedure for the Control of Documents into two separate documented procedures.

**4.2.2 Quality manual**

2.5.13 No changes in ISO 9001:2008.

**4.2.3 Control of documents**

2.5.14 The opening sentence of this clause in ISO 9001:2008 still states that documents required by the QMS are to be controlled. The only revision to clause 4.2.3 is shown below.

*f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the QMS are identified and their distribution controlled, and*

2.5.15 The change in sub-clause f) clarifies that not all external documents have to be identified and controlled; only those needed for the planning and operation of the QMS.

**4.2.4 Control of Records**

2.5.16 The opening sentence for Clause 4.2.4 has expanded from records being "maintained" to having them "controlled". Maintaining records would simply keep them in good condition. Controlling the records means to regulate their use.

~~Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS shall be controlled.~~

~~Records shall remain legible, readily identifiable and retrievable.~~

~~The organization shall establish a documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.~~

~~Records shall remain legible, readily identifiable, and retrievable.~~

2.5.17 The requirement for a documented Record Control procedure has been rewritten, but the content is basically the same. It is now a separate paragraph for emphasis and moved up in the section.

2.5.18 Note that "retention time" has been reduced to "retention". And, you can see that records must still remain legible, readily identifiable, and retrievable. This requirement is now a separate paragraph and moved to the end of clause 4.2.4.

## 2.6 ISO 9001:2008 — Clause 5

### **5. Management responsibility, 5.1 Management commitment, 5.2 Customer focus, 5.3 Quality policy and 5.4 Planning**

2.6.1 No changes in ISO 9001:2008 for clauses 5.1 through 5.4.

### **5.5 Responsibility, authority, and communication and 5.5.1 Responsibility and authority**

2.6.2 No changes in ISO 9001:2008.

#### **5.5.2 Management representative**

2.6.3 Most organizations already appoint a management representative that is a member of their own management team. The change below clarifies that requirement.

*Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes:*

2.6.3 Some companies in the past have outsourced the management representative role to someone in a different organization, or even to their consultant. This text change may be aimed at that practice.

#### **5.5.3 Internal communication**

2.6.4 No changes in ISO 9001:2008.

**5.6 Management review**

2.6.5 No changes in ISO 9001:2008.

**2.7 ISO 9001:2008 — Clause 6****6. Resource management, 6.1 Provision of resources**

2.7.1 No changes in ISO 9001:2008.

**6.2 Human Resources, 6.2.1 General**

2.7.2 The revision below changes from work affecting "product quality" to work affecting "conformity to product requirements". Since quality is the degree to which a set of inherent characteristics fulfills requirements, then product quality would be the degree of conformity to product requirements.

*Personnel performing work affecting conformity to product quality requirements shall be competent on the basis of appropriate education, training, skills and experience*

2.7.3 The revision above should not be viewed as a new requirement. Anyone performing, verifying, or managing work within the scope of the QMS, including supporting services, can affect conformity to product requirements. A new Note has been added to 6.2.1 to explain this point.

*NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the QMS.*

**6.2.2 Competence, Training, and Awareness, and Training**

2.7.4 This clause title has been changed from "Competence, Awareness, and Training" to "Competence, Training, and Awareness". Awareness comes from some form of training and should be last in the title. That is also the sequence of the requirements as listed within clause 6.2.2.

2.7.5 The change in 6.2.1 from "product quality" to "product requirements" has been made to this sub-clause:

*a) determine the necessary competence for personnel performing work affecting conformity to product ~~quality~~ requirements,*

2.7.6 Use below of the phrase "where applicable" recognizes that training or other actions may not be necessary, since individuals may already have the necessary competence. Since "these needs" could be taken out of context, the requirement has been revised to specifically mention competence.

*b) where applicable, provide training or take other actions to ~~satisfy these needs~~ achieve the necessary competence.*

### 6.3 Infrastructure

2.7.7 The only change in 6.3 was to add "information systems" as an example of a supporting service.

c) *supporting services (such as transport, ~~or~~ communication, or information systems).*

### 6.4 Work environment

2.7.8 The only change in 6.4 was to add a Note to explain the term "work environment" by giving examples of work environment conditions for achieving conformity to product requirements.

