# Manual on the Quality Management System for the Provision of Meteorological Service for International Air Navigation





Second Edition — 2010

Approved by the Secretaries General of ICAO and WMO and published under their authority

International Civil Aviation Organization

Doc 9873 AN/465

# Manual on the Quality Management System for the Provision of Meteorological Service for International Air Navigation





Second Edition — 2010

Approved by the Secretaries General of ICAO and WMO and published under their authority

International Civil Aviation Organization

Published jointly in 2010 by the WORLD METEOROLOGICAL ORGANIZATION 7 bis, avenue de la Paix, Case postale No. 2300, CH-1211 Geneva 2, Switzerland and the INTERNATIONAL CIVIL AVIATION ORGANIZATION 999 University Street, Montréal, Quebec, Canada H3C 5H7

> First edition 2007 Second edition 2010

This edition printed in Canada by ICAO.

ISBN 978-92-9231-619-8

ICAO Publication ICAO sales number: 9873

Copyright © WMO/ICAO 2010

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form or by any means, without prior permission in writing from the World Meteorological Organization or the International Civil Aviation Organization.

# AMENDMENTS

Amendments are announced in the supplements to the *Catalogue of ICAO Publications;* the Catalogue and its supplements are available on the ICAO website at <u>www.icao.int</u>. The space below is provided to keep a record of such amendments.

# **RECORD OF AMENDMENTS AND CORRIGENDA**

AMENDMENTS			CORRIGENDA		
No.	Date	Entered by	No.	Date	Entered by

# CONTENTS

			Page
Forew	ord .		(vii)
Chapte	er 1.	Policies on quality systems for aeronautical meteorological services	1-1
1.1	1	Background	1-1
1.2		Relevant provisions in ICAO Annex 3/WMO Technical Regulations [C.3.1]	1-1
Chapte	er 2.	Concepts and vocabulary	2-1
2.1	1	Standards and ISO	2-1
2.2	2	Background to ISO 9000 series	2-1
2.3	3	What is quality?	2-2
2.4	4	Quality control	2-2
2.	5	Quality assurance	2-2
2.0	6	Quality improvement	2-2
2.	7	Quality management system	2-3
2.8	3	Quantifying quality costs	2-3
2.9	9	Quality management principles	2-4
2.1	10	The ISO 9000 series of standards	2-6
Chapte	er 3.	The anatomy of ISO 9001:2008 quality management systems	3-1
3.1	1	Introduction	3-1
3.2	2	Structure of ISO 9001:2008	3-1
3.3	3	Requirements of ISO 9001:2008	3-2
		3.3.1 Clause 1 — Scope	3-2
		3.3.2 Clause 2 — Normative reference	3-2
		3.3.3 Clause 3 — Terms and definitions	3-3
		3.3.4 Clause 4 — Quality management system	3-3
		3.3.5 Clause 5 — Management responsibility	3-5
		3.3.6 Clause 6 — Resource management	3-8
		3.3.7 Clause 7 — Product realization	3-9
		3.3.8 Clause 8 — Measurement, analysis and improvement	3-15
Chapte	er 4.	Quality management system documentation	4-1
4.1	1	Structure of quality management system documentation	4-1
4.2	2	Quality manual	4-3
4.3	3	Control of documents	4-4
4.4		ISO guidance	4-5
Chapte	er 5.	Auditing processes	5-1
5.1	1	Audit objectives	5-1
5.2		Audit types	5-1

# Page

5.3	Process auditing approach	5-2
5.4	Certification/registration audit	5-2
5.5	Surveillance	5-3
5.6	ISO guidance	5-5
Chapter 6.	Nonconformance reports and corrective action	5-1
6.1	Types of nonconformity — Major and minor nonconformities	6-1
6.2	Observations and potential nonconformities	6-1
6.3	Corrective action process	6-2
Chapter 7.	Steps to certification and other practical issues7	7-1
7.1	Steps to certification	7-1
7.2	•	<b>'-</b> 2
7.3	Process analysis for the meteorological service provider	<b>'</b> -3
7.4		<b>7-</b> 4
7.5		<b>7-</b> 5
7.6	ISO assistance for developing countries	<b>'-</b> 5
Chapter 8.	Hong Kong, China case study (2002)	8-1
8.1	Background	3-1
8.2		3-1
8.3	Steps followed that led to the certification of the quality management system	3-1
8.4		3-3
8.5		3-3
8.6		3-4
8.7		3-5
8.8		3-5
8.9	Experience of a national meteorological service provider	3-6

# APPENDICES

Append	lix 1. Records required by ISO 9001:2008	APP 1-1
Append	dix 2. Hong Kong, China documentation system	APP 2-1
Α.	Quality objectives established for the airport meteorological office	APP 2-1
В.	Outline of the quality manual of the airport meteorological office	APP 2-2
C.	Quality management system procedures maintained by the airport meteorological office	APP 2-4
D.	Example of a quality management system procedure (control of nonconforming product)	APP 2-5
Ε.	Example of work instructions for weather observers	APP 2-11
F.	Example of the form being used in the airport meteorological office	APP 2-12
	lix 3. Example of a certification process undergone by a Il meteorological service provider	APP 3-1

# FOREWORD

The ICAO Meteorology (MET) Divisional Meeting (2002), held conjointly with the Twelfth Session of the WMO Commission for Aeronautical Meteorology, formulated Recommendation 4/3 — Guidance material on quality management systems, calling for ICAO and WMO to develop guidance material concerning the provision of meteorological services for international air navigation.

As a follow-up to Recommendation 4/3 approved by the ICAO Council and the WMO Executive Council and in accordance with the ICAO/WMO working arrangements, the two organizations agreed to jointly develop and publish the present guidance material. The ICAO document is being published as the *Manual on the Quality Management System* for the Provision of Meteorological Service for International Air Navigation and the WMO document as the *Guide on the Quality Management System* for the Provision of Meteorological Service for International Air Navigation and the WMO document as the *Guide on the Quality Management System* for the Provision of Meteorological Service for International Air Navigation. The responsibility for future amendments to these publications lies jointly with the two organizations. Editorial Note: Although the titles differ, ICAO's publication utilizes the content and format produced by WMO.

The terms and definitions taken from the ISO 9000 Compendium, Tenth Edition, are reproduced with the permission of the International Organization for Standardization (ISO). The ISO 9000 Compendium as well as the ISO Standards referred to herein can be obtained from any ISO member or from the website of the ISO Central Secretariat at the following address: www.iso.org. Copyright remains with ISO.

# Chapter 1

# POLICIES ON QUALITY SYSTEMS FOR AERONAUTICAL METEOROLOGICAL SERVICES

# 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 "Each Contracting State shall take all necessary measures to introduce a properly organized quality system containing procedures, processes and resources necessary to implement quality management at each function stage …" in the aeronautical information service (AIS) field. Quality management has also become increasingly important in the field of meteorological service for international air navigation. The setting up of a properly organized quality system is to ensure a continued high quality of data and products provided by the aeronautical meteorological services.

1.1.2 Amendment 72 to ICAO Annex 3 to the Convention on International Civil Aviation — *Meteorological Service for International Air Navigation* and the WMO *Technical Regulations* (WMO-No. 49), Volume II — *Meteorological Service for International Air Navigation* [C.3.1], which are identical except for a few minor editorial differences, became applicable on 1 November 2001. It introduced Recommended Practices concerning quality control and management of meteorological information supplied to users and in the training of meteorological personnel. Aligned as far as possible with "quality system" provisions in ICAO Annex 15, these provisions recommend conformity with the ISO 9000 series of quality assurance standards. While the ISO 9000 series of quality assurance standards provides a basic framework for the development of a quality assurance programme, the details of such a programme have to be formulated by each ICAO Contracting State/WMO Member.

1.1.3 The joint meeting of the ICAO Meteorology (MET) Divisional Meeting (2002)/twelfth session of the WMO Commission for Aeronautical Meteorology (CAeM-XII) discussed the above new requirements and formulated Recommendation 4/3, which requested that ICAO and WMO develop joint guidance material to assist Contracting States/Members in developing quality management systems of their own. The present publication thus provides guidance to facilitate the design, development and implementation of an ISO 9000-compliant quality management system by the aeronautical meteorological services in the provision of meteorological services for international air navigation.

1.1.4 Amendment 75 to ICAO Annex 3 introduced, as a Standard, the requirement to establish and implement a quality system, which becomes applicable on 15 November 2012.

## 1.2 RELEVANT PROVISIONS IN ICAO ANNEX 3/ WMO TECHNICAL REGULATIONS [C.3.1]

1.2.1 Definitions for quality assurance, quality control, quality management and quality system have been introduced in ICAO Annex 3/WMO Technical Regulations [C.3.1] since Amendment 72. The Standards and Recommended Practices related to quality assurance are given in ICAO Annex 3/WMO Technical Regulations [C.3.1], Chapter 2, 2.2.2 to 2.2.7. In brief, the Standards and Recommended Practices set out the following requirements:

- (a) The designated meteorological authority shall establish and implement a properly organized quality system, comprising procedures, processes and resources to provide for the quality management of the meteorological information supplied to the users (ICAO Annex 3/WMO Technical Regulations [C.3.1], Chapter 2, 2.2.2);
- (b) The quality system should be compliant with ISO 9000 (ICAO Annex 3/WMO Technical Regulations [C.3.1], Chapter 2, 2.2.4);
- (c) The quality system provides the users with assurance that the meteorological information supplied complies with the stated requirements (ICAO Annex 3/WMO Technical Regulations [C.3.1], Chapter 2, 2.2.5);
- (d) The quality system includes verification/validation procedures in regard to the operational meteorological (OPMET) information exchange, as well as resources for monitoring the adherence to the prescribed transmission schedules (ICAO Annex 3/WMO Technical Regulations [C.3.1], Chapter 2, 2.2.6); and
- (e) Audits should be conducted in order to demonstrate compliance of the quality system applied (ICAO Annex 3/WMO Technical Regulations [C.3.1], Chapter 2, 2.2.7).

1.2.2 It should be noted that all the stated requirements (1.2.1 (c) refers) have been laid down in ICAO Annex 3/WMO Technical Regulations [C.3.1], the ICAO regional air navigation plans and the WMO regulatory documents. In particular, these include product requirements concerning the geographical and spatial coverage, format and content, time and frequency of issuance and period of validity of meteorological information to be supplied to aeronautical users and requirements concerning the exchange of OPMET information. In the case of qualifications and training of meteorological personnel in aeronautical meteorology, requirements are given in the WMO *Technical Regulations* (WMO-No. 49), Volume I — *General Meteorological Standards and Recommended Practices* and also in the *Guidelines for the education and training of personnel in meteorology and operational hydrology* (WMO-No. 258), Volume I: *Meteorology*.

1.2.3 The designated meteorological authorities could achieve ISO 9000 certification for all or any part of their service, if they so decide. The certification could be limited to services provided for international air navigation. This will be indicated in the Scope attached to the Certificate.

Note.— It will not necessarily be the meteorological authority in a State which seeks ISO 9000 certification; it could be the meteorological service provider that is providing the services under contract to the meteorological authority. In the present publication, the term "meteorological service provider" will either refer to the meteorological authority itself or to an organization working under contract to the meteorological authority for the provision of meteorological services for international air navigation.

# 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 Contracting States/WMO Members follow the standards stipulated in the Annexes to the Convention on International Civil Aviation/WMO Technical Regulations in order to ensure safety, regularity and efficiency in the operation of international air navigation.

2.1.2 The International Organization for Standardization, 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 ISO 9000 SERIES

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

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. First, ISO International Standards have a normal review cycle of five years. Secondly, the user community requested it. The year 2000 revisions represented a thorough overhaul of the standards to take 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 A further updatable ISO 9000 series of standards was introduced by 2008 in order to provide clarification and to enhance compatibility with the ISO 1400:2004 standards. This update included ISO 9000:2005 containing the fundamentals and vocabulary and ISO 9001:2008 providing the requirements.

# 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 aviation weather 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 fulfils 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.

# 2.4 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 fulfil the requirements for quality. The nature of this approach remains more or less detection and that is considered a reactive downstream approach — correction only after problems occur.

# 2.5 QUALITY ASSURANCE

Quality assurance is also a part of quality management but it is focused on providing confidence that quality requirements will be fulfilled (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 fulfil 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 Plan-Do-Check-Act (PDCA) cycle as a useful tool for continual improvement. The methodology applies to both high-level strategic processes and to simple operational activities. Figure 2-1 illustrates the PDCA cycle.

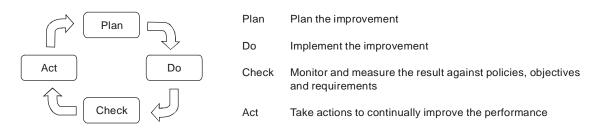


Figure 2-1. PDA cycle

#### 2.7 QUALITY MANAGEMENT SYSTEM

2.7.1 As defined in ISO 9000:2005, a quality management system 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 quality management system 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/WMO is "user". The customers of the meteorological authorities refer to the users listed in ICAO Annex 3/WMO Technical Regulations [C.3.1], Chapter 2, 2.1.2.

