

NATO STANDARD

AQAP-2110

**NATO QUALITY ASSURANCE
REQUIREMENTS FOR DESIGN,
DEVELOPMENT AND PRODUCTION**

**Edition D Version 1
JUNE 2016**



NORTH ATLANTIC TREATY ORGANIZATION

ALLIED QUALITY ASSURANCE PUBLICATION

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NORTH ATLANTIC TREATY ORGANIZATION (NATO)

NATO STANDARDIZATION OFFICE (NSO)

NATO LETTER OF PROMULGATION

24 June 2016

1. The enclosed Allied Quality Assurance Publication AQAP-2110, NATO QUALITY ASSURANCE REQUIREMENTS FOR DESIGN, DEVELOPMENT AND PRODUCTION, Edition D, Version 1, which has been approved by the nations in the Life Cycle Management Group (AC/327), is promulgated herewith. The agreement of nations to use this publication is recorded in STANAG 4107.
2. AQAP-2110, Edition D, Version 1 is effective upon receipt and on completion of a transition, ending 21 September 2018, will supersede AQAP-2110 Edition 3, AQAP-2120 Edition 3 and AQAP-2130 Edition 3 all of which which should be destroyed in accordance with local procedures for the destruction of documents.
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4. This publication shall be handled in accordance with C-M(2002)60.


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CHAPTER 1 INTRODUCTION

1.1 General

This publication contains the NATO requirements for Quality. A Quality Management System shall be established, documented, applied, maintained, assessed and improved, and evaluated, in accordance with requirements contained in this publication.

1.2 Purpose

This publication contains requirements, which, if applied appropriately, provide confidence in the Supplier's capability to deliver products that conform to Acquirer contract requirements.

1.3 Applicability

1. This publication is primarily intended for use in a contract between two or more parties.
2. When referenced in a contract, this publication shall apply to all of the processes necessary for the Supplier to fulfil the contractual requirements.
3. This publication may also be used internally by a Supplier or a potential Supplier to cover the Quality aspects of the Management System (MS).
4. Where identified by the Acquirer other appropriate standards can be used in conjunction with this publication to identify MS process requirements.
5. If inconsistencies exist between the contract requirements and this publication, the contract requirements shall prevail.

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CHAPTER 2 COMPLIANCE WITH THIS PUBLICATION
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2.1 Compliance

Compliance with this publication is defined as the fulfilment of the requirements in chapters 3, 4 and 5. All requirements are applicable unless agreement otherwise is documented as part of the contract with the Acquirer.

2.2 Notes and Guidance

In this publication 'Notes' are not contractual requirements; they are for guidance or clarifying the associated requirement.

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CHAPTER 3 COMPOSITION OF REQUIREMENTS IN AQAP 2110
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3.1 Composition

1. A requirement in this publication is composed as follows:
 - a. Chapter 4, General QMS Requirements, establishes the applicability of the requirements of ISO 9001:2015.
 - b. Chapter 5, NATO Specific QMS Requirements, establishes additional NATO specific requirements for the Supplier.
2. Whenever the ISO 9001 requirement refers to “this international standard” it shall be read as “this publication”.

3.2 References

3.2.1 Normative References

- | | | |
|----|----------------|---|
| 1. | ISO 9001:2015 | Quality Management Systems – Requirements |
| 2. | ISO 9000:2015 | Quality Management Systems – Fundamentals and Vocabulary |
| 3. | ACMP 2100 | Configuration Management Contractual Requirements |
| 4. | ISO 10012:2003 | Measurement Management Systems – requirements for measurement processes and measuring equipment |
| 5. | ISO 31000:2009 | Risk Management – Principles and Guidelines |

3.2.2 Informative References

- | | | |
|----|----------------|---|
| 1. | AQAP 2000 | NATO Policy on an Integrated Systems Approach to Quality Through the Life Cycle |
| 2. | AQAP 2009 | NATO Guidance on the use of the AQAP 2000 series |
| 3. | AQAP 2105 | NATO Requirements for Deliverable Quality Plans |
| 4. | AQAP 2070 | NATO Mutual Government Quality Assurance (GQA) Process |
| 5. | ISO 10007:2003 | Quality Management Systems – Guidelines for Configuration Management |
| 6. | ADMP | Allied Dependability Management Publications |

3.3 Definitions

Unless stated otherwise, ISO 9000:2015 definitions shall apply.

