

BS EN 9137:2012



BSI Standards Publication

**Quality management systems
— Guidance for the
Application of AQAP 2110
within an EN 9100
Quality Management System**

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National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

**Quality management systems - Guidance for the Application of
AQAP 2110 within an EN 9100 Quality Management System**

Systèmes de management de la qualité - Guide pour
l'application de l'AQAP 2110 dans un Système de
Management de la Qualité EN 9100

Qualitätsmanagementsysteme - Anleitung für die
Anwendung von AQAP 2110 in einem EN 9100
Qualitätsmanagementsystem

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Foreword

This document (EN 9137:2012) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-STAN).

After enquiries and votes carried out in accordance with the rules of this Association, this Standard has received the approval of the National Associations and the Official Services of the member countries of ASD, prior to its presentation to CEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2012, and conflicting national standards shall be withdrawn at the latest by August 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

Industry has established the International Aerospace Quality Group (IAQG), with representatives from companies in the Americas, Asia/Pacific, and Europe, to implement initiatives that make significant improvements in quality and reductions in cost throughout the value stream.

This standard has been developed under the auspices of the IAQG Defence Relationship Growth Strategy Stream and in collaboration with the North Atlantic Treaty Organization (NATO) AC/327, Working Group 2 (WG2) to provide guidance on how the requirements of AQAP 2110 and EN 9100 can be fulfilled by one common Quality Management System. This guidance document has been prepared jointly by the IAQG and NATO, and the content of this standard is identical to AQAP 2009 Annex F from this point onwards.

This is the initial release of this standard. This standard is intended to provide guidance and assist an organization in the use and understanding of the relationship between AQAP 2110 and EN 9100.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

1 Scope

1.1 This European Standard has been prepared and issued to provide information and guidance on the application of AQAP 2110 when the Supplier adheres to the provisions of EN 9100. This document is published as AQAP 2009 Annex F and EN 9137. It was jointly developed by NATO and industry representatives for use by NATO and industry to facilitate the use and understanding of the relationship between the AQAP 2110 and EN 9100.

1.2 It aims to contribute to commonality of interpretation of the AQAP 2110 requirements by the Acquirer and their EN 9100 Supplier.

1.3 Its content has no legal or contractual status nor does it supersede, add to, or cancel any of the AQAP 2110 or EN 9100 requirements.

1.4 Because of the multiplicity of conditions that can exist (dependent on such factors as the type of work or process, the devices used, and the skill of personnel involved), this guidance should not be considered as all-encompassing nor should it be considered as imposing specific means or methods for meeting contract requirements. Stakeholders should be aware that other means or methods could be used to meet these requirements.

1.5 Users of this guidance should keep in mind that the requirements of AQAP 2110 are mandatory, as cited in the contract, on Suppliers and Sub-suppliers.

2 Normative references

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

EN 9100, *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations*

AQAP 2009 Edition 3, *NATO Guidance on the Use of the AQAP 2000 Series*

AQAP 2070 Edition 2, *NATO Mutual Government Quality Assurance (GQA) Process*

AQAP 2110 Edition 3, *NATO Quality Assurance Requirements for Design, Development and Production*

AQAP 2120 Edition 3, *NATO Quality Assurance Requirements for Production*

AQAP 2130 Edition 3, *NATO Quality Assurance Requirements for Inspection and Test*

ISO 9001:2008, *Quality management systems — Requirements*

ISO 10012:2003, *Measurement management systems — Requirements for measurement processes and measuring equipment*

3 General guidance

3.1 In an EN 9100 certificated organization, the entire content of both standards is within the purview of Government Quality Assurance (GQA).

3.2 When reviewing the two documents (i.e. AQAP 2110, EN 9100) it is helpful to note the differences in wording used to describe the stakeholders. The following equivalence (see Table 1) is offered as a workable translation. The contract will normally define the points of contact, outlining their role and authority.

Table 1 — AQAP 2110 and EN 9100 stakeholder terms

AQAP 2110	EN 9100
Acquirer	Customer, only if it is the Acquiring government.
Government Quality Assurance Representative (GQAR)	A Customer's Quality Representative.
Supplier	Organization with a direct contract with the government.
Sub-supplier	Supplier or Organization without a direct contract with the government.

3.3 EN 9100 is complementary (not alternative) to contractual and applicable law and regulatory requirements. It includes ISO 9001:2008 Quality Management System (QMS) requirements and specifies additional requirements for a quality management system for the aviation, space and defence industries.