#### 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 nonconformance found before the customer receives the product or service, for example correcting a wrongly encoded forecast when captured by automatic checking procedures.

- (b) External failure costs. Costs associated with defects or nonconformance found after the customer receives the product or service, for example investigating complaints from a pilot for the late issuance of an aerodrome forecast 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 or aerodrome forecasts, and monitoring of the transit time of meteorological bulletins.
- (d) Prevention costs. Costs incurred to keep failure or nonconformance and appraisal costs to a minimum, for example training staff in quality practices and procedures, and performing preventive maintenance on an anemometer.

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 quality management system 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 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 meteorological 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. Meteorological 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 quality management system 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 quality management system, staff need 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. A quality management system 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 aviation weather services, 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.

Meteorological service 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 quality management system 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, a TAF verification system has to be developed in accordance with the ICAO/WMO requirements to ensure the accuracy of each of the weather 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 20 standards in the 1994 version to only 4 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 quality management systems 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 and regulators).

(b) ISO 9001:2008 Quality management systems — Requirements

This standard specifies requirements of a quality management system where the organization needs to demonstrate its ability to provide products that fulfil 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 quality management system. 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 quality management system. 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 programmes, conducting quality management system audits, as well as guidance on the competence of quality and management system auditors.

2.10.2 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.

# Chapter 3

# THE ANATOMY OF ISO 9001:2008 QUALITY MANAGEMENT SYSTEMS

#### 3.1 INTRODUCTION

3.1.1 The ISO 9001:2008 International Standard specifies the requirements for a quality management system applicable to all organizations, products and services. It is the only standard in the ISO 9000:2005 family of standards that can be used for certification of the system. The meteorological service provider can only seek certification of the quality management system 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 meteorological services for international air navigation.

Note.— ISO 9001:2008 only defines the fundamental requirements and lays down the framework for certification. Each meteorological service provider needs to formulate its own quality management system based on its own needs and circumstances. As operating services that have been running successfully for a long time, it is likely that the meteorological service providers will already have a system or practices in place to address the ISO requirements. They would, therefore, quite often be able to address the requirements of ISO 9001:2008 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 quality management system. For a meteorological service 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 such as aviation forecasts and warnings, observations and flight documentation;
- (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:
  - (a) Clause 1 Scope
  - (b) Clause 2 Normative references
  - (c) Clause 3 Terms and definitions

- (d) Clause 4 Quality management system
- (e) Clause 5 Management responsibility
- (f) Clause 6 Resource management
- (g) Clause 7 Product realization
- (h) 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 quality management system described in Clause 4 encompasses the four major groups of processes, within the process-based quality management system. 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.

3.2.3 Figure 3-1 illustrates the linkage between these four groups of processes in the form of a continuous loop and serves as a good starting point for developing the structure of the quality management system. Each of the four groups of processes in the loop contains specific tasks and processes, as detailed in Clauses 5 to 8, that must be accomplished. Figure 3-1 highlights the importance of the customer in defining requirements as inputs, and the need to monitor customer satisfaction. It also shows how the improvement processes, for example by means of the Plan-Do-Check-Act (PDCA) cycle (see Chapter 2, 2.6.2) revolve around all aspects of the system.

#### 3.3 REQUIREMENTS OF ISO 9001:2008

#### 3.3.1 Clause 1 — Scope

This clause emphasizes the aim to enhance customer satisfaction through the effective application of the quality management system, continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements. Where any requirement(s) cannot be applied owing to the nature of the organization and its products, this can be considered for exclusion. Exclusions are limited to requirements within Clause 7, and they must not affect the ability or responsibility of the organization to provide products that meet both customer requirements and applicable regulatory requirements.

#### 3.3.2 Clause 2 — Normative Reference

This clause states that certain provisions contained in ISO 9000:2005 are referred to in ISO 9001:2008 and as such, they also constitute provisions of ISO 9001:2008. In particular, the readers have to refer to ISO 9000 for the terms and definitions when interpreting the ISO 9001:2008 requirements.

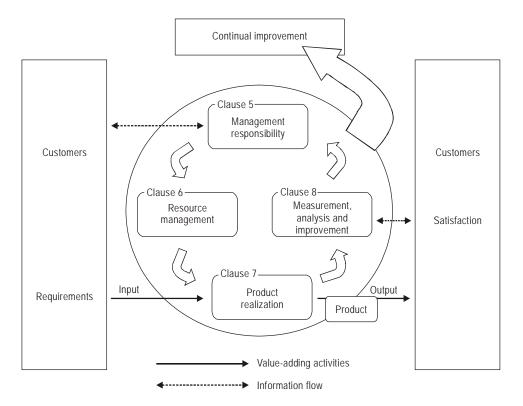


Figure 3-1. Model of a process-based quality management system (adapted from the ISO 9001:2008 standard)

#### 3.3.3 Clause 3 — Terms and Definitions

This clause clarifies that the word "product" used in the standard can also mean "service". It also covers the specific use of terminology to describe the supply chain as follows:

Supplier  $\rightarrow$  Organization  $\rightarrow$  Customer

The organization indicates the entity seeking certification to ISO 9001:2008 standard. In the present context, it indicates the meteorological service provider itself, or the part of its services that is seeking certification. A supplier is the provider of a service or information to the organization. It can be internal or external to the organization. For example, a world area forecast centre is an external supplier whereas the information technology division can be an internal supplier of the meteorological service provider. Customers of the meteorological service provider are the aviation users listed in ICAO Annex 3/WMO Technical Regulations [C.3.1], Chapter 2, 2.1.2. These are operators, flight crew members, air traffic services units, search and rescue services units, airport management and others concerned with the conduct or development of international air navigation and the meteorological information necessary for the performance of their respective functions.

#### 3.3.4 Clause 4 — Quality Management System

3.3.4.1 Clause 4 states the general requirements for ISO 9001 and the documentation requirements of the quality management system.

### Clause 4.1 — General requirements

3.3.4.2 Clause 4.1 covers the requirements for the organization to establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with ISO 9001:2008. The steps to be followed are described in the following table:

Step	Description	
1	Determine the processes needed for the quality management system and their application throughout the organization	
2	Determine the sequence and interaction of these processes	
3	Determine criteria and methods needed to ensure that both the operation and the control of the processes are effective	
4	Ensure the availability of resources and information necessary to support the operation and monitoring of these processes	
5	Monitor, measure where applicable and analyse the processes	
6	Implement actions necessary to achieve planned results and continual improvement of these processes	

#### Clause 4.2 — Documentation requirements

- 3.3.4.3 The quality management system documentation must include (Clause 4.2.1):
  - (a) Documented statements of a quality policy and quality objective:
    - requirements of which are further elaborated in Clauses 5.3 and 5.4.1 respectively;
  - (b) A quality manual:
    - which includes the scope of the quality management system, justification for any exclusions, a description of the interaction between the processes and the documented procedures or reference to them (Clause 4.2.2);
  - (c) A minimum of six documented procedures required by ISO 9001:2008 (see Chapter 4, 4.1.3), respectively on:
    - control of documents (Clause 4.2.3)
    - control of records (Clause 4.2.4)
    - internal audit (Clause 8.2.2)

- control of nonconforming product (Clause 8.3)
- corrective action (Clause 8.5.2)
- preventive action (Clause 8.5.3);
- (d) Records required by ISO 9001:2008:
  - required to provide evidence of conformity to requirements and of the effective operation of the quality management system. Examples of records are results of calibration and verification of meteorological sensors and results of evaluations of suppliers. Required records are listed in Appendix 1; and
- (e) Other documents, for example operations manuals, required to ensure the effective planning, operation and control of the processes.

#### Clause 4.2.3 — Control of documents

3.3.4.4 Proper controls are required of all documents of the quality management system. A documented procedure has to be established for this purpose. Control of documents includes the following:

- (a) Approval, review and updating of documents;
- (b) Identification of changes and current revision status;
- (c) Availability of documents at points of use, for example a meteorological office, their legibility and identification;
- (d) Identification of external documents, for example ICAO/WMO regulatory documents, States' Aeronautical Information Publications (AIP) and their distribution; and
- (e) Control of obsolete documents to prevent their unintended use.

#### Clause 4.2.4 — Control of records

3.3.4.5 Records are a special type of document. The controls needed for the identification, storage, protection, retrieval, retention time and disposition of records have to be defined in a documented procedure.

3.3.4.6 It should be noted that the documentation required can be in any form or type of medium. The extent of the documentation is dependent on the size and type of the organization; complexity and interaction of the processes; and competency of personnel. More detailed descriptions of documentation required for a quality management system are given in Chapter 4.

#### 3.3.5 Clause 5 — Management Responsibility

3.3.5.1 A genuine commitment from top management and strong leadership are instrumental in the successful implementation of an effective quality management system. Appropriate resources have to be allocated and every staff member made aware that this is a sign that top management is committed to the process. Clause 5 discusses the role and responsibility of management in developing and improving the quality management system.

#### Clause 5.1 — Management commitment

3.3.5.2 Top management of the organization, for example the General Manager or Officer-in-Charge of the meteorological service provider, must provide evidence of its commitment to the development and continual improvement of the quality management system by:

- (a) Communicating to the employees the importance of meeting customer needs as well as statutory and regulatory requirements, for example ICAO Annex 3/WMO Technical Regulations [C.3.1];
- (b) Establishing the quality policy (Clause 5.3) and quality objectives (Clause 5.4.1);
- (c) Conducting regular management reviews (Clause 5.6) to ensure the continuing suitability, adequacy and effectiveness of the quality management system; and
- (d) Ensuring the availability of resources needed by the quality management system (Clause 6).

# Clause 5.2 — Customer focus

3.3.5.3 This clause focuses attention on the application of the quality management principle of "customer focus". It emphasizes that top management must ensure that customer (i.e. aviation user) requirements are determined and met, so as to enhance customer satisfaction (Clauses 7.2.1 and 8.2.1).

## Clause 5.3 — Quality policy

3.3.5.4 The quality policy and quality objectives, as established by top management, provide the focus to direct the organization. Together they determine the desired results and guide the organization in allocating its resources to achieve these results. The quality policy provides the framework for establishing and reviewing the quality objectives. Clause 5.3 states that the quality policy must:

- (a) Be aligned with the overall business policy of the organization, that is, the provision of meteorological services for international air navigation;
- (b) Include a commitment to meeting requirements, primarily the Standards and Recommended Practices stipulated in ICAO Annex 3/WMO Technical Regulations [C.3.1] and the air navigation plan requirements, and continually improving the quality management system;
- (c) Be widely communicated throughout the organization; and
- (d) Be reviewed during regular management reviews (Clause 5.6) for continuing suitability.

#### Clause 5.4 — Planning

3.3.5.5 According to ISO 9000:2005, quality planning should be focused on setting quality objectives, specifying necessary processes and related resources to fulfil these objectives. Clause 5.4 requires that top management must ensure proper quality planning.

#### Clause 5.4.1 — Quality objectives

3.3.5.6 Top management has to ensure the establishment of quality objectives, which are quality-related goals aimed at relevant functions and levels within the organization. This does not imply that top management must define

quality objectives one by one, but that the achievement of these objectives is a priority, which should be made clear to all staff of the organization. Quality objectives include those needed to meet the requirements for products and must be measurable and consistent with the quality policy. Typical objectives for the provision of aviation meteorological services are discussed in Chapter 7.

#### Clause 5.4.2 — Quality management system planning

3.3.5.7 Top management has to ensure that quality management planning is conducted so that the general requirements given in Clause 4.1 and the quality objectives given in Clause 5.4.1 can be met. Control of changes to the system must also be implemented to preserve the integrity of the system. Within the broader context of the organization's operations, top management should exercise its authority and carefully consider any proposals for changes, in order to avoid any unexpected negative consequences prior to implementation.

#### Clause 5.5 — Responsibility, authority and communication

3.3.5.8 Clause 5.5 covers the requirements concerning how top management should administer the quality management system, including areas such as responsibility and authority, management representation and internal communications.

#### Clause 5.5.1 — Responsibility and authority

3.3.5.9 Top management needs to ensure that responsibilities and authority are properly defined, usually in the quality manual by means of organizational charts and job descriptions, and widely communicated within the organization.

#### Clause 5.5.2 — Management representative

3.3.5.10 A staff member, or a group of staff members, should be appointed as the management representative to help top management administer the quality management system. The specific responsibilities and authority of the management representative include the following:

- (a) Ensuring that all processes in the quality management system are established, implemented and maintained;
- (b) Reporting the performance of the quality management system to top management; and
- (c) Promoting awareness of customer requirements throughout the organization.

## Clause 5.5.3 — Internal communication

3.3.5.11 Top management must ensure that the effectiveness of the quality management system (requirements, objectives and performance) is also communicated widely within the organization.

#### Clause 5.6 — Management review

3.3.5.12 Management review is the process conducted by top management at planned intervals on a regular basis, for example annually, to evaluate the effectiveness and efficiency of the quality management system. It also assesses

the need for changes and opportunities for improvement to the system, including the quality policy and quality objectives. Records, usually in the form of management review meeting minutes or summary reports of the meetings, from such reviews, including the inputs, outputs and decisions and agreed actions, have to be maintained.