3.3.1 Acquirer

Governmental and/or NATO Organisations, that enter into a contractual relationship with a Supplier, defining the product and quality requirements

3.3.2 Supplier

Organisation that acts in a contract as the provider of products to the Acquirer.

3.3.3 Certificate of Conformity

A document, signed by the Supplier, which states that the product conforms with contractual requirements

3.3.4 Dependability

The ability to perform as and when required.

Notes:

1. Dependability includes availability, reliability, recoverability, maintainability and maintenance support performance, and, in some cases, other characteristics such as durability, safety, and security.
2. Dependability is used as a collective term for the time-related quality characteristic of an item

3.3.5 Government Quality Assurance

The process by which the appropriate National Authorities establish confidence that the contractual requirements relating to quality are met

3.3.6 Government Quality Assurance Representative

The Personnel with responsibility for Government Quality Assurance (GQA), acting on behalf of the Acquirer

3.3.7 GQAR and/or Acquirer

The term “GQAR and/or Acquirer” has been used in this document to enable the Acquirer to be the default in situations in which there is either no GQAR associated with the contract or where the appointed GQAR has not been delegated the authority to conduct particular activities

3.3.8 Product

The result of activities, processes and tasks. A product may include service, hardware, processed materials, software or a combination thereof. A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

3.3.9 Quality Plan

Supplier's document that specifies which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract requirement

3.3.10 Root Cause Analysis

A collective term that describes a wide range of approaches, tools and techniques used to identify causes of nonconformity.

3.3.11 Key or Critical Product Characteristics or Processes

Processes or Product elements or features which, if not properly controlled, can have an adverse impact on the product delivery, cost and performance.

3.3.12 Counterfeit Material

Materiel whose origin, age, composition, configuration, certification status or other characteristic (including whether or not the materiel has been used previously) has been falsely represented by:

- A) misleading marking of the materiel, labelling or packaging;
 - B) misleading documentation; or
 - C) any other means, including failing to disclose information;
- except where it has been demonstrated that the misrepresentation was not the result of dishonesty by a Supplier or External Provider within the supply chain.

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CHAPTER 4 GENERAL QMS REQUIREMENTS
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4.1 Applicability of ISO 9001:2015 REQUIREMENTS

The Supplier shall establish, document, implement, assess and improve an effective and economical Quality Management System in accordance with this publication which includes the requirements of ISO 9001:2015 as necessary to satisfy the contract requirements.

4.2 Quality Management System and its Processes

The Acquirer and/or Government Quality Assurance Representative (GQAR) reserve the right to reject the Supplier's Quality Management System as it applies to the contract. The Supplier's documented Scope of their System, records from internal audit, self-assessments and other objective evidence that this system is compliant with this Publication and is effective, shall be readily available to the GQAR and/or Acquirer.

In instances where the Acquirer and/or GQAR rejects the Quality Management System, the Supplier shall make proposals for corrective actions and revisions within an agreed timescale and contractual penalties will be applied as defined in the contract

4.3 Access to Supplier and External Providers and Support For GQA Activities

The Supplier and/or External Providers shall provide the GQAR and/or Acquirer:

1. The right of access to facilities where the contracted activities are being performed.
2. Information pertaining to the fulfillment of requirements in the contract.
3. Unrestricted opportunity to evaluate Supplier compliance with this Publication.
4. Unrestricted opportunity to evaluate External Providers compliance with this Publication. The Supplier will be informed before the evaluation takes place.
5. Unrestricted opportunity to conduct verification of product conformity with the contract requirements.
6. Required assistance for evaluation, verification, validation, testing, inspection or release of the product for the accomplishment of GQA to contract requirements.
7. Accommodation and facilities for performing GQA.
8. The necessary equipment available for reasonable use for performing GQA.