*NOTE: The term "work environment" relates to those conditions under which work is performed including physical, environmental, and other factors (such as noise, temperature, humidity, lighting, or weather).*

## 2.7 ISO 9001:2008 — Clause 7

### 7. Product realization, 7.1 Planning of product realization

2.7.1 The only significant change to the text of clause 7.1 is the addition of "measurement" as one of the required activities to be determined during the planning of product realization.

*In planning product realization, the organization shall determine the following, as appropriate:*

- b) *the need to establish processes; and documents, and to provide resources specific to the product;*
- c) *required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;*

### 7.2 Customer-related processes, 7.2.1 Determination of requirements related to the product

2.7.2 The change below from "related" to "applicable" shifts from determining legal requirements that are merely associated with the product to those that are relevant and can be applied to the product.

*The organization shall determine:*

- c) *statutory and regulatory requirements ~~related~~ applicable to the product, and*

2.7.3 Since the bulleted list for 7.2.1 begins with "The organization shall determine", the use of the word "determined" again in the entry below was not appropriate. The new text clarifies that the additional requirements "considered necessary" must be determined.

- d) *any additional requirements ~~determined~~ considered necessary by the organization.*

2.7.4 Organizations may not have considered the breadth of post-delivery activities as described by the new note below.

*NOTE: Post delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.*

### **7.2.2 Review of requirements related to the product, 7.2.3 Customer communication**

2.7.5 No changes in ISO 9001:2008.

### **7.3 Design and Development, 7.3.1 Design and development planning**

2.7.6 Clause 7.3.1, sub-clause b) continues to state that the organization must determine the review, verification, and validation appropriate for each design and development stage. The new note below explains that although review, verification, and validation have distinct goals, they can be carried out separately or in any combination.

*NOTE: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.*

#### **7.3.2 Design and development inputs**

2.7.7 This clause continues to require the design and development inputs to be determined and records to be maintained. It lists several types of requirements to be included. The revision below simply changes from "these inputs" to "the inputs".

*~~These~~ The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.*

#### **7.3.3 Design and development outputs**

2.7.8 The change below removes the unnecessary word, "provided". It also switches from "a form that enables verification" to "a form suitable for verification". To enable something is to make it possible. However, to be suitable means it is meant for use, or in this case, for verification.

*The outputs of design and development shall be provided in a form ~~that enables~~ suitable for verification against the design and development input and shall be approved prior to release.*

2.7.9 The change below was to simply remove the word "for".

*b) provide appropriate information for purchasing, production, and ~~for~~ service provision,*

2.7.10 The new Note below reminds the reader that Clause 7, the production and service provision, includes sub-clause 7.5.5, Preservation of Product. This is to indicate that the design output should consider product preservation, (e.g. product packaging).

*NOTE: Information for production and service provision can include details for the preservation of product.*



**7.3.4 Design and development review, 7.3.5 Design and development verification, 7.3.6 Design and development validation**

2.7.11 No changes in ISO 9001:2008 for clauses 7.3.4 through 7.3.6.

**7.3.7 Control of design and development changes**

2.7.12 The two paragraphs in this section were merged into one paragraph. No text changes.

**7.4 Purchasing'**

2.7.13 No changes in ISO 9001:2008.

**7.5 Production and service provision, 7.5.1 Control of Production and service provision**

2.7.14 This clause continues to require planning and carrying out production and service provision under controlled conditions. However, two of the listed six conditions have been revised. Later in the standard, the title of clause 7.6 has been changed to refer to the control of monitoring and measuring "equipment" instead of "devices", therefore, the terminology has been changed below:

d) *the availability and use of monitoring and measuring ~~devices~~ equipment.*

2.7.15 The change below simply clarifies that the implementation activities are those related to the "product".

f) *the implementation of product release, delivery, and post-delivery activities.*

**7.5.2 Validation of processes for production and service provision**

2.7.16 The revised text in this clause makes clear that any process output that can't be verified may result in deficiencies becoming known only after the product is in use or the service has been delivered.