3.3.5.13 The required inputs to and outputs from the reviews are shown in Figure 3-2.

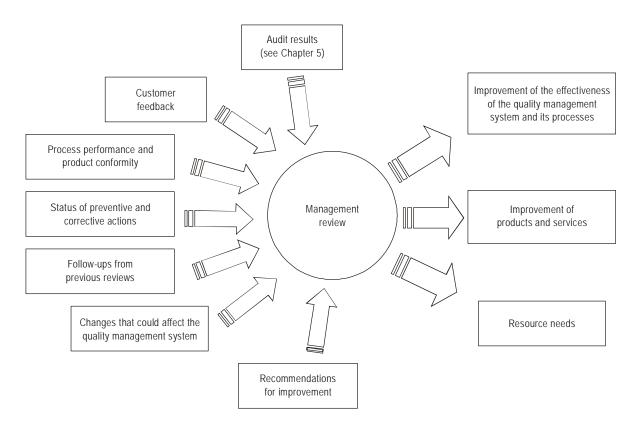


Figure 3-2. Inputs and outputs of a management review

#### 3.3.6 Clause 6 — Resource Management

3.3.6.1 Clause 6 covers requirements concerning the resources needed for the effective implementation of the quality management system.

#### Clause 6.1 — Provision of resources

3.3.6.2 The organization has to determine and make available the resources, in particular human resources, infrastructure and the work environment, needed to meet customer requirements and to implement and continually improve the quality management system.

#### Clause 6.2 — Human resources

3.3.6.3 The staff whose work affects product quality must be competent, appropriately educated and trained, skilled and experienced (Clause 6.2.1).

3.3.6.4 The organization has to determine the necessary competence for such staff. High-level guidance on the training needs of managers and key staff in meteorological offices serving aviation can be found in the *Guide to Practices for Meteorological Offices Serving Aviation* (WMO-No. 732). Detailed requirements for the qualifications and training of meteorological personnel in aeronautical meteorology are given in *Technical Regulations*, Volume I — *General Meteorological Standards and Recommended Practices* (WMO-No. 49) and the *Guidelines for the education and training of personnel in meteorology and operational hydrology* — Volume I, *Meteorology* (WMO-No. 258), complemented by *Initial formation and specialisation of meteorological personnel: Detailed syllabus examples* (WMO/TD No. 1101). The organization must provide adequate training to the staff, or take other appropriate actions to ensure that all staff are suitably qualified for the work assigned to them. The organization must also communicate to the staff their role and how they contribute to the achievement of the quality objectives. Records of education, training, skills and experience have to be maintained (Clause 6.2.2).

#### Clause 6.3 — Infrastructure

3.3.6.5 Infrastructure, which includes the workspace, process equipment (both hardware and software, for example computers and meteorological sensors) and supporting services such as communications facilities, has to be determined and maintained to achieve conformity to product requirements.

#### Clause 6.4 — Work environment

3.3.6.6 The work environment needed to achieve conformity with product requirements has to be determined and maintained. One particular issue in the context of the meteorological service provider is that a significant number of meteorological offices serving aviation are operating 24 hours a day. Appropriate and reasonable duty and shift arrangements have to be organized to cover all work required.

#### 3.3.7 Clause 7 — Product Realization

3.3.7.1 Clause 7 covers requirements concerning the entire production cycle, which involves determining product requirements, designing the product, acquiring the raw materials, manufacturing the product and delivery of the finished product.

#### Clause 7.1 — Planning of product realization

3.3.7.2 The organization has to plan and develop the processes needed for product realization. Planning of product realization must be consistent with the requirements of the other processes of the quality management system specified in Clause 4.1. In the planning process, the organization must determine, as appropriate, the following:

- (a) Quality objectives and requirements related to the product (Clause 7.2.1);
- (b) The need to establish processes, documents and provide resources specific to the product;
- (c) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; and

(d) Records required to prove that the realization processes and the resulting product meet requirements.

3.3.7.3 It should be noted that given the operational nature of the meteorological service providers, it is most likely that the products provided and the resources specific to the products have already been established. Additional resources, for example keeping extra records, may be required to maintain an effective quality management system but they should not be prohibitive. Verification, validation, monitoring, inspection, test activities and criteria for product acceptance may also already be in place so that it may not be necessary to establish additional processes or documents. The realization processes can be described concisely in the quality manual, augmented by procedures given in the operations manual.

#### Clause 7.2 — System-related processes

Clause 7.2.1 — Determination of requirements related to the product

- 3.3.7.4 The organization must determine requirements specified by the customer, including the following:
  - (a) Those for delivery and post-delivery activities, such as requirements for amended TAF or correction to meteorological reports;
  - (b) Requirements not specified by the customer but necessary for specified or intended use;
  - (c) Statutory and regulatory requirements related to the product; and
  - (d) Any additional requirements determined by the organization.

Note that most of the product and service requirements have already been determined and stated in ICAO and WMO regulatory documents and the relevant States' AIP.

Clause 7.2.2 — Review of requirements related to the product

3.3.7.5 The organization has to review the requirements related to the product determined in Clause 7.2.1 prior to committing to supply such a product to the customer. The review must ensure that:

- (a) All requirements related to the product are defined;
- (b) Any misunderstandings between the organization and the customer are resolved; and
- (c) The organization has the ability to meet the defined requirements.

Records of the review results and action arising from the review must be kept.

3.3.7.6 The organization must confirm the customer requirements before acceptance, if the customer has not already provided a documented statement of requirements.

3.3.7.7 When product requirements have been changed, for example amendments to Annex 3/WMO Technical Regulations [C.3.1], the relevant documents must be amended and the relevant parties made aware of the changes.

#### Clause 7.2.3 — Customer communication

3.3.7.8 The organization has to implement effective channels of communication with the customer in relation to product information, enquiries, contracts or order handling, amendments and customer feedback including complaints.

#### Clause 7.3 — Design and Development

3.3.7.9 Design is required in the production of a new product or of a variation to an existing product. Clause 7.3 covers the requirements for the organization to develop procedures for design and development of a product.

#### Clause 7.3.1 — Design and development planning

3.3.7.10 The organization must plan and control the design and development of the products and services it provides. In the planning stage, the organization has to determine the various stages involved, the review, verification and validation appropriate to each stage, and the relative responsibilities and authority. Effective communication and clear assignment of responsibility must be ensured when managing the interfaces between different groups involved in the design and development process. The planning output has to be appropriately updated as the design and development progresses.

#### Clause 7.3.2 — Design and development inputs

3.3.7.11 Product requirements that are complete, unambiguous and not in conflict with each other are necessary for any design. The organization has to determine and review these requirements as design and development inputs and must maintain records. The inputs include the following:

- (a) Functional and performance requirements;
- (b) Applicable statutory and regulatory requirements;
- (c) Information derived from previous similar designs, if applicable; and
- (d) Other requirements essential to design and development, for example cost and schedule for completion.

#### Clause 7.3.3 — Design and development outputs

- 3.3.7.12 The outputs must go through an approval process before they are released. They must:
  - (a) Meet the input requirements determined in Clause 7.3.2;
  - (b) Provide appropriate information for the subsequent product realization processes including purchasing (Clause 7.4), and production and service provision (Clause 7.5);
  - (c) Contain product acceptance criteria, or provide reference to them; and
  - (d) Specify the characteristics of the product that are essential for its safe and proper use.

### Clause 7.3.4 — Design and development review

3.3.7.13 The organization must, in accordance with the planned arrangements in Clause 7.3.1, perform systematic reviews to evaluate the ability of the design and development results, identify any problems and propose actions. The review needs to include all the functions affected. Records of the review results and any necessary action have to be maintained.

## Clause 7.3.5 — Design and development verification

3.3.7.14 The organization must, in accordance with the planned arrangements in Clause 7.3.1, verify that the design and development outputs meet all the input requirements determined in Clause 7.3.2. Records of the verification results and any necessary action have to be maintained.

# Clause 7.3.6 — Design and development validation

3.3.7.15 The organization must, in accordance with the planned arrangements in Clause 7.3.1, perform validation of the design and development to ensure that the product is capable of meeting the requirements for the specified application or intended use. If possible, the validation must be completed prior to the delivery or implementation of the product. Records of the validation results and any necessary actions have to be maintained.

# Clause 7.3.7 — Control of design and development changes

3.3.7.16 The organization must identify any design and development changes and have them reviewed, verified and validated, as appropriate, and approved before implementation. The review must include evaluation of the effect of the changes on the constituent parts and product already delivered. All records of the design and development changes, review results and any necessary action must be maintained.

# Clause 7.4 — Purchasing

3.3.7.17 Clause 7.4 establishes control on the purchasing phase during the product realization process to ensure good quality of purchased products. Note that the suppliers referred to under this clause include both external and internal suppliers.

# Clause 7.4.1 — Purchasing process

3.3.7.18 The organization has to ensure that the purchased product conforms to specified purchase requirements. It must evaluate and select suppliers based on their ability to supply product that meets the purchase requirements. Criteria for the selection of suppliers have to be established. In essence, tighter control must be applied to the supplier if the effect of the purchased product on subsequent product realization or final product is high.

3.3.7.19 The organization has to keep the records of the evaluation results and any necessary action arising from the evaluation.

# Clause 7.4.2 — Purchasing information

3.3.7.20 The organization must ensure adequacy of the specified purchase requirements including, where appropriate, the following:

- (a) Requirements for approval of the product and approval of procedures, processes and equipment employed by the supplier;
- (b) Requirements for qualification of supplier personnel; and
- (c) Requirements for the supplier to maintain a quality management system.

Note.— While it is not a mandatory requirement for every supplier of the meteorological service provider to maintain a quality management system, if the meteorological service provider has outsourced any of its core functions to third parties, it may be appropriate and necessary for the meteorological service provider to apply the tightest control to the suppliers and request them to maintain a quality management system.

Clause 7.4.3 — Verification of purchased product

3.3.7.21 The organization must establish and implement the inspection or other verification activities to ensure the purchased product meets the specified purchase requirements.

3.3.7.22 If verification is to be performed at the premises of the supplier, the organization must state such a requirement in the purchasing information (Clause 7.4.2) and the method of product release.

#### Clause 7.5 — Production and service provision

Clause 7.5.1 — Control of production and service provision

3.3.7.23 The organization has to control the process of planning and carrying out product and service provision. The control must include, as applicable, the following:

- (a) The availability of information that describes the characteristics of the product, for example technical specifications in the appendices to ICAO Annex 3/WMO Technical Regulations [C.3.1];
- (b) The availability of work instructions, i.e. operations procedures and manuals;
- (c) The use of suitable equipment such as computers, communication and office equipment;
- (d) The availability and use of monitoring and measuring devices such as pressure sensors and transmissometers;
- (e) The implementation of monitoring and measurement; and
- (f) The implementation of release, delivery and post-delivery activities.

Clause 7.5.2 — Validation of processes for production and service provision

3.3.7.24 Deficiencies in a product or service sometimes do not become apparent until after delivery. For example, the accuracy of forecasts and warnings cannot be verified until they have been delivered to the customer. This clause requires that the organization must validate the production and service provision processes for such products and services. The validation must be able to demonstrate the ability of the processes to achieve the planned results. Regular evaluation of the quality of aerodrome forecasts against the operationally desirable accuracy of the Standards as contained in Attachment B of ICAO Annex 3/WMO Technical Regulations [C.3.1] is an example of such validation.

3.3.7.25 The organization has to make arrangements for the processes that include, as applicable, the following:

- (a) Defined criteria for review and approval of the processes;
- (b) Approval of equipment and qualification of personnel;
- (c) Use of specific methods and procedures;
- (d) Requirements for records; and
- (e) Revalidation.

#### Clause 7.5.3 — Identification and traceability

3.3.7.26 The organization must identify the product by suitable means throughout the product realization. For example, a TAF, the identification of the type of forecast (for example TAF AMD), location indicator of the aerodrome, and time of issuance of forecasts, must be provided. The organization must also identify the product status with respect to monitoring and measurement requirements, for example signing hard copy reports or charts showing that they have been inspected or verified.

3.3.7.27 If it is a requirement that a product must be traceable to its origin, the organization must control and record the unique identification of the product. This traceability requirement is a must for virtually all the products provided by the meteorological service providers, for example the identification of the type of product (TAF, METAR, etc.), location indicator and time of issuance.

#### Clause 7.5.4 — Customer property

3.3.7.28 During the course of product realization, customer properties, which can include intellectual properties such as specifications, computer software or proprietary information, may sometimes be used by the organization. The organization must identify, verify, protect and safeguard such properties. In the event that customer properties are lost, damaged or otherwise unsuitable for use, the organization must report to the customers concerned and keep the relevant records.

#### Clause 7.5.5 — Preservation of product

3.3.7.29 The organization must preserve the conformity of product and constituent parts of the product during internal processing and delivery to the destination. The preservation includes identification, handling, packaging, storage and protection.

