

# **Advisory Circular**

CAA-AC-MET001E

December 2025

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## **QUALITY MANAGEMENT SYSTEM FOR THE PROVISION OF METEOROLOGICAL SERVICE TO AIR NAVIGATION**

### **1.0 PURPOSE**

- 1.1 This Advisory Circular (AC) provides guidance on the establishment and implementation of a Quality Management System (QMS) for the provision of Meteorological Service for Air Navigation. The Quality System established shall comprise procedures, processes and resources necessary to provide for the Quality Management of Meteorological Information to be supplied to the users.
- 1.2 This advisory Circular supersedes CAA-AC-MET-001D issued in December 2024.

### **2.0 REFERENCES**

- 2.1 The Civil Aviation Regulations.
- 2.2 WMO-No. 1100 – Guide to the Implementation of Quality Management System (QMS) for National Meteorological and Hydrological Service and other relevant service providers.
- 2.3 ISO 9000:2015, Quality Management Systems - Fundamentals and Vocabulary.
- 2.4 ISO 9001:2015, Quality Management Systems – Requirements.

### **3.0 GUIDANCE AND PROCEDURES**

#### **3.1 General**

- 3.1.1 The Civil Aviation (Meteorological Service for Air Navigation) Regulations requires that the Meteorological services provider establishes and implements a properly organized Quality System comprising of procedures, processes and resources necessary to provide for the Quality Management of the Meteorological Information to be supplied to users.
- 3.1.2 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 Service Provider (AMSP).

- 3.1.3 The Quality System established in accordance with this Advisory Circular should be in conformity with the International Organization for Standardization (ISO) 9000 series of Quality Assurance Standards and shall be certified by an approved organization.
- 3.1.4 The International Organization for Standardization (ISO) 9000 series of Quality Assurance Standards shall provide a basic framework for the development of a Quality Assurance Programme.

### **3.2 Development of the Quality System**

- 3.2.1 In developing the Meteorological Service for Air Navigation QMS, the designated Meteorological authority shall take into consideration the following;
  - 3.2.1.1 The Meteorological information supplied by AMSP to users complies with requirements of the Civil Aviation (Meteorological Service for Air Navigation) Regulations, as amended.
  - 3.2.1.2 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.
  - 3.2.1.3 The demonstration of compliance of the Quality System applied shall be by Audit. If non-conformity of the system is identified, action should be initiated to determine and correct the cause. All Audit observations shall be evidenced and properly documented.

## **4.0 Requirements of Quality Management Systems**

### **4.1 Scope**

- 4.1.1 The QMS to be implemented by AMSP shall:
  - 4.1.1.1 Demonstrate its ability to consistently provide products and services that meet customers and applicable statutory and regulatory requirements; and
  - 4.1.1.2 Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

### **4.2 Context of the AMSP**

- 4.2.1 The AMSP shall determine external and internal issues that are relevant to its purpose and its strategic direction that affect its ability to achieve the quality of Meteorological service provided for Air Navigation. The AMSP shall monitor and review information about these external and internal issues.

### **4.3 Understanding the needs and expectations of interested parties**

- 4.3.1 Due to their effect or potential effect on the AMSP's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the AMSP shall determine:
  - 4.3.1.1 the interested parties that are relevant to their QMS;
  - 4.3.1.2 the requirements of these interested parties that are relevant to their QMS.

#### **4.4 Determining the scope of the Quality Management System**

- 4.4.1 The AMSP shall determine the boundaries and applicability of the QMS to establish its scope. When determining this scope, the AMSP shall consider:
  - 4.4.1.1 the external and internal issues.
  - 4.4.1.2 the requirements of relevant interested parties.
  - 4.4.1.3 the products and services of the AMSP.
- 4.4.2 The AMSP shall apply all the requirements of ISO 9001: 2015 if they are applicable within the determined scope of its Quality Management System.
- 4.4.3 The scope of the AMSP's Quality Management System shall be available and be maintained as documented information. The scope shall state the types of products and services covered and provide justification for any requirement of ISO 9001: 2015 that the AMSP determines is not applicable to the scope of its QMS.