3.4 The common ISO 9001:2008 baseline inherently makes EN 9100 and AQAP 2110 appear almost identical. However, four features differentiate the two documents:

- a) AQAP 2110 defines contractual requirements; while EN 9100 defines organizational provisions to be addressed within the scope of certification;
- b) AQAP 2110 reflects the agreement between NATO members to contract using the mandatory QMS clauses that enables reciprocal GQA; while industry conformance to EN 9100 is voluntary;
- c) The additions to ISO 9001:2008 of both documents add higher level quality management functions. AQAP 2110 also includes additional requirements related to communication and GQAR access to contract pertinent facilities, information and processes;
- d) EN 9100 can be tailored by exclusions, according to the scope of the QMS; whereas AQAP 2110 is pre-tailored into AQAP 2120 and AQAP 2130.

3.5 It is acceptable for a Supplier to offer a QMS that complies with the provisions of EN 9100 as a satisfactory response to the QMS requirements of AQAP 2110, under two conditions:

- a) The Supplier formally states that, "All EN 9100 requirements applicable to the organization are applicable to this contract";
- b) The Supplier formally states that, "No exclusions to EN 9100 taken by the organization shall in any way diminish, alter, or relieve the AQAP 2110 requirements of this contract";

These formal statements could be made in tender documentation, the contract, or the Quality Plan (QP) and should always be brought to the attention of the GQAR.

4 Detailed guidance

Detailed guidance is provided only where there is either the need for clarification or the potential for conflict or misunderstanding exists. Each paragraph and sub-paragraph of the standards (i.e., EN 9100, AQAP 2110) are listed below in Table 2 – EN 9100 and AQAP 2110 Detailed harmonization guidance. Where either standard contains additional requirements or notes to the base standard (i.e. ISO 9001:2008), the clause heading text is bolded.

Table 2 — EN 9100 and AQAP 2110 detailed harmonization guidance

EN 9100 CLAUSE	AQAP 2110 CLAUSE	DETAILED HARMONIZATION GUIDANCE
4. Quality management system	4.0 Quality management system	
4.1 General Requirements	4.1 General requirements	<p>The Acquirer has chosen the Supplier based in part, on their EN 9100 QMS.</p> <p>With respect to the NATO specific requirements:</p> <p>EN 9100 highlights the need to include customer and applicable statutory and regulatory requirements in the scope of the QMS in addition to the ISO 9001:2008 provisions relating to the product (see 7.2.1).</p> <p>The Acquirer and/or GQAR have the right to review and verify that the QMS meets the certification and contractual requirements. Where objective evidence of non-compliance is presented, the Supplier is obliged to take corrective action. If corrective action is not taken or is shown to be persistently ineffective then ultimately the QMS might be rejected, but this is neither a desired or common outcome.</p> <p>Sharing details of EN 9100 certification results from the Online Aerospace Supplier Information System (OASIS) and audit reports provides ongoing evidence of how the system is meeting the certification requirements and may reduce the need for the Acquirer/GQAR to conduct additional audits.</p>
4.2 Documentation Requirements	4.2 Documentation requirements	
4.2.1 General	4.2.1 General	
4.2.2 Quality Manual	4.2.2 Quality manual	<p>In EN 9100 exclusions can be made based on the processes within the organization. Such exclusions are permissible as long as they match the tailoring criteria of the AQAP series as shown in AQAP 2009 Figure 2.</p> <p>With reference to AQAP 2110 subclause 5.4 it is permissible to detail any interpretational clarifications or specific application of AQAP requirements in the QP.</p>
4.2.3 Control of Documents	4.2.3 Control of documents	
4.2.4 Control of Records	4.2.4 Control of records	
5. Management responsibility	5.0 Management responsibility	
5.1 Management Commitment	5.1 Management commitment	
5.2 Customer Focus	5.2 Customer focus	
5.3 Quality Policy	5.3 Quality policy	