3.3.7.30 It is important for aviation safety that the observations, forecasts and warnings should be issued to the customer in accordance with the appropriate templates included in ICAO Annex 3/WMO Technical Regulations [C.3.1]. They should also be in the appropriate WMO code format, or in a format agreed with local customers. It is also important to ensure that the message received is the same as that originally issued. Where facilities are provided to enable customers to interrogate a central database for obtaining products provided by the meteorological service provider, the availability of the latest products in the correct format should be ensured. Where products are provided via the Internet, it is imperative to advise customers that they must ensure that they are accessing current product pages, and not cached product pages that may be out of date.

## Clause 7.6 — Control of monitoring and measuring equipment

3.3.7.31 This clause requires that the organization determine the monitoring and measurement, and the associated equipment, needed to provide evidence of conformity of product to the product requirements determined in Clause 7.2.1. Meteorological instruments such as dry- and wet-bulb thermometers, barometers, anemometers, transmissometers and scatterometers required for taking observations at the aerodrome are examples of monitoring and measuring devices.

3.3.7.32 The organization has to establish processes to ensure that monitoring and measurement can be carried out as planned and in a manner that is consistent with the monitoring and measurement requirements.

- 3.3.7.33 The measuring devices must be:
  - (a) Calibrated or verified 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 must be recorded;
  - (b) Adjusted or readjusted as necessary, but at the same time safeguarded from adjustments that would invalidate the measurements;
  - (c) Identified, enabling the calibration status to be determined; and
  - (d) Protected from damage and deterioration during handling, maintenance and storage.

3.3.7.34 The organization must record and maintain the results of calibration and verification. When the equipment is found not to conform to requirements, the organization has to assess and record the validity of previous measuring results, and take appropriate action on the equipment and the products affected.

3.3.7.35 Prior to initial use of any computer software in the monitoring and measurement of specified requirements, the organization must confirm the ability of the computer software to satisfy the intended application. An example of such computer software is a program used by a meteorological service provider for checking errors in coding TAFs before dispatch.

# 3.3.8 Clause 8 — Measurement, Analysis and Improvement

3.3.8.1 Clause 8 addresses requirements for monitoring and measuring the effectiveness of the quality management system of the organization, and conformity of its products, and continual improvement of the quality management system.

#### Clause 8.1 — General

3.3.8.2 This clause requires the organization to plan and implement the monitoring, measurement, analysis and improvement processes to demonstrate conformity of its quality management system and products, and to continually improve the effectiveness of the system.

3.3.8.3 The organization has to determine the appropriate methods to be used, such as:

- (a) The conduct and analysis of customer satisfaction surveys;
- (b) Counting the number of retard messages issued; and
- (c) Evaluation of supplier performance records.

## 3.3.8.4 Suitable statistical techniques such as:

- (a) Trend analysis, and
- (b) Sampling and statistical process control,

can be applied to identify the variations, irregularities or nonconformities in the processes, products and services.

#### Clause 8.2 — Monitoring and measurement

#### Clause 8.2.1 — Customer satisfaction

3.3.8.5 It is a specific requirement that the organization monitor customer satisfaction. The organization has to determine how this information can be collected, such as:

- (a) Through the conduct of customer surveys;
- (b) Customer complaint records; or
- (c) Regular liaison meetings with customers.

The information collected will be used to improve the quality management system.

#### Clause 8.2.2 — Internal audit

3.3.8.6 The organization is also required to conduct internal audits at planned intervals, typically at 6- or 12-month intervals between visits by registered auditors, to determine whether the quality management system conforms to various requirements stipulated in ISO 9001:2008 and whether the system has been effectively implemented.

3.3.8.7 A documented procedure has to be established to define the responsibilities and requirements for planning and conducting the audits, in particular:

- (a) The scope;
- (b) Frequency and methods to be used; and
- (c) Reporting the results and maintaining records.

Auditors selected must not be responsible for the product or processes being audited. For example, a forecaster could not be assigned as the internal auditor to audit the forecast process.

3.3.8.8 The manager responsible must ensure that, following each audit, prompt action is taken so that any nonconformities detected and their causes are rectified. Verification of the action taken must be conducted and the results reported.

3.3.8.9 More information on the conduct of internal audits is given in Chapter 5.

#### Clause 8.2.3 — Monitoring and measurement of processes

3.3.8.10 The quality management system processes must be monitored, and where applicable, measured to demonstrate the ability of the processes to achieve the planned results, in particular, the assurance that no nonconforming

product will be produced. Internal audit is one way to monitor and measure the processes. There are many other methods that can be applied, such as the use of suitable statistical techniques, or regular verification against the prescribed objectives of the processes.

3.3.8.11 It is essential that, when the planned results are not achieved, appropriate corrective action is taken to ensure conformity of the product.

#### Clause 8.2.4 — Monitoring and measurement of product

3.3.8.12 By the same token, the quality of the products has to be monitored and measured, at appropriate stages during the product realization process, to verify that they meet the product requirements. It is required that evidence of conformity with the acceptance criteria be maintained and that records indicate the personnel responsible for the release of the product. For example, implementation of automatic quality checking routines, along with the requirement to sign the TAF issued by the duty forecasters after a satisfactory product checking, are considered evidence of product conformity.

Note.— In the event that the quality of a product cannot be monitored and measured before delivery, Clause 7.5.2 of ISO 9001:2008 then applies, such that the process for production provision must be validated to demonstrate its ability to produce the planned results (see 3.3.7.23).

3.3.8.13 A product must not be released to customers before the satisfactory completion of all planned arrangements from the planning of product realization process (Clause 7.1). Exception is allowed under extraordinary situations, that is, when the relevant authority within the organization authorizes the release of the product and, where applicable, upon the approval of the customers.

#### Clause 8.3 — Control of nonconforming product

3.3.8.14 Nonconforming products have to be identified and controlled to prevent them from being inadvertently released. The organization must establish a documented procedure detailing the control, associated responsibilities and authority for dealing with those nonconforming products.

3.3.8.15 Nonconforming products must be handled in one of the following ways:

- (a) Reworked to eliminate the nonconformity detected, followed by reverification to demonstrate conformance;
- (b) Isolation or scrapping of the nonconforming products; or
- (c) Their release authorized by the relevant authority and, where applicable, upon the approval of the customers.

3.3.8.16 In the event that nonconforming products are detected after delivery, the organization has to take appropriate action regarding the effects, or potential effects, of the nonconformity, for example issuance of correction messages.

3.3.8.17 The organization has to maintain records of the nature of the nonconformities and the subsequent actions taken (3.3.8.15 refers).

#### Clause 8.4 — Analysis of data

3.3.8.18 The organization must determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system, and to evaluate the opportunities for continual improvement of system

effectiveness. The data can be generated by the monitoring and measurement processes conducted by the organization (Clause 8.2) or from other relevant sources, both internal and external, for example evaluation of supplier performance and audit reports.

- 3.3.8.19 Information relating to the following must be provided through the analysis of data:
  - (a) Customer satisfaction;
  - (b) Conformity to product requirements;
  - (c) Characteristics and trends of processes and products including opportunities for preventive action; and
  - (d) Performance of suppliers.

#### Clause 8.5 — Improvement

#### Clause 8.5.1 — Continual improvement

3.3.8.20 This requires the organization to seek continual improvement to the effectiveness of the quality management system through the use of the following:

- (a) Quality policy (Clause 5.3);
- (b) Quality objectives (Clause 5.4.1);
- (c) Audit results, including those from both internal (Clause 8.2.2) and external audits;
- (d) Analysis of data (Clause 8.4);
- (e) Corrective and preventive action (Clauses 8.5.2 and 8.5.3); and
- (f) Management review (Clause 5.6).

## Clause 8.5.2 — Corrective action

3.3.8.21 The organization has to take corrective action to prevent recurrence of detected nonconformities. ISO defines corrective action as "action to eliminate the cause of a detected nonconformity or other undesirable situation" (ISO 9000:2005, Clause 3.6.5). The organization must develop a documented procedure to define requirements for the following:

- (a) Reviewing nonconformities and determining their cause;
- (b) Evaluating the need for a corrective action;
- (c) Determining and implementing action needed;
- (d) Recording the results of action taken; and
- (e) Reviewing corrective action taken.

#### Clause 8.5.3 — Preventive action

3.3.8.22 The organization has to determine the preventive action needed to prevent the actual occurrence of potential nonconformities. ISO defines preventive action as "action to eliminate the cause of a potential nonconformity or other undesirable potential situation" (ISO 9000:2005, Clause 3.6.4). Potential nonconformities can be revealed in various ways, such as outputs from management review (Clause 5.6), outputs from analysis of data (Clause 8.4), review of customer needs and expectations, and risk analysis.

- 3.3.8.23 Again the organization must develop a documented procedure to define the requirements for the following:
  - (a) Identifying potential nonconformities and their cause;
  - (b) Evaluating the need for a preventive action;
  - (c) Determining and implementing action needed;
  - (d) Recording the results of action taken; and
  - (e) Reviewing preventive action taken.

### Chapter 4

### **QUALITY MANAGEMENT SYSTEM DOCUMENTATION**

### 4.1 STRUCTURE OF QUALITY MANAGEMENT SYSTEM DOCUMENTATION

4.1.1 The ISO 9000 series of standards requires that the quality management system be properly documented. In addition to describing the quality management system, 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 quality management system. The documentation in the quality management system is constructed in a hierarchical form as shown in Figure 4-1.

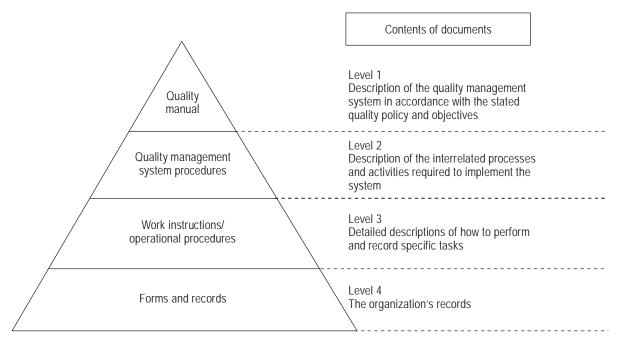


Figure 4-1. Hierarchy of quality management system documentation

4.1.2 Level 1 documentation defines the principles and approaches of the meteorological service 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 meteorological service provider manages the quality management system. It corresponds to the processes described in Clauses 4 through 8 of ISO 9001:2008. Note that while ISO 9001:2008 explicitly requires a minimum of six documented procedures respectively on the following:

- control of documents (Clause 4.2.3)
- control of records (Clause 4.2.4)

- internal audit (Clause 8.2.2)
- control of nonconforming product (Clause 8.3)
- corrective action (Clause 8.5.2) and
- preventive action (Clause 8.5.3),

the meteorological service 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 quality management system. Records explicitly required by ISO 9001:2008 are listed in Appendix 1.

4.1.6 In essence, the quality management system documentation usually includes the following:

- (a) Quality policy and objectives an explicit requirement;
- (b) Quality manual an explicit requirement;
- (c) Documented procedures an explicit requirement;
- (d) Work instructions/operational procedures implicitly required by Clause 4.2.1 of ISO 9001:2008;
- (e) External documents documents which can include specifications, statutory and regulatory requirements, standards, codes, etc. ICAO Annex 3/WMO Technical Regulations [C.3.1], States' AIPs and regional air navigation plans also fall under this category; implicitly required by Clause 4.2.1 of ISO 9001:2008;
- (f) Forms and records an 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 9000:2005). 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 meteorological service 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 meteorological service 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 quality management system 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 meteorological service providers, extensive work instructions and operational procedures should naturally be expected for the realization of products and services (i.e. meteorological reports, forecasts, warnings and briefings and consultations to users, etc.). Whenever appropriate, reference to the relevant external documents containing the product requirements, such as ICAO Annex 3/ WMO Technical Regulations [C.3.1], States' AIPs and the regional air navigation plans, should be incorporated.

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 meteorological service provider has performed and, therefore, would indicate whether or not the quality management system 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 QUALITY MANUAL

4.2.1 Clause 4.2.2 of ISO 9001:2008 requires the development of a quality manual for the meteorological service provider. The quality manual is the home for all quality management system documentation of the meteorological service provider from which the staff or auditors could easily locate the documentation. The manual must include or make reference to the quality policy and documented quality procedures of the meteorological service provider and provide a description of interaction between the quality management system processes.

4.2.2 The manual has to address all applicable clauses of ISO 9001. One way to embark on the preparation of the quality manual is to adapt the ISO clauses by replacing every reference to phrases such as "the organization shall ..." with "we will ...", and for clarification supplement them with additional text specific to the meteorological service provider. The combined statements then become the meteorological service provider's own statements to be included in its quality manual.

4.2.3 Typical elements of a quality manual consist of the following:

- (a) Title and scope the manual should make reference to the specific quality management system standard (i.e. ISO 9001) on which the quality management system is based;
- (b) Table of contents;
- (c) Review, approval and revision evidence of the review, approval, revision status and date of the quality manual should be clearly stated;
- (d) Quality policy and objectives can be separately documented but referenced in the manual or be included in the quality manual;
- (e) Organization, responsibility and authority a description of the structure of the organization is to be included. Organization charts, flow charts and job descriptions may be included or referenced in the manual;

- (f) References a list of documents referred to but not included in the manual;
- (g) Quality management system description descriptions of the processes and their interactions, documented procedures or references to them are to be included; and
- (h) Appendices any supportive information such as flow charts of processes and organization charts.