### **5.0 Quality Management System and its processes**

#### **5.1 Quality Management Systems**

- 5.1.1 The AMSP shall establish, implement, maintain and continually improve a Quality Management System, including the processes needed and their interactions, to meet the requirements of the Civil Aviation (Meteorological service for air navigation) Regulations, as amended.
- 5.1.2 The AMSP shall determine the processes needed for the QMS and their application throughout the regulatory requirements, and shall:
  - 5.1.2.1 determine the inputs required and the outputs expected from these processes.
  - 5.1.2.2 determine the sequence and interaction of these processes.
  - 5.1.2.3 determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes.
  - 5.1.2.4 determine the resources needed for these processes and ensure their availability.
  - 5.1.2.5 assign the responsibilities and authorities for these processes.
  - 5.1.2.6 address the risks and opportunities as determined in accordance with the requirements of actions to address risks and opportunities;

- 5.1.2.7 evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results.
- 5.1.2.8 improve the processes and the Quality Management System.

5.1.3 To the extent necessary, the AMSP shall:

- 5.1.3.1 maintain documented information to support the operation of its processes;
- 5.1.3.2 retain documented information to have confidence that the processes are being carried out as planned.

## **5.2 Leadership and commitment**

5.2.1 Top management shall demonstrate leadership and commitment with respect to the QMS by:

- 5.2.1.1 taking accountability for the effectiveness of the QMS;
- 5.2.1.2 ensuring that the Quality Policy and Quality Objectives are established for the QMS and are compatible with the context and strategic direction of the AMSP;
- 5.2.1.3 ensuring the integration of the QMS requirements into the AMSP's business processes;
- 5.2.1.4 promoting the use of the process approach and risk-based thinking;
- 5.2.1.5 ensuring that the resources needed for the QMS are available;
- 5.2.1.6 communicating the importance of effective Quality Management and of conforming to the QMS requirements;
- 5.2.1.7 ensuring that the QMS achieves its intended results;
- 5.2.1.8 engaging, directing and supporting personnel to contribute to the effectiveness of the QMS;
- 5.2.1.9 promoting continuous improvement;
- 5.2.1.10 supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

## **5.3 Customer focus**

5.3.1 Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

- 5.3.1.1 customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- 5.3.1.2 the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- 5.3.1.3 the focus on enhancing customer satisfaction is maintained.

## **5.4 Establishing the Quality Policy**

5.4.1 Top management shall establish, implement and maintain a Quality Policy that:

- 5.4.1.1 is appropriate to the purpose and context of the AMSP and supports its strategic direction;
- 5.4.1.2 provides a framework for setting quality objectives;



- 5.4.1.3 includes a commitment to satisfy applicable requirements; and
- 5.4.1.4 includes a commitment to continual improvement of the QMS.

5.4.2 The Quality Policy shall:

- 5.4.2.1 be available and maintained as documented information;
- 5.4.2.2 be communicated, understood and applied within the AMSP; and
- 5.4.2.3 be available to relevant interested parties, as appropriate.

**5.5 AMSP's roles, responsibilities and authorities**

5.5.1 Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the AMSP.

5.5.2 Top management shall assign the responsibility and authority for:

- 5.5.2.1 ensuring that the QMS conforms to the requirements of ISO 9001:2015.
- 5.5.2.2 ensuring that the processes are delivering their intended outputs;
- 5.5.2.3 reporting on the performance of the QMS and opportunities for improvement in particular to top management;
- 5.5.2.4 ensuring the promotion of customer focus throughout the AMSP; and
- 5.5.2.5 ensuring that the integrity of the Quality Management System is maintained when changes to the QMS are planned and implemented.

**5.6 Actions to address risks and opportunities**

5.6.1 When planning for the Quality Management System, the AMSP shall consider the issues within the organization and the needs and expectations of interested parties and determine the risks and opportunities that need to be addressed to:

- 5.6.1.1 give assurance that the QMS can achieve its intended result(s);
- 5.6.1.2 enhance desirable effects;
- 5.6.1.3 prevent or reduce undesired effects; and
- 5.6.1.4 achieve improvement.