9. Supplier and/or External Providers personnel for operation of such equipment as required.
10. Access to information and communication facilities.
11. The necessary Supplier documentation to confirm product conformance to specification.
12. Copies of necessary documents, including those on electronic media.

CHAPTER 5 NATO SPECIFIC QMS REQUIREMENTS
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Note: The paragraph number of ISO 9001:2015 mentioned in brackets at the end of the paragraph title is only for information purposes.

5.1 Leadership

5.1.1 Organizational roles, responsibilities and authorities [5.3]

1. Top management shall appoint a management representative for GQA issues from the organization's management who, irrespective of other responsibilities shall have the necessary organisational authority and freedom to resolve matters pertaining to quality. The management representative shall report directly to top management.
2. The management representative shall have responsibility and authority that includes ensuring that processes needed for the quality management system are established, implemented and maintained and shall include liaison with the GQAR and/or Acquirer on matters related to quality.
3. The management representative shall have the appropriate competence related to Quality Management.

5.2 Planning

5.2.1 Risk Management [6.1]

1. The Supplier and External Provider shall provide objective evidence that risks, including External Provider risks, are considered during planning, including but not limited to Risk Identification, Risk Analysis, Risk Control and Risk Mitigation. The planning shall start with risk identification during contract review and be updated thereafter in a timely manner.
2. Unless otherwise stated in the contract, the Risk Management applied shall meet the principles and guidelines of ISO 31000:2009. The Risk Management Plan shall be made available to the GQAR and/or Acquirer.
3. The Acquirer and/or GQAR reserve the right to reject Risk Plans and their revisions.

5.3 Support

5.3.1 Infrastructure [7.1.3]

The infrastructure shall include an area to segregate nonconforming product (see paragraph 5.4.12 of this publication).

5.3.2 Monitoring and measuring resources [7.1.5]

1. The measurement and calibration system applied to the contract shall meet the requirement of ISO 10012:2003.
2. When an item of measuring equipment fails calibration the Supplier shall advise the GQAR and/or Acquirer of the impact of the failure on previous measuring results where this affects delivered products or verification, validation and acceptance results. The GQAR and/or Acquirer may request that measurements taken shall be repeated with calibrated equipment.

5.3.3 Competence [7.2]

The Supplier shall establish and maintain a process for identifying training needs and achieving competence of all personnel performing activities affecting product quality.

5.3.4 Awareness [7.3]

Persons involved with the contract, including External Providers, shall be aware of the specific arrangements contained in the quality plan that are applicable to their activities / area of responsibility.

5.3.5 Documented information [7.5]

The Supplier shall provide the GQAR and/or the Acquirer with the necessary access to the documented information pertinent to the contract, in a format agreed with the GQAR and/or Acquirer.

5.4 Operation

5.4.1 Operational planning and control [8.1]

1. The Supplier shall identify the documented information, including acceptance criteria and configuration information that will be used as objective evidence of product conformance with requirements. This information shall be acceptable to the Acquirer and/or GQAR and made available prior to acceptance of the product.
2. The supplier shall maintain and retain documented information for product approval and production process approval. These approvals shall also be applied to External Providers.

5.4.1.1 Quality Plan

1. The Supplier shall submit an acceptable Quality Plan (QP) which addresses the contractual requirements to the GQAR and/or the Acquirer in a mutually agreed

timescale but prior to the start of work which can be defined as a project or contract initiation meeting or as otherwise stated in the contract or purchase order. The QP shall be a clearly identified discrete document or part of another document that is prepared under the contract.

