Agenda Item 3: Implementation of the Quality Management System in AIM units

New requirements of Standard ISO 9001

(Presented by the Secretariat)

SUMMARY

This working paper presents the changes in Standard ISO 9001 and their effect in the Implementation of the Quality Management System in aeronautical information services (QMS/MET).

REFERENCES

- Annex 15 to the Convention of International Civil Aviation
- International Organization for Standardization - ISO 9001:2015
- Report of PPRC/4 Meeting
- Report of the Third Meeting of Air Navigation and Flight Safety Directors of the SAM Region (AN&FS/3)

ICAO strategic objectives:	*A - Safety* *B – Air navigation capacity and efficiency* *E – Environmental protection*

1. **Antecedentes**

1.1 The implementation of the Quality Management System in AIS/AIM services is presented as a Standard in Annex 15, Chapter 3, 3.7.1.

1.2 Annex 15 recommends that the Quality Management System (QMS/AIM) established in accordance with 3.7.1 should ISO 9000 series of quality assurance standards, and be certified by an approved organization.

1.3 States that have implemented and certified QMS/AIM, have made it based on the requirements contained in Standard ISO 9001 in its 2008 version.

2. **Analysis**

2.1 PPRC/4 Meeting expressed that the change in Standard ISO 9001 in September 2015 would affect the States that have already implemented and certified QMS/AIM, as well as the schedule of tasks to be developed by the States that have not yet completed QMS/AIM implementation.

2.2 The Meeting shall recall that STANDARD ISO 9001 has experienced modifications. These changes have been published in September 2015.

2.3 The Third Meeting of Air Navigation and Flight Safety Directors of the SAM Region (AN&FS/3) analyzed the impact of these changes in the States, noting that the period of transition for the validity of the certifications issued under Standard ISO 9001:2088 ends in September 2018, date in which all the certifications will expire and will need to be re-certified under Standard ISO 9001:2015.

2.4 It is important to inform the Meeting that the new structure of Standard ISO 9001 is presented in **Appendix A** to this working paper. This situation would affect future implementations since the issuance of a new version of the standard will imply a period of transition of three years, which has started since the moment of publication of the standard until the end of 2018. Therefore, the certificates issued in respect of the standard of 2008 will not be valid when this period ends.

2.5 This change will also affect the QMS Guide, which would have to be updated in accordance with the new standards of Standard ISO 9001. A correlation matrix between Standard ISO 9001:2015 and Standard 9001:2008 is presented in **Appendix B** to this working paper.

2.6 States should note that one of the most important requirements included by the Standard in its 2015 version is the assessment and management of processes-related risks. The Secretariat presents some assessment and risk management tools as a guide for this task, which could be considered by the States.

2.7 The Secretariat has prepared an assessment matrix for the planning of this transition, which is presented as **Appendix C**.

3. Discussion

3.1 The Meeting should take into account that the changes in Standard ISO 9001 affect all the States that have already certified and those which have not yet implemented QMS/AIM.

3.2 The Meeting should consider that planning is necessary in order to adjust to the new standards within the period of transition of three years after the publication.

3.3 In addition, the Meeting shall consider the review of the Guide to support QMS/AIM Implementation in the SAM Region. In this regard, the Meeting could assign an expert to work with the Secretariat in the update of the Guide.

4. Suggested action

4.1 The Meeting is invited to:

a) take note of the information provided in this working paper;

b) review and analyze Appendices A and B;

c) complete Appendix C;

d) review the Guide to support QMS/MET Implementation in the SAM Region and, if deemed appropriate, update it; and

e) agree on other actions as necessary.

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APPENDIX A

New structure of Standard ISO 9001:2015

One of the main changes in the Standard will be its structure. These changes are originated from the adjustment of the common scheme from Annex SL.

The titles that will be part of this structure are the following:

- 0. Introduction
- 1. Scope
- 2. Normative references
- 3. Terms and definitions
- 4. Context of the organization
- 4.1. Understanding the organization and its context
- 4.2. Understanding the needs and expectations of interested parties
- 4.3 Determining the scope of the quality management system
- 4.4 Quality management system and its processes
- 5. Leadership
- 5.1. Leadership and commitment
- 5.2 Policy
- 5.3 Organizational roles, responsibilities and authorities
- 6. Planning
- 6.1 Actions to address risks and opportunities
- 6.2 Quality objectives and planning to achieve them
- 6.3 Planning of changes
- 7. Support
- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information
- 8. Operation
- 8.1 Operational planning and control
- 8.2 Requirements for products and services
- 8.3 Design and development of products and services
- 8.4 Control of externally provided processes, products and services
- 8.5 Production and service provision
- 8.6 Release of products and services
- 8.7 Control of nonconforming outputs
- 8.8 Nonconformities of products and services
- 9. Performance evaluation
- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review
- 10. Improvement
- 10.1 General
- 10.2 Nonconformity and corrective action
- 10.3 Continual improvement