5.6.2 The AMSP shall plan:

- 5.6.2.1 actions to address these risks and opportunities;
- 5.6.2.2 how to integrate and implement the actions into its QMS processes; and
- 5.6.2.3 how to evaluate the effectiveness of these actions.

**5.7 Quality Objectives**

5.7.1 The AMSP shall establish Quality objectives at relevant functions, levels and processes needed for the QMS. The Quality objectives shall:

- 5.7.1.1 be consistent with the Quality Policy.
- 5.7.1.2 be measurable; and
- 5.7.1.3 take into account applicable requirements.
- 5.7.1.4 be relevant to conformity of products and services and enhancement of customer satisfaction;
- 5.7.1.5 be monitored;
- 5.7.1.6 be communicated;
- 5.7.1.7 be updated as appropriate.
- 5.7.1.8 maintain documented information on the Quality objectives.

5.7.2 When planning how to achieve its quality objectives, the AMSP shall determine:

- 5.7.2.1 what will be done;
- 5.7.2.2 what resources will be required;
- 5.7.2.3 who will be responsible;
- 5.7.2.4 when it will be completed;
- 5.7.2.5 how the results will be evaluated.

## **5.8 Planning of changes**

5.8.1 The AMSP shall determine the need for changes to the QMS and the changes shall be carried out in a planned manner.

5.8.2 The AMSP shall consider:

- 5.8.2.1 the purpose of the changes and their potential consequences;
- 5.8.2.2 the integrity of the Quality Management System;
- 5.8.2.3 the availability of resources; and
- 5.8.2.4 the allocation or reallocation of responsibilities and authorities.

## **5.9 Resources**

5.9.1 The AMSP shall determine and provide the resources needed for establishment, implementation, maintenance and continual improvement of the QMS.

5.9.2 The AMSP shall consider:

- 5.9.2.1 the capabilities of, and constraints on, existing internal resources; and
- 5.9.2.2 what needs to be obtained from external providers.

## **5.10 Personnel**

5.10.1 The AMSP shall determine and provide the personnel necessary for the effective implementation of its QMS and for the operation and control of its processes.

## **5.11 Infrastructure**

5.11.1 The AMSP shall determine, provide and maintain the infrastructure necessary for operation of its processes and to achieve conformity of products and services.

5.11.2 Infrastructure may include:

- 5.11.2.1 buildings and associated utilities;
- 5.11.2.2 equipment, including hardware and software;
- 5.11.2.3 transportation resources; and
- 5.11.2.4 Information and communication technology (ICT).

## **5.12 Environment for the operation of processes**

5.12.1 The AMSP shall determine, provide and maintain the environment necessary for operation of its processes and to achieve conformity of products and services.

5.12.2 A suitable environment shall be a combination of human and physical factors, such as:

- 5.12.2.1 social (non-discriminatory, calm, non-confrontational);
- 5.12.2.2 psychological (stress-reducing, burnout prevention, emotionally protective);
- 5.12.2.3 physical (temperature, heat, humidity, light, airflow, hygiene, noise).

## **5.13 Monitoring and measuring resources**

5.13.1 The AMSP shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

5.13.2 The AMSP shall ensure that the resources provided:

- 5.13.2.1 are suitable for the specific type of monitoring and measurement activities being undertaken; and
- 5.13.2.2 are maintained to ensure their continuing fitness for their purpose.

5.13.3 The AMSP shall retain appropriate documented information as evidence of fitness for the purpose of monitoring and measurement of resources.

## **5.14 Measurement traceability**

5.14.1 Measurement traceability is an essential part of providing confidence in the validity of product and services provided by AMSP for Air Navigation. The measuring equipment shall be:

- 5.14.1.1 calibrated at specified intervals, against measurement standards traceable to international or national measurement standards.
- 5.14.1.2 identified in order to determine their status; and

5.14.1.3 safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

5.14.2 The AMSP shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose and shall take appropriate action as necessary.