EN 9100 CLAUSE	AQAP 2110 CLAUSE	DETAILED HARMONIZATION GUIDANCE
5.4 Planning	5.4 Planning	<p>Both EN 9100 and AQAP 2110 require planning for quality to be undertaken and recorded, describing how the product will be realized (reference to 7.1). AQAP 2110 requires a contract specific QP be documented and provided to the Acquirer so that it may be reviewed against the contractual requirements.</p> <p>The QP describes the application of the QMS to fulfill the contract requirements; describing what the Supplier will actually do (e.g. what requirements apply or how they are interpreted).</p> <p>To be compliant, QPs should address subclause 5.4 of AQAP 2110 and subclause 7.1 of both standards. QPs should be developed in conjunction with other project related planning (reference to EN 9100 subclause 7.1.1).</p>
5.4.1 Quality Objectives	5.4.1 Quality objectives	
5.4.2 Quality Management System Planning	5.4.2 Quality Management system planning	
5.5 Responsibility, Authority and Communication	5.5 Responsibility, authority and communication	
5.5.1 Responsibility and Authority	5.5.1 Responsibility and authority	
5.5.2 Management Representative	5.5.2 Management representative	<p>AQAP 2110 requires that the management representative reports directly to top management. EN 9100 requires that the management representative has unrestricted access to top management.</p> <p>The key aspect is that AQAP 2110 requires the management representative to have the necessary organizational authority and freedom to resolve matters pertaining to the QMS and product quality. In that respect, the standards are considered to be in harmony.</p>
5.5.3 Internal Communication	5.5.3 Internal communication	The NATO Specific requirement for communication with the GQAR should be considered as part of EN 9100 subclause 7.2.3 customer communication.
5.6 Management Review	5.6 Management review	
5.6.1 General	5.6.1 General	
5.6.2 Review Input	5.6.2 Review input	
5.6.3 Review Output	5.6.3 Review output	
6. Resource management	6.0 Resource management	
6.1 Provision of Resources	6.1 Provision of resources	
6.2 Human Resources	6.2 Human resources	
6.2.1 General	6.2.1 General	
6.2.2 Competence, Awareness and Training	6.2.2 Competence, awareness and training	
6.3 Infrastructure	6.3 Infrastructure	
6.4 Work Environment	6.4 Work environment	

EN 9100 CLAUSE	AQAP 2110 CLAUSE	DETAILED HARMONIZATION GUIDANCE
7. Product realization	7.0 Product realisation	
7.1 Planning of Product Realization	7.1 Planning of product realisation	
7.1.1 Project Management		
7.1.2 Risk Management		
7.1.3 Configuration Management		The EN 9100 additional requirement should be viewed in conjunction with AQAP 2110 subclause 7.7.
7.1.4 Control of Work Transfers		With respect to the EN 9100 additional requirement, work transfers include transfers within and outside of the organization.
7.2 Customer-Related Processes	7.2 Customer-related processes	
7.2.1 Determination of Requirements Related to the Product	7.2.1 Determination of requirements related to the product	
7.2.2 Review of Requirements Related to the Product	7.2.2 Review of requirements related to the product	
7.2.3 Customer Communication	7.2.3 Customer communication	The NATO Specific requirement for communication with the GQAR includes the NATO specific requirement in AQAP 2110 subclause 5.5.3 Internal communication.
7.3 Design and Development	7.3 Design and development	
7.3.1 Design and Development Planning	7.3.1 Design and development planning	
7.3.2 Design and Development Inputs	7.3.2 Design and development inputs	
7.3.3 Design and Development Outputs	7.3.3 Design and development outputs	
7.3.4 Design and Development Review	7.3.4 Design and development review	The authorization referred to in EN 9100 for progressing to the next stage in design and development is the Supplier's process and should not be confused with Acquirer intermediate or final acceptance of product.
7.3.5 Design and Development Verification	7.3.5 Design and development verification	
7.3.6 Design and Development Validation	7.3.6 Design and development validation	
7.3.6.1 Design and/or development verification and validation testing		Within EN 9100 'prove' means to demonstrate or to provide evidence. The intent is that the act of planning, controlling, reviewing and documenting verification and validation testing will collectively ensure that the requirements contained in a) and b) are fulfilled and that c), d) and e) are proved.
7.3.6.2 Design and/or development verification and validation documentation		