*The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. ~~This includes any processes where~~ and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.*

**7.5.3 Identification and traceability**

2.7.17 This clause continues to state that, where appropriate, the organization must identify the product by suitable means "throughout product realization". The text below refers to inspection and test status of the product, and some organizations may have thought it only applied to the final product. The revision below clarifies that identifying the product monitoring and measurement status applies throughout product realization, from received product to final product, including in-process product.

*The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.*

2.7.18 By moving the "records" reference to the end of the sentence below, the meaning has expanded from recording the product identification, to keeping any type of record associated with product traceability.

*Where traceability is a requirement, the organization shall control and record the unique identification of the product and maintain records (see 4.2.4).*

#### **7.5.4 Customer Property**

2.7.19 The change below reads better, but hasn't changed the requirement to report customer property issues to the customer and keep records.

*If any customer property is lost, damaged, or otherwise found to be unsuitable for use, ~~this shall be reported the~~ organization shall report this to the customer and ~~records maintained~~ maintain records (see 4.2.4).*

2.7.20 The existing Note in 7.5.4 has been revised to include "personal data" as an example of customer property, broadening its applicability to more organizations, especially service organizations.

*NOTE: Customer property can include intellectual property and personal data.*

#### **7.5.5 Preservation of product**

2.7.21 If anyone was confused over the meaning of "conformity of product" in the current text, using "conformity to requirements" should be easier to understand in the new text.

*The organization shall preserve the ~~conformity~~ of product during internal processing and delivery to the intended destination in order to maintain conformity to requirements.*

2.7.22 The current requirement that begins with, "This preservation shall include", doesn't give the flexibility to include, or not include, the identification, handling, packaging, storage, and protection of the product. The change below allows product preservation to be applied as applicable.

*This ~~As applicable,~~ preservation shall include identification, handling, packaging, storage, and protection. Preservation shall also apply to the constituent parts of a product.*

#### **7.6 Control of monitoring and measuring devices equipment**

2.7.23 The second clause title to change in ISO 9001:2008 is clause 7.6, where "devices" has been changed to "equipment". The term equipment was already used in several places in clause 7.6. The term "devices" has a broader scope and could include non-equipment types of tools. Equipment is the better choice for this calibration clause.

2.7.24 The changes to the clause below are to replace "devices" with "equipment" and to remove the reference to Clause 7.2.1, *Determination of Requirements Related to the Product*.

*The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring ~~devices~~ equipment needed to provide evidence of conformity of product to determined requirements (see 7.2.1).*

2.7.25 A minor change to 7.6, sub-clause a) is shown below. This requirement went from "calibrated or verified" to "calibrated or verified, or both", meaning a type of equipment might be calibrated and/or verified.

*Where necessary to ensure valid results, measuring equipment shall:*

*a) ~~be calibrated or verified,~~ or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);*

2.7.26 The prior statement below, that measuring equipment must "be identified" sounded like the organization was to add identification. However, the measuring equipment may come with the identification already in place.

*c) ~~be identified~~ have identification to enable in order to determine the its calibration status to be determined;*

2.7.27 The text below was split from its old paragraph and made a standalone sentence for emphasis.

*Records of the results of calibration and verification shall be maintained (see 4.2.4).*

2.7.27 Software development organizations may have been unsure how to "confirm", per clause 7.6, that software used for monitoring and measurement has the ability to satisfy the intended application.

2.7.28 The last paragraph in Clause 7.6 (see below) was deleted and a new note added to explain that confirmation of software would typically include verification and configuration management.

*~~When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.~~*

*NOTE: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.*

2.7.29 The prior note to Clause 7.6 was dropped. It referred the reader to the ISO 10012-1 and ISO 10012-2 standards for guidance. Although these standards have been replaced with ISO 10012:2003, the reference was not retained.

