

**EASA QUALITY MANAGEMENT STANDARDS**Doc # **E.L001-02**
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Directorate in charge: Executive Directorate

Process concerned: Quality Management System Process/ Management Review

Process owner: Quality Section Manager – Véronique Magnier

Purpose and Scope of the List :

The MB Decision 9-2003 (Article 38 of the Financial Regulation) requires the Agency to set up a Quality Management System in compliance with the minimum standards adopted by the Management Board, on the basis of equivalent standards laid down by the Commission (Internal Control Standards - ICS).

Furthermore the Agency is implementing a Quality Management System based upon international quality standards 9000 series (ISO).

Therefore, this list provides the revised Agency Quality Management Standards, highlighting the correspondence with the new 16 Internal control standards of the Commission (revised in 2007 and applicable since January 2008), the ISO9001 standards (Quality Management System – Requirements) and the previous EASA quality management standards defined in the list E.L001-00.

This list is related to:

	Name	Signature	Date
Prepared by :	Veronique Magnier	Original signed	17/07/2008
	Jean-Michel Mastio	Original signed	17/07/2008
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Reviewed by :	Luca Burello	Original signed	18/07/2008
Authorised by:	Patrick Goudou	Original signed	18/07/2008

Log of issues:

Issue #	Issue date	Change description	Related documents affected by new issue
00	02/06/06	First issue (MB 9-2006)	Any QMS document released before this issue 02. Mapping is provided between issue 00 and issue 02 of E.L001 so as to provide traceability for QMS documents released before this issue 02. Note: Former EASA standard 26 is cancelled.
02	18/07/2008	Update taking into account the new 2008 ICS (16 instead of 24 standards) and the ISO9001 Requirements Issue index aligned with actual Issue number (see E.H002-02)	



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	EASA Quality Management Standards	ISO9001 standard	ICS standard	E.L001-00 mapping
General Principles				
1	The Agency shall develop and monitor its EASA quality management standards. The EASA quality management standards shall be assessed once a year. The assessment shall be reported and used for improvement of the Quality Management System.	4.1 General requirements 4.2 Documentation requirements 5.6 Management review 8.5.1 Continual improvement	Standard 15: Assessment of internal control systems	EASA standard 1 EASA standard 2
2	The Agency shall develop, monitor, communicate and continually improve the efficiency and effectiveness of the Quality Management System through the use of the policy, objectives, audit results, analysis of data, corrective and preventive actions and management review. The Agency Quality Management System shall be described in the Quality Manual of the Agency.	4. Quality management system 5.5.3 Internal communication 5.6 Management review 8.5.1 Continual improvement	Standard 12: Information and communication Standard 14: Evaluation of activities Standard 15: Assessment of internal control systems	EASA standard 3 EASA standard 37
Strategy and Planning				
3	The Agency shall define, implement and monitor a strategy and planning process so as to cover long-term, medium and short term planning, including the Agency objectives.	5.4 Planning 4.2 Documentation requirements	Standard 5: Objectives and performance indicators	EASA standard 4 EASA standard 5 EASA standard 6 EASA standard 7
4	The Agency shall define, implement, monitor and report on Key Performance Indicators in order to measure the achievement of its objectives as defined in the planning plans.	8.2.3 Monitoring and measurement of processes 8.2.4 Monitoring and measurement of products 5.6 Management review	Standard 5: Objectives and performance indicators Standard 12: Information and communication	EASA standard 7



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5	The Agency shall set out, maintain and communicate the policy for professional ethics and organisational values of its staff.		Standard 2: Ethics and organisational values	EASA standard 8 EASA standard 36
6	The Agency shall set out Agency wide policies, where necessary, in particular the internal and external communication, quality, resources, etc....	5.3 Quality policy 5.5.3 Internal Communication 8.5.1 Continual improvement 4.2 Documentation requirements	Standard 8: Processes and procedures Standard 11: Documentation management Standard 12: Information and communication	EASA standard 9 EASA standard 24 EASA standard 37
7	The Agency shall define and implement the Agency risks management policy and procedures, including actions follow-up in order to monitor, mitigate and report its critical risks annually.	5.4 Planning 8.5.4 Preventive actions 5.6 Management review	Standard 6: Risk management process	EASA standard 10
Resources				
	Human Resources			
8	The Agency shall define and implement human resources management process, including recruitment, mobility, annual performance assessment and training.	6.2 Human resources 4.2 Documentation requirements	Standard 3: Staff allocation and mobility Standard 4: Staff evaluation and development	EASA standard 12 EASA standard 13
9	The Agency shall communicate to all staff an up to date and written basis: - the responsibility and authority,	6.2.2 Competence, awareness and training 5.5.1 Responsibility and authority	Standard 1: Mission Standard 3: Staff allocation and mobility	EASA standard 11 EASA standard 21