2. The QP shall:

- a. Describe and document the quality management system requirements "contract-specific" necessary to satisfy the contract requirements (making reference, where applicable, to the "company-wide" quality management system);
- b. Describe and document the planning of the product realisation in terms of quality requirements for the product, needed resources, required control activities (verification, validation, monitoring, inspection, testing), and acceptance criteria. This shall include specific arrangements and communication requirements where work is to be conducted at locations external to the Suppliers premises.
- c. Document, and maintain traceability of requirements from the planning process by including a requirement and solution compliance matrix, justifying fulfilment of all contractual requirements (making reference where applicable).

3. The Acquirer and/or GQAR reserve the right to reject QPs and their revisions.

NOTE:

Contractual requirement for the content of the Quality Plan is established in AQAP 2105 "NATO requirements for Deliverable Quality Plans."

Requirement and solution compliance matrix can be a part of Quality Plan or a separate document as an annex to it. This matrix can be prepared and annexed to the Quality Plan after the initial issue, within a timescale mutually agreed with GQAR and/or Acquirer by taking into account the content of the Contract or Purchase Order.

5.4.1.2 Configuration Management

5.4.1.2.1 Configuration Management (CM) requirements

The Supplier shall manage configuration through the implementation of Configuration Management Planning, Configuration Identification, Change Control, Configuration Status Accounting and Configuration Audit in accordance with the requirements of ACMP 2100 and any additional CM clauses in the contract or a nationally recognised equivalent.

5.4.1.2.2 Configuration Management Plan (CMP)

The Supplier shall prepare a Configuration Management Plan (CMP) which describes the application of CM to the contract in accordance with ACMP 2100 and any additional CM clauses in the contract or nationally recognised equivalent. The CMP may form part of another plan if appropriate.

NOTE:

Further information on NATO Configuration Management Policy and Requirements are contained within Allied Configuration Management Publications (ACMP) ACMP 2000 and ACMP 2009.

5.4.2 Customer communications [8.2.1]

1. If requested by the Acquirer and/or GQAR, the Supplier and/or External Providers shall attend a Post Award GQA meeting focused on the contract arrangements for Quality Assurance of the product and/or GQA practicalities.
2. The Supplier shall ensure that lines of communication are established with the GQAR and/or Acquirer. The designated management representative shall ensure that the adequate level of information is supplied to satisfy the GQAR and/or Acquirer.
3. The Supplier shall notify the GQAR and/or Acquirer of changes to its organisation that affect product quality or the Quality Management System.

5.4.3 Determining the requirements related to products [8.2.2]

The Supplier shall identify product requirements and functions that relate to critical characteristics such as health, safety, performance, and dependability.

5.4.4 Design and development controls [8.3.4]

Unless otherwise stated in the contract, the Supplier shall determine the verification and validation methods required and demonstrate conformity with the corresponding requirements at appropriate stages up to and including the final product.

5.4.5 Dependability

If stated in the contract, the Supplier shall ensure that Dependability issues and related documents, including those from associated External Providers, are controlled.

NOTE:

Further information on NATO Dependability Management is contained within Allied Dependability Management Publications (ADMP).

5.4.6 Control of externally provided processes, products and services [8.4]

The Supplier shall retain documented information of verification and/or validation of purchased products. The documented information shall be made available to the GQAR and/or Acquirer.

5.4.6.1 General

1. Where the Supplier has decided to externally source a critical item, significant work content, design, immature technical solutions or a configuration item then the Supplier shall establish and maintain knowledge of the supply chain and External Provider quality assurance activities.
2. The Supplier shall flow down the applicable contractual requirements to External Providers by referencing the stated contractual requirement, including relevant AQAP(s). The Supplier shall insert the following in all purchasing documents: "All requirements of this contract may be subject to GQA. You will be notified of any GQA activity to be performed."
3. Suppliers shall conduct a formal review of purchasing documents to verify that the correct contractual requirements have been flowed down. The Supplier shall retain documented information of this review.
4. The Supplier shall document their arrangements for these requirements at the planning stage (see paragraph 5.4.1. of this publication) and identify their proposed quality assurance activities for specific sub-contracts or orders that meet the above criteria.