*NOTE: See ISO 10012-1 and ISO 10012-2 for guidance.*

## 2.8 ISO 9001:2008 — Clause 8

### 8. Measurement, analysis, and improvement, 8.1 General

2.8.1 The prior use of "conformity of the product" has been revised to "conformity to product requirements".

*The organization shall plan and implement the monitoring, measurement, analysis, and improvement processes needed a) to demonstrate conformity of the to product requirements.*

## **8.2 Monitoring, 8.2.1 Customer satisfaction**

2.8.2 A note has been added to Clause 8.2.1 to provide examples of monitoring customer perceptions.

*NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.*

### **8.2.2 Internal audit**

2.8.3 The change below was to simply add the word "the" at the beginning of the sentence.

*The Sselection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.*

2.8.4 The requirement below was edited to emphasize the need for a documented procedure (by placing it first in the sentence). Also, "establishing records" has been moved ahead of "reporting results" in the list of topics to be defined in the procedure. Records are being captured throughout the audit and should be listed before the reporting of results.

*A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.*

*~~The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.~~*

2.8.5 The new sentence below highlights the need to maintain records of the audit and its results. The reference in the old text to 4.2.4 for record control was moved to this new sentence.

*Records of the audits and their results shall be maintained (see 4.2.4).*

2.8.6 Expanding from "actions" to "any necessary corrections and corrective actions" reminds us that an immediate correction might be needed before determining the cause of the non-conformity and taking corrective action to prevent its recurrence. Clause 8.2.3 also refers to corrections and corrective actions.

*The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.*

2.8.7 The reference in the note below to the withdrawn ISO 10011, *Guidelines for Auditing Quality Systems*, has been replaced with a reference to ISO 19011, *Guidelines for Quality and/or Environmental Management Systems Auditing*.

*NOTE: See ISO 10011 1, ISO 10011 2 and ISO 10011 3 ISO 19011 for guidance.*

### 8.2.3 Monitoring and measurement of processes

2.8.8 This clause requires applying suitable methods for monitoring and measuring processes to demonstrate their ability to achieve planned results. For some supporting processes, these results are only indirectly related to product conformity. Therefore, the reference to product conformity was moved from this paragraph to the new Note below.

*When planned results are not achieved, correction and corrective action shall be taken, as appropriate, ~~to ensure conformity of the product.~~*

2.8.9 What is a "suitable" method for monitoring and measuring processes? The Note below says to consider the type and extent of monitoring or measurement based on the impact of the process on conformity to product requirements and system effectiveness.

*NOTE: When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the QMS.*

### 8.2.4 Monitoring and measurement of product

*The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.*

2.8.9 The requirement to maintain evidence of conformity with acceptance criteria has been moved from the paragraph below to the paragraph above. And, the release of product is not to the next in-process stage, but for delivery to the customer.

*~~Evidence of conformity with the acceptance criteria shall be maintained.~~ Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).*

2.8.10 The requirement below has been edited to clarify that the release of product and delivery of service is to the customer.

*The release of product ~~release~~ and delivery of service ~~delivery to the customer~~ shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.*

### 8.3 Control of non-conforming product

2.8.11 The sentence below has been edited to begin with (instead of end with) the requirement for a documented procedure.

*A documented procedure shall be established to define ~~the controls and related responsibilities and authorities for dealing with nonconforming product.~~ ~~shall be defined in a documented procedure.~~*

2.8.12 The requirement below adds "where applicable", meaning where relevant and suitable, to deal with non-conforming product in one or more of the four ways listed.

*Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:*

2.8.13 The new entry below, in the list of ways to deal with non-conforming product, is edited text from the last sentence in clause 8.3 to become part of the list of ways to deal with non-conforming product.

*d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.*

2.8.14 The deleted text below wasn't actually deleted, just moved from paragraph 3 to paragraph 4.

~~*Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).*~~

2.8.15 The text below was moved from paragraph 4 to become paragraph 3. The requirement is nearer the list of ways for dealing with non-conforming product, which includes taking action to eliminate the detected non-conformity, e.g., rework. Therefore, the requirement for re-verification in that situation is nearby.

*When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.*

2.8.16 The requirement in paragraph 4 below is from paragraph 3. No changes were made. Since it includes "subsequent actions", e.g., re-verification, it is appropriate for recordkeeping to be last in the section.

*Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4)*

2.8.17 The deleted text below was moved to sub-clause d) in the list of ways to deal with non-conforming product.

~~*When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.*~~

#### **8.4 Analysis of data**

2.8.18 The analysis of data provides information on customer satisfaction, conformity to product requirements, characteristics and trends of processes and products, and suppliers. The changes below were to revise a reference (from 7.2.1 to 8.2.4) and to add new references (8.2.3, 8.2.4, and 7.4).