### 4.3 CONTROL OF DOCUMENTS

4.3.1 ISO 9001:2008 describes what has to be documented in the quality management system but it does not specify the format for the various documents or records required. The meteorological service provider can thus align the quality management system documentation format with that of the organization. Nevertheless, it is recommended that the meteorological service providers use a consistent format for preparing the documentation. A control status must be included so that the document in question could be readily identifiable as current or obsolete, for example by way of stamp chop such as "CONTROLLED COPY" to properly label those controlled copies of documents and to mark those obsolete documents that need to be retained as "SUPERSEDED". In general, written documentation for the documented procedures, work instructions and operational procedures should include the following:

- (a) Name and logo of the meteorological service provider;
- (b) Title, purpose and scope of document;
- (c) Document number, revision status and date of issuance;
- (d) Review and approval signatures;
- (e) Responsibility and authority;
- (f) History of past amendments; and
- (g) Content of document.

4.3.2 It should be remembered that the quality management system documentation can exist in any form — hard copy or electronic format. The use of electronic media, for example the intranet of the meteorological service provider, is increasingly common and has the following advantages:

- (a) Staff always have access to the current copies of the documents;
- (b) Distribution is much simplified and efficient;
- (c) Access and changes can easily be made and controlled;
- (d) Access from remote locations is possible, given the staff have the necessary equipment to view the documentation at such locations; and
- (e) The possibility of unintended use of obsolete documents is eliminated.

Note.— As records by nature do not change, normally they are not under revision control, which is required for other quality management system documentation.

### 4.4 ISO GUIDANCE

A complete description and guidance on how to document a quality management system can be found in ISO 10013:2001 — *Guidelines for quality management system documentation.* 

### 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 9000:2005). 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 quality management system documentation. The policies and procedures are developed by the meteorological service provider and the requirements may originate from ISO 9001:2008, users, regulatory and legislative bodies and the meteorological service provider itself. During the audit, the certification body/registrar will try to verify if the meteorological service provider is doing what it says it will do (according to the quality management system documentation) and to confirm if the quality management system is effectively implemented.

5.1.2 While the obvious reason for the meteorological service provider to conduct an audit is to obtain or retain the ISO 9000 certification, the real importance of such audits is to confirm that the quality management system 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 as follows:

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

### 5.2 AUDIT TYPES

#### 5.2.1 First-party Audit

First-party audit refers to an internal audit conducted by, or on behalf of, the meteorological service 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 quality management system 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 meteorological service provider and the quality management system for the next visit of the certification body/registrar.

### 5.2.2 Second-party Audit

Second-party audit refers to an audit conducted by an interested party, such as a user of the meteorological service provider or ICAO/WMO. The meteorological service provider may be audited by a user for the purpose of awarding a service contract, or evaluating the performance of the meteorological service provider.

### 5.2.3 Third-party Audit

5.2.3.1 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 meteorological service provider to consistently provide services that meet the user and applicable regulatory requirements, thereby eliminating the need for repeating second-party audits conducted by various interested parties.

5.2.3.2 Second- and third-party audits are collectively known as "external audits".

### 5.3 PROCESS AUDITING APPROACH

5.3.1 ISO 9000:2005 promotes the adoption of "process approach" in implementing the quality management system. Consequently, in contrast with the audits described in previous versions of ISO 9000 that focused on procedure compliance and record verification, the ISO 9000:2005 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 meteorological service 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 meteorological service provider. Upon satisfactory completion of the certification/registration audit, the quality management system of the meteorological service 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 meteorological service provider, and one or more auditors depending on the size and scope of the quality management system being audited. Technical experts, and in particular in the meteorological field, may be employed by the certification body/registrar to assist in dealing with technical matters related to meteorology 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 quality management system documentation including, among others, the quality manual, external documents that contain information on users of the meteorological service 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 quality management system. This process is called "document review" or "adequacy audit".

5.4.4 The second phase of the certification/registration audit refers to the actual on-site audit of the quality management system. 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 meteorological service provider and observing their work. They will sometimes ask to inspect certain documents, samples of products or the records maintained by the meteorological service 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 meteorological service provider. The auditors should advise of any nonconformity identified in the quality management system during the audit. All such nonconformities must be corrected within a certain time period as agreed between the certification body/registrar and the meteorological service provider. 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 nonconformities 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 quality management system before the actual audit is carried out. This preliminary assessment could be very useful to the meteorological service provider especially if it has not had the assistance of consultants or experienced ISO 9000 auditors in the implementation process of the quality management system.

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 quality management system. For example, it will normally take three auditor days to complete the initial certification/registration audit of a meteorological service provider with 20 employees.

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

### 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 quality management system 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 quality management system with regard to achieving the organization's objectives, changes and improvements implemented to the quality management system since the last visit, areas that have generated nonconformities and results of the corrective actions taken by the meteorological service provider. The minimum frequency of surveillance audits is once every 12 months, but some certification bodies/registrars will audit once every 6 months.

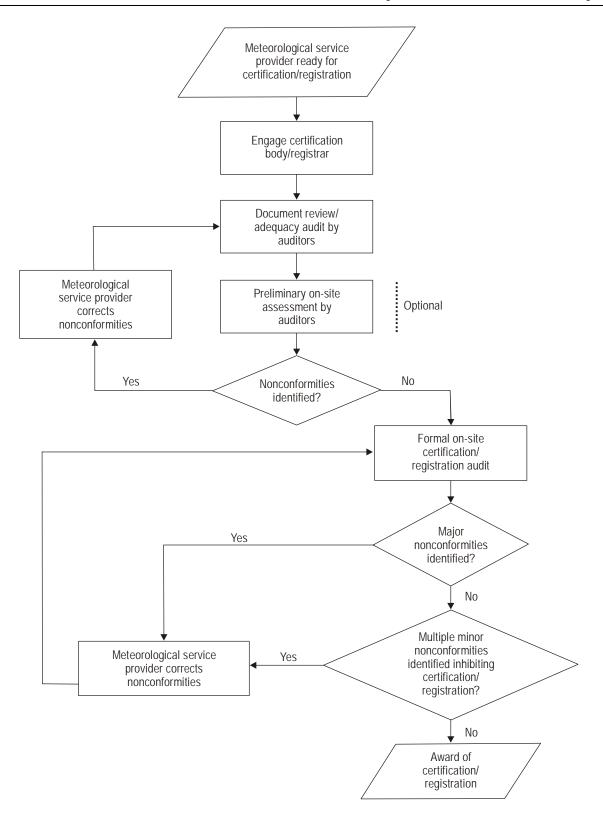


Figure 5-1. Steps of certification/registration audit

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 quality management system should be implemented as an internal improvement instrument or as an external business tool in most cases involving aviation services.

### 5.6 ISO GUIDANCE

ISO has published ISO 19011:2002, *Guidelines for Quality and/or Environmental Management Systems Auditing,* to provide guidance on auditor qualification and managing audit programmes for both internal and external auditing of the quality management system.

### Chapter 6

### NONCONFORMANCE REPORTS AND CORRECTIVE ACTION

### 6.1 TYPES OF NONCONFORMITY — MAJOR AND MINOR NONCONFORMITIES

6.1.1 The monitoring and measuring processes of the system may reveal nonconformities<sup>1</sup> of the quality management system (Clause 8.2 of ISO 9001:2008). They may also be revealed during the certification/registration process by the external auditors, or by subsequent surveillance audits. Nonconformities are material non-fulfilment of a quality management system requirement that includes the ISO 9001 requirements, standards set out in relevant ICAO and WMO regulatory documents, and any other applicable statutory and regulatory requirements. Two levels of nonconformities are defined, as follows:

(a) Minor nonconformity;

A single lapse in implementing a quality management system requirement is seen as an anomaly rather than a systematic issue, for example the copy of ICAO Annex 3/WMO Technical Regulations [C.3.1] kept at the forecaster's bench has not been updated to the latest edition. This is non-compliant with Clause 4.2.3 (g) of ISO 9001:2008 concerning the control of documents.

(b) Major nonconformity;

A failure to fulfil any requirement of ISO 9001 or the identification of multiple minor nonconformities sufficient for the auditors to conclude that the quality management system is not effectively implemented, for example management reviews as required by Clause 5.6 of ISO 9001:2008 to ensure the continuing suitability, adequacy and effectiveness of the quality management system have never been performed.

6.1.2 Major nonconformities inhibit certification during the certification/registration audit and continued certification/ registration during surveillance audits, but minor nonconformities do not necessarily cause the certification body/registrar to withhold certification.

### 6.2 OBSERVATIONS AND POTENTIAL NONCONFORMITIES

6.2.1 In addition to major and minor nonconformities, potential nonconformities of the quality management system, or alternatively termed as "observations" by the auditors, may also be identified. These potential nonconformities or observations represent anomalies, in the absence of evidence to support an actual nonconformity, in the quality management system that may impair the effectiveness or conformance of the system.

<sup>1.</sup> Differences between national practices of the meteorological service provider and the Standards contained in ICAO Annex 3/WMO Technical Regulations [C.3.1] will not be reported as nonconformities by the auditors provided that the differences are duly notified to ICAO/WMO and no air navigation deficiencies are raised in connection with such differences by users. However, an air navigation deficiency for any non-compliance with ICAO Annex 3/WMO Technical Regulations [C.3.1] or air navigation plans represents persistent failures of the meteorological service provider to meet certain stated requirements. It indicates the existence of a major nonconformity in the quality management system.

6.2.2 Observations or potential nonconformities have a low impact on the effectiveness of the quality management system. However, they may develop into actual nonconformities if appropriate action is not taken to correct them.

### 6.3 CORRECTIVE ACTION PROCESS

6.3.1 The auditors will compile a nonconformance report when a major/minor nonconformity is discovered. A corrective action request form will also have to be completed to document the nonconformity. The meteorological service provider and the auditors should agree to a formal schedule to complete the corrective action for the identified nonconformities. A corrective action request cannot be considered closed until the satisfactory completion of the planned corrective action and the lead auditor (leader of the audit team) has signed off to indicate that has been done.

6.3.2 In general each nonconformity will go through the following stages:

- (a) An auditor identifies a nonconformity;
- (b) The auditor completes a nonconformance report and a corrective action request form;
- (c) Findings are presented to and agreed with the auditee (the meteorological service provider);
- (d) The target date for the nonconformity to be addressed is agreed;
- (e) The meteorological service provider determines the appropriate corrective action based on the cause of the nonconformity;
- (f) The meteorological service provider takes the corrective action and verifies if it is effective. Repeat step (e) if it is not;
- (g) The auditor verifies the effectiveness of the corrective action taken during the next auditor visit or by evaluating the evidence or written response submitted by the meteorological service provider;
- (h) Repeat steps (d) to (g) if the auditor is not satisfied;
- (i) The lead auditor signs off the corrective action request form and the case is formally closed.

6.3.3 The meteorological service provider should ensure that prompt action is also taken against any nonconformities/potential nonconformities identified through the monitoring and measuring processes of the quality management system. ISO 9001:2008 requires that a documented procedure be established on corrective action and preventive action respectively (Clauses 8.5.2 and 8.5.3 of ISO 9001:2008). The meteorological service provider should follow these procedures to eliminate the causes of the internally identified or potential nonconformities in an expeditious manner.

### Chapter 7

### **STEPS TO CERTIFICATION AND OTHER PRACTICAL ISSUES**

### 7.1 STEPS TO CERTIFICATION

There are a number of steps that the meteorological service provider will go through in the development and implementation of a quality management system, and ultimately taking the system to certification. These steps typically include the following:

(a) Commitment from top management;

It is of foremost importance to obtain a formal and strong commitment from the highest level of management as it has to allocate all the necessary resources required by the quality management system.

(b) Setting up of a project team;

This involves the appointment of a project team leader who will eventually become the management representative in the quality management system. The work of the project team should be directed by the Chief Executive or Director of the meteorological service provider, or a steering committee chaired by senior management. As a starting point, the project team will prepare the budget estimate and seek financial commitment from top management.

(c) Engagement of a consultant;

Additional costs will be incurred for engaging an external consultant but the consultant will guide the meteorological service provider throughout the implementation process. In particular, the consultant will assist in the preparation of the quality management system documentation to ensure that every requirement of ISO 9001 is properly addressed. Alternatively, the development of the quality management system can be done totally in-house. To this end, senior staff who are familiar with the operation of the meteorological service provider can be provided with intensive training in the ISO 9000 series of standards. They would then take up the assignment as the internal consultants in helping the meteorological service provider to achieve ISO 9000 certification. It may be possible for such capacity-building training courses to be organized centrally or on a regional basis to make them more cost-effective.

(d) Process and gap analysis;

The existing key business and quality processes of the meteorological service provider will be identified and documented (see 7.3). This is to be followed by an objective assessment on these processes, to determine what needs to be done to close the gap and meet the requirements of ISO 9001.