APPENDIX B

CORRELATION MATRIX OF THE MAIN CHANGES BETWEEN STANDARD ISO 9001:2015 AND STANDARD ISO 9001:2008

ISO 9001:2015	ISO 9001:2008
0. Introduction	0. Introduction
0.1 General	0.1 General
0.2 Principles of quality management	
0.3 Approach to processes	0.2 Process approach
0.4 Relationship with other management systems	0.3 Relationship with ISO 9004
1. Quality management systems - Requirements	1. Quality management systems - Requirements
1. Scope	1. Scope
2. Normative references	2. Normative references
3. Terms and definitions	3. Terms and definitions
4. Context of the organization	
4.1 Understanding the organization and its context	
4.2 Understanding the needs and expectations of interested parties	
4.3 Determining the scope of the quality management system	4.2.2 Quality manual
4.4 Quality management system and its processes	4.1 General requirements
5. Leadership	
5.1 Leadership and commitment	5.1 Management commitment
5.1.1 General	5.4.2 Quality management system planning
5.1.2 Customer focus	5.2 Customer focus
5.2 Policy	5.3 Quality policy
5.3 Organizational roles, responsibilities and authorities	5.5.1 Responsibility and authority

ISO 9001:2015	ISO 9001:2008
6. Planning	
6.1 Actions to address risks and opportunities	
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives
6.3 Planning of changes	5.4.2. Quality management system planning
7. Support	
7.1 Resources	
7.1.1 General	6.1 Provision of resources
7.1.2 People	6.2 Human resources
7.1.3 Infraestructure	6.3 Infraestructure
7.1.4 Environment for the operation of processes	6.4 Work environment
7.1.5 Monitoring nad measuring resources	7.6 Control of monitoring and measuring equipment
7.1.6 Organizational knowledge	
7.2 Competence	6.2.2 Competence, training and awareness
7.3 Awareness	6.2.2 Competence, training and awareness
7.4 Communication	5.5.3 Internal communication
7.5 Documented information	4.2 Documentation requirements
8. Operation	
8.1 Operational planning and control	7.1 Planning of product realization
8.2 Requirements for products and services	7.2 Customer-related processes
8.3 Design and development of products and services	7.3 Design and development
8.3.1 General	
8.3.2 Design and development planning	7.3.1 Design and development planning

ISO 9001:2015	ISO 9001:2008
8.3.3 Design and development inputs	7.3.2 Design and development inputs
8.3.4 Design and development controls	7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation
8.3.5 Design and development outputs	7.3.3 Design and development outputs
8.3.6 Design and development changes	7.3.7 Control of design and development changes
8.4 Control of externally provided processes, products and services	7.4 Purchasing
8.5 Production and service provision	7.5 Production and service provision
8.5.1 Control of production and service provision	7.5.1 Control of production and service provision 7.5.2 Validation of processes for production and service provision
8.5.2 Identification and traceability	7.5.3 Identification and traceability
8.5.3 Property belonging to customers or external providers	7.5.4 Customer property
8.5.4 Preservation	7.5.5 Preservation of product
8.5.5 Post-delivery activities	
8.5.6 Control of changes	
8.6 Release of products and services	8.2.4 Monitoring and measurement of product
8.7 Control of nonconforming outputs	8.3 Control of nonconforming products
9. Performance evaluation	
9.1 Monitoring, measurement, analysis and evaluation	8.2.3 Monitoring and measurement of processes
9.1.1 General	8.2.3 Monitoring and measurement of processes
9.1.2 Customer satisfaction	8.2.1 Customer satisfaction
9.1.3 Analysis and evaluation	8.4 Analysis of data
9.2 Internal audit	8.2.2 Internal audit
9.3 Management review	5.6 Management review

ISO 9001:2015	ISO 9001:2008
10. Improvement	8.5 Improvement
10.1 General	
10.2 Nonconformity and corrective action	8.5.2 Corrective action
10.3 Continual improvement	8.5.1 Continual improvement

APPENDIX C

Survey on the planning for the Implementation of the changes of Standard ISO 9001

State: _____ Date: _____

1- Do you know that Standard ISO 9001 has changed its standards and requirements? Indicate publication date and implementation date.

2- Do you know how long will the transition period take? Brief explanation.

3- Do you know the new requirements included? Indicate.

4- Are you aware of the application of assessment and risk management tools? Mention the main ones known in your State

5- If your QMS/AIM is already implemented and certified, which is the programme made by the section involved to adjust QMS/AIM to the new requirements of Standard ISO 9001. Complete the following table.

Date	**Action**	**Expected results**

- *Remark: Include more lines if necessary.*

6- If QMS/AIM is not yet implemented in your State, have you considered, within the planning of implementation activities, how does the changes of Standard ISO 9001 impact? Indicate how do you plan to implement them.

Date	**Action**	**Expected results**

7- Are you aware of the guidelines on risk management assessment provided by ISDO 31000? Brief explanation.

8- Include any additional information that could be provided regarding the status to adjust QMS/AIM to the changes of Standard ISO 9001 in your State.