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	<ul style="list-style-type: none">- the mission statement of their directorate, department/section,- their role in their section/department,- their tasks assignment (job description),- the delegation authorisations.	4.2 Documentation requirements 5.5.3 Internal communication	Standard 7: Operational structure Standard 12: Information and communication	EASA standard 37
10	The Agency shall draw up an inventory of sensitive functions in order to evaluate and mitigate related risks.		Standard 7: Operational structure	EASA standard 14
	Infrastructure			
11	The Agency shall determine, provide and maintain the infrastructure and work environment needed to achieve its objectives.	6.3 Infrastructure 6.4 Work environment	Standard 7: Operational structure	EASA standard 15
	Financial Resources			
12	The Agency shall set up an accounting and financial management system to determine, allocate, monitor and report its financial resources to perform its activities.		Standard 5: Objectives and performance indicators Standard 13: Accounting and financial reporting	EASA standard 16
	Purchasing			
13	The Agency shall define and implement purchasing policy, including supplier evaluation and monitoring; and the verification of purchased product.	7.4 Purchasing	Standard 8: Processes and procedures	EASA standard 17



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	Information System			
14	The Agency shall define and implement a process for the medium-term management of the information systems of the Agency, including security and data quality.		Standard 12: Information and communication Standard 7: Operational structure	EASA standard 23
Management Responsibility				
15	The Directors of the Agency shall provide evidence of their commitment to the development and implementation of the management system.	5. Management responsibility	Standard 1: Mission Standard 8: Processes and procedures	EASA standard 18
16	The Directors shall appoint a member of management responsible for ensuring that the process needed for implementing the Quality Management System is in place, reporting on it and promoting the EASA quality management standards.	5.5.2 Management representative	Standard 1: Mission Standard 7: Operational structure	EASA standard 22
Processes and Products				
17	The Agency shall describe and manage its processes (core processes, management processes, support processes) in compliance with its Requirements (e.g. Basic Regulation, Implementing Rules, Financial Regulation....). This management should ensure appropriate segregation of duties, traceability and evidence of the work performed.	4.1 General requirements 4.2 Documentation requirements 5.2.3. Statutory and regulatory requirements 7.1 Planning of product realisation 7.5.1 Control of production and service operation 7.5.2 Validation of processes for	Standard 8: Processes and procedures Standard 9: Management supervision	EASA standard 25 EASA standard 27 EASA standard 31 EASA standard 38



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	EASA Quality Management Standards	ISO9001 standard	ICS standard	E.L001-00 mapping
		production and service operation 7.5.3 Identification and traceability 7.5.5 Preservation of product		
18	The Agency shall describe and manage its design and development processes, including planning, interfaces, input and output requirements, internal and external reviews, verification and validation of the products and change management.	7.3 Design and development	Standard 8: Processes and procedures Standard 9: Management supervision	None
19	The Agency shall monitor, analyse and review its processes and related products; and verify that they are systematically and consequently performed.	8.2.2 Internal audit 8.2.3 Monitoring and measurement of processes 8.2.4 Monitoring and measurement of products 8.5.3 preventive actions 5.6 Management review	Standard 9: Management supervision Standard 15: Assessment of internal control systems Standard 16: Internal audit capability	EASA standard 28 EASA standard 29
20	The Agency shall define and implement the exceptions and nonconformities management process, including the necessary corrective actions related to nonconformities.	8.3 Control of nonconforming product 8.5.2 Corrective action 4.2 Documentation requirements	Standard 8: Processes and procedures	EASA standard 30 EASA standard 32
21	The Agency shall ensure the continuity of operations at any times.		Standard 10: Business continuity	EASA standard 33
22	The Agency shall identify, verify, protect and preserve stakeholder property.	7.5.4 Customer property 7.5.5 Preservation of product		EASA standard 34



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Stakeholders				
23	The Agency shall identify, implement and continually improve a stakeholder-related process so as to determine and review the stakeholder needs, to collect and analyse their feedback and to monitor their satisfaction.	5.2 Customer focus 7.2 Customer-related processes 7.2.3 customer communication 8.2.1 Customer satisfaction 5.6 Management review	Standard 8: Processes and procedures Standard 12: Information and communication	EASA standard 19 EASA standard 20
Documentation				
24	The Agency shall implement a documentation management system to manage the lifecycle of its internal and external documents, including identification, registration, versioning, availability, filing, archiving and retrieval capabilities.	4.2 Documentation requirements	Standard 11: Documentation management	EASA standard 39 EASA standard 40 EASA standard 41
Audit				
25	The Agency shall set up an appropriate audit capability, including definition and monitoring of action plans of all type of audits and assessments.	8.2.2 Internal audit 8.5.3 Corrective action 8.5.4 Preventive action 5.6 Management review	Standard 16: Internal audit capability Standard 9: Management supervision	EASA standard 42 EASA standard 43