EN 9100 CLAUSE	AQAP 2110 CLAUSE	DETAILED HARMONIZATION GUIDANCE
7.3.7 Control of Design and Development Changes	7.3.7 Control of design and development changes	
7.4 Purchasing	7.4 Purchasing	
7.4.1 Purchasing Process	7.4.1 Purchasing process	<p>With respect to the NATO specific requirement to provide copies of subcontracts or orders for products, those documents may obscure or exclude pricing information.</p> <p>With respect to the NATO Specific requirement for notification of risks in subcontracts or orders; the Acquirer and/or GQAR, need to be aware of risks in the supply chain so that appropriate GQA activities can be planned. The Supplier (AQAP definition) will be informed of any GQA activities to be planned and performed in the Supplier chain (see AQAP 2070 subclause 11.4).</p>
7.4.2 Purchasing Information	7.4.2 Purchasing information	<p>Flowing down the relevant contractual requirements, not necessarily the full AQAP 2110 or EN 9100 is the key aspect of the NATO specific requirement.</p> <p>This means that flowing down standard Supplier requirements for the supply chain, which cover the relevant contractual requirements, is compliant with this clause of AQAP 2110 but should be detailed in the QP.</p> <p>The NATO specific requirement states the text to be included on purchasing information to ensure that rights of access to perform GQA are provided.</p> <p>The text may be amended, if agreed through the QP provided that rights to conduct GQA, through the supply chain are preserved.</p>
7.4.3 Verification of Purchased Product	7.4.3 Verification of purchased product	
7.5 Production and Service Provision	7.5 Production and service provision	
7.5.1 Control of Production and Service Provision	7.5.1 Control of production and service provision	
7.5.1.1 Production Process Verification		
7.5.1.2 Control of Production Process Changes		
7.5.1.3 Control of Production Equipment, Tools and Software programs		
7.5.1.4 Post-delivery Support		
7.5.2 Validation of Processes for Production and Service Provision	7.5.2 Validation of processes for production and service provision	
7.5.3 Identification and Traceability	7.5.3 Identification and traceability	

EN 9100 CLAUSE	AQAP 2110 CLAUSE	DETAILED HARMONIZATION GUIDANCE
7.5.4 Customer Property	7.5.4 Customer property	
7.5.5 Preservation of Product	7.5.5 Preservation of product	
7.6 Control of Monitoring and Measuring Equipment	7.6 Control of monitoring and measurement equipment	With respect to the NATO specific requirement to implement ISO 10012:2003, the QP should establish what requirements of ISO 10012:2003 are appropriate to the contract.
	7.7 Configuration Management	For specific Configuration Management (CM) requirements refer to the contractual conditions. Either NATO, International or National standards may be acceptable. This requirement directly relates to EN 9100 subclause 7.1.3.
	7.7.1 Configuration Management (CM) requirements	
	7.7.2 Configuration Management Plan (CMP)	
	7.8 Reliability and Maintainability (R&M)	
	7.8.1 (No Title)	
8. Measurement, analysis and improvement	8.0 Measurement, analysis and improvement	
8.1 General	8.1 General	
8.2 Monitoring and Measurement	8.2 Monitoring and measurement	
8.2.1 Customer Satisfaction	8.2.1 Customer satisfaction	
8.2.2 Internal Audit	8.2.2 Internal audit	Traceability is the key aspect of the NATO specific requirement and is related to 'planned arrangements' defined in the EN 9100 note. Internal audits themselves do not need to reference the AQAP. They need only demonstrate traceability to AQAP 2110 requirements.
8.2.3 Monitoring and Measurement of Processes	8.2.3 Monitoring and measurement of processes	
8.2.4 Monitoring and Measurement of Product	8.2.4 Monitoring and measurement of product	
8.3 Control of Nonconforming Product	8.3 Control of Nonconforming product	AQAP 2110 does not allow the delivery of nonconforming product, unless by Concessions/waiver or Deviation Permit (C/DP). There is no AQAP 2110 clause defining how to apply for C/DP, therefore, the process to be applied to C/DP should be covered by separate contractual arrangements and/or addressed in the QP.
8.4 Analysis of Data	8.4 Analysis of data	
8.5 Improvement	8.5 Improvement	
8.5.1 Continual Improvement	8.5.1 Continual improvement	
8.5.2 Corrective Action	8.5.2 Corrective Action	
8.5.3 Preventive Action	8.5.3 Preventive Action	

EN 9100 CLAUSE	AQAP 2110 CLAUSE	DETAILED HARMONIZATION GUIDANCE
	9.0 NATO additional requirements	
	9.1 Access to Supplier and Sub-suppliers and support for GQA activities	Unrestricted access is within the limitations of the national laws within the acquisition process. Any limitations must be fully justified and documented (in the tender, contract documentation and/or QP) and brought to the attention of the GQAR.
	9.1.1 (No Title)	
	9.2 Products for release to the Acquirer	
	9.2.1 (No Title)	

NOTE 1 Throughout this document EN 9100 is used to refer to AS/JISQ 9100.

NOTE 2 Nonconforming Product (8.3) – the method of handling rework should be defined in the quality plan.

NOTE 3 This guidance applies equally to AQAP 2120 and AQAP 2130. (see AQAP 2009 Figure 2).

NOTE 4 For the purposes of this guidance, the terms within AQAP 2110 have been used. (see General Guidance 3.2 Table 1).

NOTE 5 AQAP 2009 Annex C provides general guidance for the application of AQAP 2110.

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