(e) Formal training;

This should be provided to the entire workforce of the meteorological service provider or section seeking ISO 9000 certification. It is an integral part of the quality management system. The training should include the following:

- Basic awareness training for all staff to increase their awareness about the quality management system;
- Documentation writing for staff who are responsible for the preparation of documentation required by ISO 9001; and
- Internal auditor training for staff selected to conduct the internal audits.
- (f) Documentation;

The quality policy and objectives, quality manual, documented procedures for various processes as appropriate and quality records will be developed and communicated to all staff. Details on the documentation required by the year 2000 version of ISO 9001 (ISO 9001:2008) can be found in Chapter 4.

(g) Formal implementation of the quality management system;

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 (see Chapter 2, 2.6.2).

(h) Internal audit;

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

(i) Certification/registration audit;

The successful completion of the above steps would indicate that the meteorological service provider is ready to proceed with the certification/registration audit. Normally the certification bodies/registrars will request that the quality management system be running for at least three months before they are convinced that the system has been implemented successfully and is ready for the certification/ registration audit. Detailed descriptions of a certification/registration audit are provided in Chapter 5, 5.4.

### 7.2 TIME AND COST CONSIDERATIONS

7.2.1 With the assistance of outside consultants, the whole process from implementation to certification would typically take from 12 to 18 months to complete. Should the implementation be performed totally in-house, the completion period may need to be prolonged as the internal consultants appointed may work only part-time. The period actually required does vary considerably and is dependent on the scope and complexity of the quality management system to be implemented and whether or not some form of quality management practices and/or procedures is already in place.

7.2.2 In general, the costs involved in the implementation and certification of a quality management system should include the following:

(a) Wages for quality function personnel;

- (b) Consultancy;
- (c) Training;
- (d) Internal audits;
- (e) Certification/registration audit and certification cost; and
- (f) Incentives to staff, if any.

7.2.3 Any costs associated with the implementation of the quality management system for the meteorological service provider can be subject to cost recovery following the ICAO *Manual on Air Navigation Services Economics* (Doc 9161), specifically paragraphs 6.16 and 6.18, and Appendix 3 — Guidance for determining the costs of aeronautical meteorological services, and the WMO *Guide on Aeronautical Meteorological Services Cost Recovery* (WMO-No. 904).

# 7.3 PROCESS ANALYSIS FOR THE METEOROLOGICAL SERVICE PROVIDER

7.3.1 To embark on the analysis and documentation of the processes needed by the quality management system of the meteorological service provider, it is convenient to start from the process-based quality management system model introduced in ISO 9001:2008 (see Figure 3-1). The model basically covers all the requirements of ISO 9001:2008, however, it only shows the major processes and their linkages at the highest level, namely the following:

- (a) Respective process for management responsibility (Clause 5 of ISO 9001:2008);
- (b) Resource management (Clause 6 of ISO 9001:2008);
- (c) Product realization (Clause 7 of ISO 9001:2008); and
- (d) Measurement, analysis and improvement (Clause 8 of ISO 9001:2008).

The meteorological service provider needs to identify and describe the subprocesses and their sequence and interaction, for example in the form of a series of process flow diagrams, so that proper control can be placed on each of the processes.

7.3.2 It is important to remember that there is no need to control every activity. It would be adequate to only focus on and develop procedures for those activities that have an impact on the quality of the products and services provided to the users. Typically, management review and provision of training should be the key process of management responsibility and resource management respectively. The existing operational activities or processes of the meteorological service provider would naturally combine to form the product realization process. The key processes involved and their interaction under product realization for a typical meteorological service provider may be similar to that described in Figure 7-1.

7.3.3 To address the requirements set out in ISO 9001:2008, the measurement, analysis and improvement process may, as a minimum, be subdivided into the process of internal audit, the process of customer satisfaction, products and processes monitoring, and also the process of analysis of data. For the last major block of continual improvement, two key processes, namely the corrective action and the preventive action, are explicitly required by ISO 9001:2008 (Clauses 8.5.2 and 8.5.3).

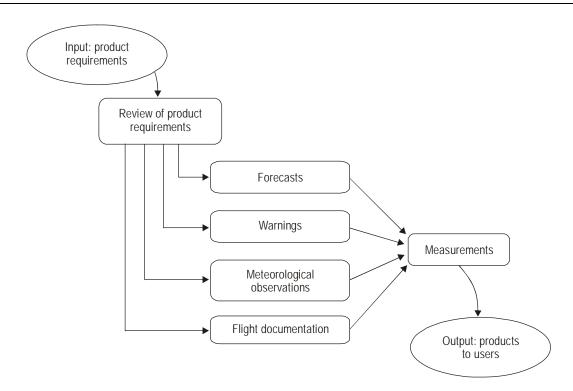


Figure 7-1. Key process of product realization

### 7.4 PERFORMANCE INDICATORS FOR METEOROLOGICAL PRODUCTS AND SERVICES

7.4.1 It is required by ISO 9001:2008 that performance of the quality management system be measured (Clause 8.1). In particular, information on customer satisfaction has to be monitored by the meteorological service provider (Clause 8.2.1). Measurements are extended to the monitoring and measurement of the products and also the quality management system processes (Clauses 8.2.3 and 8.2.4).

7.4.2 The measurements are to be compared against the prescribed quality objectives. The quality objectives, as determined by management, should be measurable and consistent with the quality policy (Clause 5.4.1 of ISO 9001:2008). The performance indicators that are of particularly relevance to the meteorological service provider are as follows:

- (a) Satisfaction rate of airline/aircrew customers;
- (b) Timely implementation of new/modified ICAO/WMO standards;
- (c) Number of corrected or retard messages issued;
- (d) Timely issuance of flight documents to airline operators;
- (e) Timely preparation of routine reports; and
- (f) Accuracy of forecasts issued.

### 7.5 INTERFACING ASPECTS WITH EXTERNAL SYSTEMS

7.5.1 Meteorological service providers rely on the products provided by a number of suppliers external to the quality management system in the provision of weather services for international air navigation. These external suppliers include the following:

- The two world area forecast centres (WAFCs) for supply of global forecasts of upper winds and temperatures, and significant en-route weather for upper levels;
- The nine volcanic ash advisory centres (VAACs) for advisory information on the extent and forecast
  movement of volcanic ash in the atmosphere following volcanic eruptions; and
- The seven tropical cyclone advisory centres (TCACs) for advisory information on the position, forecast movement and intensity of tropical cyclones.

7.5.2 These products constitute the major sources of information required by meteorological service providers in the product realization process and will therefore have a profound effect on the quality of the services provided by the meteorological service providers. It is in this aspect that Clause 7.4 of ISO 9001:2008 on purchasing process will apply and the meteorological service providers should exercise tight control on the products provided by these external suppliers (inspections, follow-up actions, etc.). It is important for these external suppliers to assist the meteorological service providers by establishing and maintaining their own quality management systems, that should preferably be in conformity with the ISO 9000 series of standards. If the meteorological services is assured and having their quality management system certified/registered.

#### 7.6 ISO ASSISTANCE FOR DEVELOPING COUNTRIES

ISO has established the ISO Committee on developing country matters (DEVCO) to identify the needs and requirements of the developing countries relating to standardization. It also provides a forum for the discussion of all aspects of standardization activities in developing countries. DEVCO also provides its developing country members with regular information about courses on standardization that are available worldwide. ISO programmes for developing countries are drawn up on a three-yearly basis and implemented by DEVCO to assist these countries. The assistance provided through these programmes includes training, preparation and publication of development manuals, seminars, sponsorships/fellowships and other activities. Further details about the programmes can be obtained from the ISO website at http://www.iso.org.

### Chapter 8

## HONG KONG, CHINA CASE STUDY (2002)

### 8.1 BACKGROUND

8.1.1 This case study is written based on the experience of the Hong Kong Observatory in implementing a quality management system for its aviation weather service and obtaining the ISO 9000 certification of the system.

8.1.2 The Hong Kong Observatory, the designated meteorological authority of Hong Kong, China, operates the airport meteorological office at the Hong Kong International Airport. The airport meteorological office, with a total of 23 employees, serves as the aerodrome meteorological office and aeronautical meteorological station at the Hong Kong International Airport, and the meteorological watch office for the Hong Kong airspace. It embarked on quality management in late 2001 and a quality management system in conformity with the ISO 9000 series of standards was implemented in early 2002. An accredited certification body awarded certification to the ISO 9001:2008 standard in late 2002.

8.1.3 As the Management Representative of the airport meteorological office has remarked, "the certification of the Hong Kong aviation weather service demonstrates to the aviation community that the products and services provided by the airport meteorological office meet the standards that have come to be expected internationally. It also enhances user satisfaction by assuring to the user that continual improvement to the system remains a permanent objective."

### 8.2 QUALITY POLICY

The quality policy as endorsed by the directorate/management of the Hong Kong Observatory is:

"Provide professional meteorological service for international air navigation.

Aim at complying with all relevant requirements, standards and regulations and ensuing continued enhancement of the service levels, operations and effectiveness of the quality management system."

### 8.3 STEPS FOLLOWED THAT LED TO THE CERTIFICATION OF THE QUALITY MANAGEMENT SYSTEM

8.3.1 The officer-in-charge of the airport meteorological office was appointed the Management Representative to spearhead the project. A Deputy Management Representative was also appointed to assist the Management Representative. The Management Representative prepared the budget and sought financial commitment from the management of the Hong Kong Observatory.

8.3.2 An external consultant was contracted to guide the airport meteorological office through the process of quality management system implementation.

8.3.3 The operational and quality processes of the airport meteorological office were reviewed and the disparity between these processes and the ISO requirements were identified. Procedures were then developed to eliminate the differences.

8.3.4 Formal training on basic awareness to all staff, documentation writing to those involved in preparing documentation, and internal audit to internal auditors were provided by a consultant. One of the senior staff in the airport meteorological office was also nominated to attend the International Register of Certificated Auditors (IRCA)-certified ISO 9000 Series Auditor/Lead Auditor Training Course.

8.3.5 The quality management system documentation, which includes the quality policy and objectives, quality manual, quality management system procedures, operational manuals and work procedures, forms and records, was developed.

8.3.6 Regular meetings were held with the consultant to resolve issues related to the implementation of the quality management system. The quality management system was formally launched following a system implementation briefing to all staff to raise their awareness of the system that had been set up for the airport meteorological office.

8.3.7 The quality management system was allowed to run for six months to familiarize staff with the system and to verify that it was implemented and maintained effectively.

8.3.8 A formal internal audit was then performed to detect and remove any nonconformities in the quality management system in preparation for the initial certification audit.

8.3.9 Following the formal internal audit, a mock certification audit was conducted by the consultant as the final check.

8.3.10 The initial certification audit was conducted by an accredited certification body which had been selected and appointed earlier following the formal implementation of the quality management system.

8.3.11 The entire process from start to finish took about 16 months to complete. The implementation timetable followed by the airport meteorological office is as shown in Table 8-1.

044444		2007				2002											
	Stages	J	А	S	0	Ν	D	J	F	М	А	М	J	J	А	S	0
1.	Engagement with an external consultant																
2.	Process and gap analysis																
3.	Formal training																
4.	Preparation of documentation																
5.	System implementation																
6.	Maintenance of system																
7.	Internal audit																
8.	Mock certification audit by consultant																
9.	Certification audit																

# Table 8-1. Action plan and timetable of implementation of quality management systemby the Hong Kong Observatory

### 8.4 DOCUMENTATION SYSTEM PUT IN PLACE

8.4.1 *Level 1 documentation* consists of the quality manual, quality policy and objectives. The established quality objectives, along with an outline of the airport meteorological office quality manual are given in Appendix 2, A and B.

8.4.2 Level 2 documentation consists of the quality management system procedures describing how the quality management system is managed. A list of the quality management system procedures maintained by the airport meteorological office is given in Appendix 2, C. An example of the procedures on control of nonconforming product (one of the six mandatory documented procedures required by ISO 9001:2008) is also reproduced in Appendix 2, D.

8.4.3 Level 3 documentation consists of two sets of documents. The first is an operational forecasting manual, which details the services provided to various users, namely flight crew members, airline operators, air traffic services units, Hong Kong airport authority, search and rescue services, and overseas meteorological services, etc. It also describes the equipment and facilities and forecasting techniques available for use by the airport meteorological office staff in the provision of service. The second is a set of procedure manuals containing the detailed work instructions for each operational staff position in the airport meteorological office, namely the aviation forecasters, assistant aviation forecasters, weather observers and weather service officers. An example of the work instructions on reporting of special observations for the weather observers is given in Appendix 2, E.

8.4.4 *Level 4 documentation* consists of all quality forms and records of the quality management system. As an example, the corrective/preventive action request form being used by the airport meteorological office is reproduced in Appendix 2, F.

Note.— Examples of documentation are included in Appendix 2 to illustrate the format required and the desirable level of detail of the documentation. They represent a snapshot of the documentation of the quality management system taken in December 2004. The documents are subject to changes arising from new user, statutory or regulatory requirements, and the continual improvement process of the system.