The analysis of data shall provide information relating to

- a) customer satisfaction (see 8.2.1)
- b) conformity to product requirements ~~(see 7.2.1)~~ (see 8.2.4).
- c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- d) suppliers (see 7.4).

### 8.5 Improvement, 8.5.1 Continual improvement

2.8.19 No changes in ISO 9001:2008.

#### 8.5.2 Corrective action

2.8.20 The requirement below switched from “cause” to “causes” to match with “non-conformities” and to be consistent with a similar sentence in 8.5.3, *Preventive Action*.

The organization shall take action to eliminate the ~~cause~~ causes of nonconformities in order to prevent recurrence.

2.8.21 ISO 9000:2005 defines “review” as an activity to determine the effectiveness of a subject to achieve established objectives. However, the “reviewing” in the requirement below was often interpreted as checking to see if an action was taken, instead of determining its effectiveness. It has been clarified.

f) reviewing the effectiveness of the corrective action taken

#### 8.5.3 Preventive action

2.8.22 As explained under 8.5.2, *Corrective Action*, the “reviewing” of the action has been clarified to include determining the effectiveness of the action.

e) reviewing the effectiveness of the preventive action taken.

## 2.9 Annex A

2.9.1 Table A.1 in the Annex was revised to show the correspondence of ISO 9001:2008 clauses with ISO 14001:2004 (instead of ISO 14001:1996). Table A.2 shows the reverse correspondence, from ISO 14001:2004 clauses to ISO 9001:2008 clauses.

## 2.10 Annex B

2.10.1 The old Annex B, that showed the correspondence of ISO 9001:2000 and ISO 9001:1994 clauses, has been replaced since the clause structure of ISO 9001:2000 and ISO 9001:2008 are the same. The new Annex B (Table B.1) identifies the text changes from ISO 9001:2000 to ISO 9001:2008.

## 2.11 Bibliography

2.11.1 The Bibliography for ISO 9001:2008 has been updated to reflect new standards, new editions of standards, and withdrawn standards since the publication of ISO 9001:2000.

## 3. NEW STANDARDS

ISO 10001:2007, *Customer satisfaction — Guidelines for codes of conduct for organizations*  
ISO 10002:2004, *Customer satisfaction — Guidelines for complaints handling in organizations*  
ISO 10003:2007, *Customer satisfaction — Guidelines for dispute resolution external to organizations*  
ISO 10019:2005, *Guidelines for the selection of QMS consultants and use of their services*  
ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*  
IEC 61160:2006, *Design review*  
ISO 90003:2004, *Software engineering — Guidelines for the application of ISO 9001:2000 to computer software*

## 4. NEW EDITIONS

ISO 9004:200x, *Managing for the sustained success of an organization — A quality management approach*  
ISO 10005:2005, *QMS — Guidelines for quality plans*  
ISO 10006:2003, *QMS — Guidelines for quality management in projects*  
ISO 10007:2003, *QMS — Guidelines for configuration management*  
ISO 10012:2003, *Requirements for measurement processes and measuring equipment*  
ISO/TR 10013:2001, *Guidelines for QMS documentation*  
ISO 10014:2006, *Quality management — Guidelines for realizing financial and economic benefits*  
ISO/TR 10017:2003, *Guidance on statistical techniques for ISO 9001:2000*  
ISO 14001:2004, *Environmental management systems — Requirements with guidance for use*  
IEC 60300-1:2003, *Dependability management — Part 1: Dependability management systems*

## 5. WITHDRAWN STANDARDS

ISO 9000-3:1997 (replaced by ISO 90003:2004)  
ISO 10011-1: 1990 (replaced by ISO 19011:2002)  
ISO 10011-2: 1991 (replaced by ISO 19011:2002)  
ISO 10011-3:1991 (replaced by ISO 19011:2002)  
ISO 10012-1:1992 (replaced by ISO 10012:2003)  
ISO 10012-2:1997 (replaced by ISO 10012:2003)