#### **5.15 Organizational knowledge**

5.15.1 The AMSP shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

5.15.2 This knowledge shall be maintained and be made available to the extent necessary.

5.15.3 When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

##### **NOTE 1:**

*Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.*

##### **NOTE 2:**

*Organizational knowledge can be based on:*

- a) Internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);*
- b) External sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).*

#### **5.16 Competence**

5.16.1 The AMSP shall:

- 5.16.1.1 determine the necessary competence of personnel doing work under its control that affects the performance and effectiveness of the Quality Management System;
- 5.16.1.2 ensure that the personnel are competent on the basis of appropriate qualification, education, training or experience in accordance with regulatory requirements;
- 5.16.1.3 where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- 5.16.1.4 retain appropriate documented information as evidence of competence; and
- 5.16.1.5 Maintain personnel competence through periodic competence assessments.

##### **NOTE:**



*Applicable actions can include, for example, the provision of Training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons*

## **5.17 Training and Education of AMSP Personnel**

### **5.17.1 The AMSP shall -**

- 5.17.1.1 comply with the requirements of the World Meteorological Organisation in respect of qualifications, competencies, education and training of meteorological personnel providing services for air navigation;
- 5.17.1.2 establish a procedure to assess the competency of personnel authorised to install meteorological facilities for operational use and to perform meteorological services; and
- 5.17.1.3 maintain the competence of the personnel authorised to provide the meteorological services.

## **5.18 Awareness**

### **5.18.1 The AMSP shall ensure that personnel providing services for Air Navigation are aware of:**

- 5.18.1.1 the Quality Policy;
- 5.18.1.2 the Quality objectives;
- 5.18.1.3 their contribution to the effectiveness of the QMS, including the benefits of improved performance; and
- 5.18.1.4 the implications of not conforming with the QMS requirements.

## **5.19 Communication**

### **5.19.1 The AMSP shall determine the internal and external communications relevant to the QMS, including:**

- 5.19.1.1 on what will be communicated;
- 5.19.1.2 when to communicate;
- 5.19.1.3 with whom to communicate;
- 5.19.1.4 how to communicate; and
- 5.19.1.5 who communicates.

## **5.20 Documented information**

### **5.20.1 The AMSP's Quality Management System shall include:**

- 5.20.1.1 documented information required by this Advisory Circular; and
- 5.20.1.2 documented information determined by the AMSP as being necessary for the effectiveness of the QMS.

## **5.21 Creating and updating documents**

- 5.21.1 When creating and updating documented information, the AMSP shall ensure as appropriate:
- 5.21.1.1 identification and description (title, date, author, or reference number);
  - 5.21.1.2 format (language, software version, graphics)
  - 5.21.1.3 media (paper, electronic); and
  - 5.21.1.4 review and approval for suitability and adequacy.

## **5.22 Control of documented information**

5.22.1 Documented information required by the QMS and by this Advisory Circular shall be controlled to ensure that:

- 5.22.1.1 it is available and suitable for use, where and when it is needed; and
- 5.22.1.2 it is adequately protected from loss of confidentiality, improper use or loss of integrity.

5.22.2 For the control of documented information, the AMSP shall address the following activities, as applicable:

- 5.22.2.1 distribution, access, retrieval and use;
- 5.22.2.2 storage and preservation, including preservation of legibility;
- 5.22.2.3 control of changes (version control); and
- 5.22.2.4 retention and disposition.

5.22.3 Documented information of external origin determined by the AMSP to be necessary for the planning and operation of the QMS shall be identified as appropriate and be controlled.

5.22.4 Documented information retained as evidence of conformity shall be protected from unintended alterations.

## **5.23 Control of non-conforming outputs**

5.23.1 The AMSP shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

5.23.2 The organization shall take appropriate action based on the nature of the non-conformity and its effect on the conformity of products and services. This shall also apply to non-conforming products and services detected after delivery of products, during or after the provision of services.

5.23.3 The organization shall deal with non-conforming outputs in one or more of the following ways:

- 5.23.3.1 correction;
- 5.23.3.2 segregation, containment, return or suspension of provision of products and services;
- 5.23.3.3 informing the customer;
- 5.23.3.4 obtaining authorization for acceptance under concession; and
- 5.23.3.5 conformity to the requirements shall be verified when non-conforming outputs are corrected.