### 8.5 SPECIFIC MONITORING AND MEASUREMENT ACTIVITIES EMPLOYED

8.5.1 A user survey is conducted every year to monitor information on user perception as to whether the airport meteorological office has met user requirements. Liaison group meetings are held twice a year for face-to-face discussion with airline operators and pilots to listen to their suggestions and feedback on the services provided. The liaison group meetings also provide a forum for considering agreements on local arrangements in the provision of the services as stipulated in ICAO Annex 3/WMO Technical Regulations [C.3.1].

8.5.2 Regular meetings with air traffic personnel, and visits to airlines and to the airport meteorological office are conducted to foster better mutual understanding. A working group comprising representatives from the user community has also been set up to discuss issues specifically related to the wind shear and turbulence warning services provided by the airport meteorological office for the Hong Kong International Airport.

8.5.3 User suggestions and feedback are formally recorded and followed up. Formal response will be given to the user before a suggestion or feedback is considered closed.

8.5.4 All meteorological instruments are calibrated regularly for traceability to international or national standards following the *Guide to Meteorological Instruments and Methods of Observation* (WMO-No. 8). Where international or national standards are not available, the basis for calibration will be defined or supplied by the manufacturer, for example, in the case of the runway visual range transmissometers. Procedures have also been established for the observers to check the official recording instruments against their standbys when making observations to ensure that the instruments are working properly.

8.5.5 A forecast verification system has been developed to monitor the accuracy of the aerodrome forecasts issued by the airport meteorological office in accordance with the ICAO/WMO guidance on the desirable accuracy of each of the weather elements (Attachment B of ICAO Annex 3/WMO Technical Regulations [C.3.1] refers).

8.5.6 The technical know-how of all aviation forecasters is audited on an annual basis by way of a self-audit check form.

8.5.7 In addition to the yearly management reviews, an operation and management group comprising representatives from all staff grades involved in the airport meteorological office operation and systems are also formed. Meetings of the group are regularly held to identify areas of improvement to the service.

8.5.8 Formal internal service agreements laying down the scope of service to be provided have been established with the internal suppliers to ensure that both parties fully understand their responsibilities.

### 8.6 QUALITY MANAGEMENT SYSTEM COST TO THE HONG KONG OBSERVATORY

8.6.1 Staff time accounted for a major part of the cost incurred for the establishment of the quality management system. While the Management Representative and the Deputy Management Representative worked part-time on the quality management system, considerable staff time was needed in different phases in the implementation process, vis-à-vis, to:

- (a) Conduct system review;
- (b) Attend training;
- (c) Prepare the documentation;
- (d) Apply the quality procedures;
- (e) Carry out internal audit and the follow-up action; and
- (f) Prepare for and participate in the initial certification audit.

It is estimated that a total of about 180 staff-days had been spent on these activities with about half being incurred by managers and the remainder by operational staff.

8.6.2 Part of the cost incurred was for consultancy fees. The services provided by the external consultant included the following:

- (a) The conduct of the system review to identify the discrepancies between the existing system and the requirements of ISO 9001:2008;
- (b) Provision of training and briefings for the Hong Kong Observatory staff;
- (c) Provision of advice on the selection of and liaison with the certification body;
- (d) Provision of detailed guidance on the preparation of the quality management system documentation;
- (e) The conduct of a mock certification audit; and

(f) Provision of support in operating and maintaining the system for six months. The total consultancy fees for all of the above services were about US\$13 000.

8.6.3 As with consultancy fees, the certification costs depend largely on the scope of the quality management and the size of the organization. In the case of the airport meteorological office, which had a total workforce of 23 employees, the certification cost was about US\$2 500. The recurrent cost for maintaining the certification (surveillance cost) was about US\$1 000 per year.

### 8.7 CRITICAL SUCCESS FACTORS

8.7.1 Several critical factors were identified for the successful implementation of the quality management system of the airport meteorological office, as follows:

(a) Full commitment from top management;

Top management provided support by allocating all the resources required which made the implementation quick and successful.

(b) Commitment and understanding from all parts of the organization; and

Staff had to take on additional responsibilities such as day-to-day consistency checks and other quality control processes. Staff buy-in was a major contributing factor to the system's success.

(c) The provision of adequate training to staff.

This was critical in raising quality awareness among the staff and allowing them to acquire the skills necessary to make the effective implementation and maintenance of the system possible.

### 8.8 QUALITY MANAGEMENT SYSTEM BENEFITS TO THE ORGANIZATION

8.8.1 The quality management system guides the airport meteorological office to focus on user satisfaction and to address user concerns. A closer relationship is fostered between the airport meteorological office and the users, who are gaining deeper appreciation for the services provided. Overall it helps to improve user loyalty.

8.8.2 The system helps control and improve service quality, increase responsibility, accountability and quality consciousness among staff.

8.8.3 The system helps enhance efficiency through the streamlining of processes.

8.8.4 With the establishment of clearly defined and measurable objectives, both management and staff are guided towards achieving the goals.

8.8.5 The system provides a mechanism for prompt follow-up to any problems identified and feedback received from the users.

8.8.6 The performance and effectiveness of the operation are regularly measured and reported to management.

8.8.7 A formal mechanism is now in place for conscious continual improvement to the airport meteorological office operation.

# 8.9 EXPERIENCE OF A NATIONAL METEOROLOGICAL SERVICE PROVIDER

In addition to the Hong Kong, China example above, another example of the certification process based on the experience of a medium-sized national meteorological service provider which has undergone certification and recertification processes with a broad scope covering the headquarters, regional centres, observation and telecommunication networks is given in Appendix 3. The case has been generalized to suppress information that is specific to a particular State.

\_\_\_\_\_

# Appendix 1

## **RECORDS REQUIRED BY ISO 9001:2008**

(4.1.5 refers)

Relevant ISO 9001:2008		Paragraph in this
clause	Records required	publication
5.6.1	Management review	3.3.5.12 3.3.5.13
6.2.2	Records of education, training, skills and experience	3.3.6.4
7.1	Evidence that the realization processes and resulting product meet requirements	3.3.7.2 3.3.7.3
7.2.2	Results of the review of the requirements related to the product and actions arising from the review	3.3.7.5
7.3.2	Design and development inputs related to product requirements	3.3.7.11
7.3.4	Results of design and development reviews and any necessary actions	3.3.7.13
7.3.5	Results of design and development verification and any necessary actions	3.3.7.14
7.3.6	Results of design and development verification and any necessary actions	3.3.7.15
7.3.7	Design and development changes and the results of the review of changes and any necessary actions	3.3.7.16
7.4.1	Results of evaluations of suppliers and any necessary actions	3.3.7.18
7.5.2	Results of validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement	3.3.7.24
7.5.3	Unique identification of the product where traceability is a requirement	3.3.7.27
7.5.4	User property which is lost, damaged or otherwise found to be unsuitable for use	3.3.7.28
7.6	Basis used for calibration or verification when no measurement standards exist	3.3.7.33
7.6	Results of calibration and verification of measuring equipment	3.3.7.34
7.6	Validity or previous measuring results when equipment is found not to conform to requirements	3.3.7.34
8.2.2	Results of internal audits	3.3.8.8
8.2.4	Evidence of conformity with the acceptance criteria. Indication of the person(s) authorizing release of product	3.3.8.12
8.3	Nature of the nonconformities of product and any subsequent actions taken, including concessions obtained	3.3.8.17
8.5.2	Results of corrective action taken	3.3.8.21
8.5.3	Results of preventive action taken	3.3.8.23

## Appendix 2

## HONG KONG, CHINA DOCUMENTATION SYSTEM

(8.4 refers)

### A. QUALITY OBJECTIVES ESTABLISHED FOR THE AIRPORT METEOROLOGICAL OFFICE

- 1. Satisfaction rate of airline/aircrew users on the aviation meteorological service provided shall be 95 per cent or over.
- 2. Annual average of forecasting accuracy shall comply with the requirement based on ICAO recommendations and desirable accuracy of forecasts.
- 3. Implement new/modified ICAO standards before the applicability date.
- 4. Work shall be performed in accordance with the work schedule for each staff position as laid down in the procedure manuals.
- 5. Number of correction messages ("CC" as shown in teleprinters) after message issuance shall be less than 1 per cent.
- 6. Number of retard messages ("RR" as shown in teleprinters) shall be less than 1 per cent.
- 7. Over 99 per cent of flight documents shall be issued to the airline operators 2 hours before the scheduled time of departure.
- 8. Over 95 per cent of reports in METAR code form shall be filed for transmission within 5 minutes.
- 9. Check the compliance with quality objectives on a quarterly basis.

### B. OUTLINE OF THE QUALITY MANUAL OF THE AIRPORT METEOROLOGICAL OFFICE

AIRPORT METEOROLOGICAL OFFICE HONG KONG OBSERVATORY QUALITY MANUAL Version: X.X

- A. Table of Contents
- B. Control Sheet

[A description of the purpose and scope of the manual, the mechanism to control and maintain the manual and an amendment history of the manual follow.]

C. Distribution List

[Personnel and locations to which the manual will be distributed are listed here.]

Prepared by:	 Copy No.:	
Reviewed by:	 Approved by:	
Date:	 Date:	

1 Introduction

[An introduction of the airport meteorological office (AMO) and its functions are described here.]

2 Scope

The scope (i.e. provision of aviation weather services for international air navigation) of the quality management system, with reference to the specific quality management standard (ISO 9001:2008) being applied, is stated here.]

3 Reference, Abbreviations and Definitions [A list of references, abbreviations and definitions referred to in the manual follows.]

### 4 Quality Management System

A quality management system has been established, documented and maintained with the objective of continual improvement in the AMO in accordance with the requirements of ISO 9001:2008 and ICAO documents.

•••

[Statements describing how AMO intends to conform to each of the requirements of the ISO 9001:2008 standard, with references to specific quality management system procedures, operation manuals and external documents are put under the respective sections 4 to 8 of the manual.]

- 4.1 General Requirements
- 4.2 Documentation Requirements
- 5 Management Responsibility
  - 5.1 Management Commitment
  - 5.2 Customer Focus
  - 5.3 Quality Policy
  - 5.4 Planning
  - 5.5 Responsibility, Authority and Communication
  - 5.6 Management Review

- 6 Resource Management
  - 6.1 Provision of Resources
  - 6.2 Human Resources
  - 6.3 Infrastructure
  - 6.4 Work Environment

### 7 Product Realization

- 7.1 Planning of Product Realization
- 7.2 User-related Processes
- 7.3 Design and Development
- 7.4 Purchasing
- 7.5 Production and Service Provision
- 7.6 Control of Monitoring and Measuring Devices
- 8 Measurement, Analysis and Improvement
  - 8.1 General
  - 8.2 Monitoring and Measurement
  - 8.3 Control of Nonconforming Product
  - 8.4 Analysis of Data
  - 8.5 Improvement

### Appendix I — Quality Policy

[The quality policy of AMO is included in the manual as an appendix.]

### Appendix II — Procedure Cross-reference Table

[A cross-reference table listing all the quality management system procedures is included here.]

### Appendix III — Organization Chart

[A description of the structure of AMO in the form of an organization chart follows.]

### Appendix IV — Responsibilities and Authorities

[Responsibilities and authorities of each staff position follow.]

### Appendix V — Description of Interaction between Key Processes

[Process flow diagrams showing the processes of the quality management system and their interaction follow.]

Procedure reference number	Description	Relevant ISO 9001:2000 clauses	Explicitly required by ISO 9001:2000 (Y/N)?
QSP-1	Document Control — Quality Management System Documents	4.2.3	Y
QSP-2	Document Control — Forms	4.2.3	Y
QSP-3	Document Control — Regulations, Manuals and Notices	4.2.3	Y
QSP-4	Control of Records	4.2.4	Y
QSP-5	Planning	5.4.2, 7.3	Ν
QSP-6	Management Review	5.6	Ν
QSP-7	Training	6.2.2	Ν
QSP-8	Review of Product Requirements	7.2.2	Ν
QSP-9	Evaluation and Control of Suppliers for Products and Services	7.4.1	Ν
QSP-10	Purchasing of Products and Services	7.4.2	Ν
QSP-11	Provision of AMO Services	7.5	Ν
QSP-12	Calibration of Measuring and Monitoring Devices	7.6	Ν
QSP-13	User Satisfaction Survey	8.2.1	Ν
QSP-14	Internal Audit	8.2.2	Y
QSP-15	Monitoring and Measurement of AMO Processes/Products	8.2.3, 8.2.4	Ν
QSP-16	Control of Nonconforming Product	8.3	Y
QSP-17	Analysis of Data and Continual Improvement	8.4	Ν
QSP-18	Corrective Action and Preventive Action	8.5.2, 8.5.3	Y

### C. QUALITY MANAGEMENT SYSTEM PROCEDURES MAINTAINED BY THE AIRPORT METEOROLOGICAL OFFICE



### D. EXAMPLE OF A QUALITY MANAGEMENT SYSTEM PROCEDURE (CONTROL OF NONCONFORMING PRODUCT)

	Distrib	ution of Controlled Copy						
Сору No.		Holder						
	1	SSO(A)1						
	2	ISO Library						
	3	Intranet						
Prepared by:	Signed	Сору No.:	3					
Received by:	Signed	Approved by:	Signed					
Date:	1/6/2004	Date:	1/6/2004					

	Amendment History						
Change Number	Description	Pages Affected	Version Number	Version Date			
1	First Published	All	1.0	18 March 200			
2	Amend Distribution List after reorganization	3	1.1	1 June 2004			

APP 2-7

Ref. No.: QSP-16 Version 1.1

1 June 2004

Page 3 of 6

#### QUALITY SYSTEM PROCEDURE

#### CONTROL OF NONCONFORMING PRODUCT

#### 1. Purpose and Scope

Nonconforming products or services are identified or discovered as a result of monitoring, checking, verification or review activities performed on products or services at predefined stages/times.

This procedure describes the system for control of nonconforming products or services including the identification, documentation, evaluation or review, segregation (when practical), disposal of nonconforming product, and for notification to the parties concerned.

Nonconformities found by external bodies (e.g. Certification Body) will be dealt with in the Corrective Actions and Preventive Actions (QSP-18).

Nonconformities found during internal quality audits will be dealt with in the Internal Audit (QSP-14).

## 2. References

QSP-14Internal AuditQSP-15Measurement and Monitoring of AMO Processes/ProductsQSP-18Corrective Action and Preventive Action

## 3. Definitions

Nil.

#### 4. Responsibilities

Management Representative (MR)/Deputy Management Representative (DMR) and his delegate are responsible for the effective implementation of this procedure.

## 5. Procedure

#### 5.1 Identification of nonconforming products:

Nonconforming products/services are identified through various inspection, monitoring, checking, verification and review activities.

For purchased goods, nonconforming products are identified by labels, signs or markings prior to being returned to the supplier.

Ref. No.: QSP-16 Version 1.0 18 March 2002

Page 4 of 6

5.2	Review and disposition of nonconforming products:					
	a.	For nonconforming goods from suppliers:				
		For nonconforming purchased goods, the designated staff shall conclude the disposal of the incoming goods by clear instructions given to the suppliers or by recording in the delivery document.				
	b.	For nonconforming AMO services in general:				
		The designated staff shall convey the details of the nonconforming areas to the staff concerned for explanations, rework, replacement or other appropriate actions.				
	c.	For nonconforming meteorological information:				
		Where it has been identified, by making use of the Procedure QSP-15, that the meteorological information to be supplied to the users does not comply with the stated requirements, and automatic error correction procedures are not appropriate, such information shall be handled in accordance with the following procedure:				
		i) For information obtained from external sources, the information shall be handled in accordance with ICAO Annex 3, Chapter 9.				
		ii) For information/products produced by AMO (or Internal Suppliers), the originators/ responsible party shall be notified for explanations, rework, replacement or any other appropriate actions.				
5.3	Segregation of nonconforming products:					
	Nonconforming products are segregated from other products (if practical) by the responsible staff.					
	They can be:					
	a.	marked/labelled as such, or				
	b.	not marked as "accepted", etc.				
	This helps to prevent them from being inadvertently used or further processed.					
5.4	Notification to the concerned staff about nonconforming materials/work:					
5.4		The party responsible for the nonconformity is notified.				

## QUALITY SYSTEM PROCEDURE

## CONTROL OF NONCONFORMING PRODUCT

## 5.5 Actions taken after delivery or use of nonconforming products:

When nonconforming product is detected after delivery or being used, the relevant staff (or his/her superior) who was responsible for that product shall be notified. If necessary, appropriate actions shall be taken by relevant staff.

Ref. No.: QSP-16 Version 1.0 18 March 2002

Page 6 of 6

## E. EXAMPLE OF WORK INSTRUCTIONS FOR WEATHER OBSERVERS

## REPORTING SPECIAL OBSERVATIONS

- Local special reports and SPECI should be issued WHENEVER one or more criterion given in Appendix II (Criteria for making special reports in the SPECI code form and local special reports)<sup>1</sup> is met. When deterioration of one weather element is accompanied by improvement in another, only one special report should be issued. The distinction between local special reports and SPECI must be clearly understood. SPECI will be disseminated beyond the aerodrome while local special reports will only be made available to the operators and to other users at the aerodrome.
- 2 A SPECI/local special report representing a deterioration of conditions should be issued immediately after the observation. Those representing improvements of conditions should be issued only after the improvement has lasted for TEN MINUTES. When issued, the report should reflect the conditions at the end of this 10-minute period.
- 3 A web-based tool is available on the Intranet to alert Observers that the criteria given in Appendix II are met.

<sup>1.</sup> Determined in consultation with the appropriate ATS authority, operators and others concerned in accordance with ICAO Annex 3, Chapter 4, 4.4.1.

## F. EXAMPLE OF THE FORM BEING USED IN THE AIRPORT METEOROLOGICAL OFFICE

Hong Kong Observatory Airport Meteorological Office				
Description of <u>existing</u> / <u>potential</u> (delete where inapproprial service, process, quality system):	te) nonconformity (including where appropriate product,			
Personnel responsible for the corrective/preventive actions:				
CPAR PREPARED:	DATE:			
Cause of existing / potential (delete where inappropriate) no	onconformity:			
Agreed corrective actions or preventive actions:				
Target completion dates				
- for Corrective Actions or Preventive Actions:				
AUTHORIZED:	DATE:			

## Appendix 3

# EXAMPLE OF A CERTIFICATION PROCESS UNDERGONE BY A NATIONAL METEOROLOGICAL SERVICE PROVIDER

(8.9 refers)

## 1. SUMMARY OF THE STATEMENT OF MISSION, VISION AND QUALITY POLICY

1.1 *Mission* — To provide reliable meteorological information to the society contributing positively in the decisionmaking process associated with the development of the country.

1.2 *Vision* — To be a major contributor to the development of the knowledge and use of meteorology and climatology at both national and international levels through innovation and partnership with social and productive sectors of the society.

1.3 *Quality Policy* — Search for recognition, trust and high level of satisfaction of users through the efficient monitoring of meteorological conditions, use of modern weather forecast tools, and timely delivery of the products and services required.

## 2. STATE REASONS TO IMPLEMENT A QUALITY MANAGEMENT SYSTEM

The reasons to implement a quality management system are as follows:

- (a) Obtain national recognition through the ISO certification;
- (b) Search excellence through continuous improvement of activities, processes, products, services and customer satisfaction;
- (c) Use and expand the knowledge of meteorology;
- (d) Involve staff in all processes, from data collection to realization of products; and
- (e) Have an integrated view of the organization.

## 3. UNDERSTANDING QUALITY MANAGEMENT SYSTEM

The principles required to understand quality management system are as follows:

- (a) Standardization and implementation of documented procedures for the development of the end activities;
- (b) Based on the government regulations, ICAO and WMO standards and the ISO 9001:2000 international standard;

- (c) Structuring of the processes/services oriented to customer satisfaction and continuous improvement; and
- (d) Management of processes through the indicators of quality objective and the continuous monitoring of activities.

## 4. PERCEPTION OF WHAT IS NEEDED TO BE DONE TO FULFIL THE REQUIREMENTS OF ISO 9001

The following are needed in order to fulfil the requirements of ISO 9001:

- (a) The commitment and involvement of top management;
- (b) Statement of a quality policy, mission and vision;
- (c) Writing of a quality manual;
- (d) Writing and implementing procedures, instructions and manual/guides;
- (e) Management review of the quality management system; and
- (f) Internal and external auditing.

## 5. HOW IT IS DONE

## The following are needed:

- (a) Hiring of a national consultancy firm, a national association of quality control, that is a non-profit organization;
- (b) Definition of a high-level quality committee;
- (c) Designation of a quality representative;
- (d) Creation of a quality control section;
- (e) Preparation of documentation through a multifunctional group;
- (f) Training of instructors;
- (g) Certification through an international accredited company; and
- (h) Recertification three years later.

## 6. LEVEL OF DOCUMENTATION

The level of documentation needed is as follows:

- (a) Strategic the quality manual, including the statement of mission, vision and quality policy;
- (b) Tactic documented procedures; and
- (c) Operational working instructions.

## 7. STAFF STRUCTURE

The following staff are required:

- (a) Quality representative of the top management at headquarters;
- (b) Head of the quality section at headquarters;
- (c) Internal auditor(s) at headquarters;
- (d) Lead auditor(s) at headquarters;
- (e) Quality engineer; and
- (f) Quality representative at each regional centre.

## 8. NUMBER OF QUALITY PROCEDURES

Fourteen documented procedures were implemented, including the six mandatory ones.

## 9. EXAMPLES OF QUALITY INDICATORS

Examples of quality indicators are as follows:

- (a) Number of hours of staff training per year;
- (b) Success index of the weather forecast per region of the country;
- (c) Provision of meteorological data;
- (d) Measure of success of the model output;
- (e) Availability of the climatological data records;
- (f) Number of messages received;
- (g) Availability of telecommunication lines; and
- (h) Number of stations inspected.

## 10. MONITORING FORMS AND TOOLS

The following are needed in order to fulfil the requirements of ISO 9001:

- (a) Daily reports of nonconformity or report of trouble detection;
- (b) Monthly reports covering nonconformities; and
- (c) Half-yearly internal and external audits; request of preventive and corrective actions and meetings of the high-level quality committee.

Procedure	Objective
Control of documents	Establishes the criteria for the control of the quality management system documents, including those of external origin
Control of records	Establishes the guidelines for identification, storage, protection, retrieval, retention time and disposal manner
Internal audit	Establishes a system for planning, coordination and execution of the internal quality audits
Corrective and preventive actions	Establishes a system for implementation of corrective and preventive actions with a view to eliminating actual and potential nonconformity causes
Control of nonconforming products	Ensures that products and services non-compliant with the requirements be identified and controlled to avoid their use or non-intentional delivery
Meteorological products and services	Establishes the basic guidelines for the coordination, execution, monitoring and process control for the products and services provided
Installation and maintenance of equipment and instruments	Establishes the basic guidelines for coordination, execution and process control of the installation and maintenance of equipment and station instruments
Data collection, transmission and storage of meteorological data	Establishes the basic guidelines for coordination, execution and process control of the data collection and transmission
Telecommunication instruction	Establishes the instruction for compilation of meteorological bulletins for transmission
Measurement and monitoring	Establishes a systematic control of all meteorological measurement and monitoring devices with a view to ensuring their adequate use

## Table A3-1. List of quality management system procedures

## Example A3-1. Outline of quality manual

QM.001 10/08/2004-Rev. 00

#### QUALITY MANUAL

#### 1. Introduction

This Section contains an introduction of the quality management system, historical facts of the organization and describes the objectives and the structure of the Quality Manual and the mechanisms to control and make appropriate revision of the quality management system documents.

### 2. Scope

This section describes the scope of the Quality Manual and includes the statement of the Mission, Vision and Quality Policy of the organization. It also includes a flowchart of the organization and makes reference to pertinent government regulations and provides a list of products and services available to users.

#### 3. Responsibility

The responsibilities of top management, including the Director, the Representative of Quality, the Head of Quality Section, Technical Divisions, Administration Division and Heads of regional centres and concerned staff, with respect to the quality management system are included in this section.

#### 4. Structure of the QMS

This constitutes the main section of the Quality Manual. It includes a general description of the quality management system requirements and flowcharts depicting processes. It also includes the description of the activities related to the following headings:

- 4.1 Documentation requirements, including Quality Manual, Quality procedures, Quality Instructions, Guides, Manuals, Records, Control of documents and Control of records
- 4.2 Management responsibility, customer focus, quality policy and objectives, planning process, internal communication and the mechanisms for management review
- 4.3 Resource management
- 4.4 Product realization
- 4.5 Measurement, Analyses and Improvement
- 4.6 Correlation Matrix indicating the responsibility of each section/division with sections of the standard
- 4.7 History of reviews of the document

Prepared by Chief of Laboratory Approved by Chief of Division

## Example A3-2.Outline of a quality management system procedure

INSTRUM.QP.001 10/08/2004-Rev.00

## **Control of Measurement and Monitoring Devices**

#### 1. Objective

To establish a systematic control of all meteorological measurement and monitoring devices with a view to ensuring their adequate use.

## 2. Definitions

This section contains definitions of terms related to instruments and methods of observation, such as Measurement and Monitoring Devices, Calibration, Calibration Standard, Inspection Standard, Management Calibration System, etc.

## 3. General Principles

This section provides general guidance about the quality and accuracy required, the traceability of calibrated instruments, the conditions for outsourcing calibration and measurements, the rejection of uncalibrated instruments, the care with handling the instruments, etc.

## 4. Responsibilities

The responsibilities of concerned staff are indicated in this section, including those of the Director, Division and Section chiefs, Laboratory chief and staff, concerned staff at the regional centres, etc.

## 5. Description of the Procedures

This is the main section of the document. It provides details of the work processes of the Central Laboratory, Regional Laboratories, Calibration Management system, and also the instructions for calibration of the instruments of the observation stations.

#### 6. Flowchart Description of the Procedures

Graphical description of the procedures to facilitate understanding.

## 7. Annex

Includes forms and models of identification tags containing information about the current status of the instruments.

#### 8. Reviews of the Document

Includes the history of reviews of this document according to the adopted procedure of controlling documents to ensure the correct version is used.

Prepared by Chief of Laboratory Approved by Chief of Division

— END —