5.23.4 The AMSP shall retain documented information that:

- 5.23.4.1 describes the non-conformity;

- 5.23.4.2 describes the actions taken;
- 5.23.4.3 describes any concessions obtained; and
- 5.23.4.4 identifies the authority deciding the action in respect of the non-conformity.

## **5.24 Non-conformity and corrective action**

5.24.1 When a non-conformity occurs, including any arising from complaints, the AMSP shall:

- 5.24.1.1 react to the non-conformity and, as applicable:
  - 1. take action to control and correct it; and
  - 2. deal with the consequences;
- 5.24.1.2 evaluate the need for action to eliminate the cause(s) of the non-conformity, in order that it does not recur or occur elsewhere, by:
  - 1. reviewing and analysing the non-conformity;
  - 2. determining the causes of the non-conformity; and
  - 3. determining if similar non-conformities exist, or could potentially occur;
- 5.24.1.3 implement any action needed;
- 5.24.1.4 review the effectiveness of any corrective action taken;
- 5.24.1.5 update risks and opportunities determined during planning, if necessary;
- 5.24.1.6 make changes to the QMS, if necessary; and
- 5.24.1.7 corrective actions shall be appropriate to the effects of the non-conformities encountered.

5.24.2 The AMSP shall retain documented information as evidence of:

- 5.24.2.1 the nature of the non-conformities and any subsequent actions taken; and
- 5.24.2.2 the results of any corrective action.

## **5.25 Continual improvement**

5.25.1 The AMSP shall continually improve the suitability, adequacy and effectiveness of the Quality Management System.

## **5.26 Performance evaluation**

### **5.26.1 Monitoring, measurement, analysis and evaluation**

- 5.26.1.1 The AMSP shall determine:
  - 1. what needs to be monitored and measured;

2. the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
3. when the monitoring and measuring shall be performed; and
4. when the results from monitoring and measurement shall be analysed and evaluated.

5.26.1.2 The AMSP shall evaluate the performance and the effectiveness of the QMS;

5.26.1.3 The AMSP shall retain appropriate documented information as evidence of the results.

#### **5.26.2 Customer satisfaction**

5.26.2.1 The AMSP shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled.

5.26.2.2 The AMSP shall determine the methods for obtaining, monitoring and reviewing this information.

5.26.2.3 Monitoring customer perceptions shall include customer surveys, customer feedback on delivered products and services, meetings with customers and compliments.

#### **5.26.3 Analysis and evaluation**

5.26.3.1 The AMSP shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

5.26.3.2 The results of analysis shall be used to evaluate:

1. conformity of products and services;
2. the degree of customer satisfaction;
3. the performance and effectiveness of the QMS;
4. if planning has been implemented effectively;
5. the effectiveness of actions taken to address risks and opportunities;
6. the performance of external providers; and
7. the need for improvements to the QMS.

5.26.3.3 Methods to analyse data shall include statistical techniques.

#### **5.27 Internal audit**

5.27.1 The AMSP shall conduct Internal Audits at planned intervals to provide information on whether the Quality Management System conforms to:

5.27.1.1 the AMSP's own requirements for its QMS;

5.27.1.2 the regulatory requirements; and

5.27.1.3 effective implementation and maintenance of the QMS.



5.27.2 The AMSP shall:

- 5.27.2.1 plan, establish, implement and maintain an Audit Programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization and the results of previous audits;
- 5.27.2.2 define the audit criteria and scope for each audit;
- 5.27.2.3 select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- 5.27.2.4 ensure that the results of the audits are reported to management;
- 5.27.2.5 take appropriate correction and corrective actions without undue delay; and
- 5.27.2.6 retain documented information as evidence of the implementation of the Audit Programme and the audit results.

**5.28 Management review**

5.28.1 Top management shall review the AMSP's Quality Management System, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the AMSP.

5.28.2 The Management Review shall be planned and carried out taking into consideration:

- 5.28.2.1 the status of actions from previous Management Reviews;
- 5.28.2.2 changes in external and internal issues that are relevant to the Quality Management System;
- 5.28.2.3 information on the performance and effectiveness of the QMS, including trends in:
  - 1. customer satisfaction and feedback from relevant interested parties;
  - 2. the extent to which Quality objectives have been met;
  - 3. process performance and conformity of products and services;
  - 4. non-conformities and corrective actions;
  - 5. monitoring and measurement results;
  - 6. audit results; and
  - 7. the performance of external providers;
- 5.28.2.4 the adequacy of resources;
- 5.28.2.5 the effectiveness of actions taken to address risks and opportunities; and
- 5.28.2.6 opportunities for improvement.

**5.29 Management review outputs**

5.29.1 The output of the Management Review shall include decisions and actions related to:

- 5.29.1.1 opportunities for improvement;
- 5.29.1.2 any need for changes to the QMS; and
- 5.29.1.3 resource needs.

- 5.29.2 The organization shall retain documented information as evidence of the results of Management Reviews.

### 5.30 Operation

- 5.30.1 **Operational Planning and Control:** The AMSP shall plan, implement and control the processes needed to meet the requirements for the provision of products and services, by:

- 5.30.1.1 determining the requirements for the products and services;
- 5.30.1.2 establishing criteria for: the processes; and the acceptance of products and services;
- 5.30.1.3 determining the resources needed to achieve conformity to the product and service requirements;
- 5.30.1.4 implementing control of the processes in accordance with the criteria; and
- 5.30.1.5 determining, maintaining and retaining documented information to the extent necessary.

- 5.30.2 **Design and development controls:** The AMSP shall apply controls to the design and development process to ensure that:

- 5.30.2.1 the results to be achieved are defined;
- 5.30.2.2 reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- 5.30.2.3 verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- 5.30.2.4 validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
- 5.30.2.5 any necessary actions are taken on problems determined during the reviews, or verification and validation activities; and
- 5.30.2.6 documented information of these activities is retained.

- 5.30.3 **Design and development outputs:** The AMSP shall ensure that design and development outputs:

- 5.30.3.1 meet the input requirements;
- 5.30.3.2 are adequate for the subsequent processes for the provision of products and services;
- 5.30.3.3 include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; and
- 5.30.3.4 specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision; and
- 5.30.3.5 retain documented information on design and development outputs.

- 5.30.4 **Design and development changes:** The AMSP shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

**5.30.5 Control of externally provided processes, products and services:** The AMSP shall ensure that externally provided processes, products and services conform to requirements and determine the controls to be applied to externally provided processes, products and services when:

- 5.30.5.1 products and services from external providers are intended for incorporation into the AMSP's own products and services;
- 5.30.5.2 products and services are provided directly to the customer(s) by external providers on behalf of the AMSP;
- 5.30.5.3 a process, or part of a process, is provided by an external provider as a result of a decision by the AMSP.

**5.30.6 Production and service provision:** The AMSP shall implement production and service provision under controlled conditions.

**5.30.7 Identification and traceability:**

The AMSP shall;

- 5.30.7.1 use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.
- 5.30.7.2 identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.
- 5.30.7.3 control the unique identification of the outputs when traceability is a requirement and shall retain the documented information necessary to enable traceability.

**5.30.8 Preservation:** The AMSP shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

**NOTE:**

*Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation and protection.*

**5.30.9 Control of changes:**

The AMSP shall;

- 5.30.9.1 review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.
- 5.30.9.2 retain documented information describing the results of the review of changes, the person(s) authorizing the change and any necessary actions arising from the review.

#### 5.30.10 Control of non-conformity outputs:

The AMSP shall;

- 5.30.10.1 ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.
- 5.30.10.2 take appropriate action based on the nature of the non-conformity and its effect on the conformity of products and services. This shall also apply to non-conforming products and services detected after delivery of products, during or after the provision of services.
- 5.30.10.3 deal with non-conforming outputs in one or more of the following ways:
  - 1. correction;
  - 2. segregation, containment, return or suspension of provision of products and services;
  - 3. informing the customer; and
  - 4. obtaining authorization for acceptance under concession.
- 5.30.10.4 ensure conformity to the requirements is verified when non-conforming outputs are corrected.



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