5.4.6.2 Type and extent of control [8.4.2]

1. It is the Supplier's responsibility to ensure that the procedures and processes required to fulfil contract requirements are fully implemented at the External Provider's facilities.
2. The Supplier shall establish and implement a process for the avoidance, detection, mitigation, and disposition of Counterfeit Materiel.
3. Only the Supplier placing the purchasing documents with an External Provider will issue contractual instructions to that External Provider.
4. GQA activities at External Provider's facilities do not relieve the Supplier from any contractual quality responsibilities.

NOTE:

Conduct of GQA and associated GQAR and/or Acquirer access rights, at External Provider's facilities can only be requested by the GQAR and/or Acquirer.

5.4.6.3 Communication

1. The Supplier shall on request provide the GQAR and/or Acquirer with a copy of any subcontracts, orders, related contractual documents and their modifications, for products related to the contract.
2. The Supplier shall notify the GQAR and/or Acquirer if a subcontract or order has been identified involving a critical item, significant work content, design, immature technical solutions or where External Provider performance is unknown or causes concern.
3. The Supplier shall notify the GQAR and/or Acquirer if an externally provided product is rejected, reworked, or repaired which has been identified as involving risk or supplied by an External Provider whose selection or subsequent performance has been identified as involving risk.

5.4.7 Control of Production and Service Provision [8.5.1]

1. The Supplier shall develop and maintain instructions for the conduct of activities related to the control of production of material, part, component, subsystem and system level for the product supplied to ensure that the specified requirements are met.
2. The Supplier shall establish and maintain criteria for workmanship in the clearest practical manner (e.g. written standards, representative samples or illustrations).

5.4.8 Identification and traceability [8.5.2]

Where the failure of an item or component could lead to the loss of equipment, performance or life then it is mandatory to maintain traceability.

5.4.9 Property belonging to customers or External Providers [8.5.3]

1. If products provided by the Acquirer are lost, damaged or otherwise found to be unsuitable for their intended use in accordance with the contract, the Supplier shall immediately inform the Acquirer and GQAR and retain documented information.
2. When the Supplier establishes that an acquirer supplied product is unsuitable for its intended use, they shall immediately report to and coordinate with the Acquirer the remedial actions to be taken. The Supplier shall also inform the GQAR.

5.4.10 Preservation [8.5.4]

1. Products with limited shelf life shall be subject to control of their expiry dates.
2. If applicable, the control of expiry date/shelf life shall be applied during maintenance, servicing, storage or when fitted.
3. Remaining shelf-life shall be identified and communicated to the GQAR and/or Acquirer prior to delivery.

5.4.11 Release of products [8.6]

1. The Supplier shall ensure that only acceptable products, intended for delivery, are released. The GQAR and/or Acquirer reserve the right to reject nonconforming products.
2. The Supplier shall provide a Certificate of Conformity at release of product to the GQAR and/or Acquirer unless otherwise instructed.
3. The Supplier is solely responsible for the conformance to requirements, of products provided to the Acquirer.
4. Where the GQAR/and or Acquirer is required to perform any final inspection or formal acceptance activities, the Supplier shall provide the GQAR/and or Acquirer with a minimum of 10 working days notification of the event unless otherwise stated in the contract.

5.4.12 Control of nonconforming products [8.7]

1. The Supplier shall issue and implement documented procedures which identify, control and segregate all nonconforming products. Product with unidentified or unknown status shall be classified as nonconforming product.
2. Documented procedures for the identification, control, and segregation of nonconforming product are subject to disapproval by the GQAR and/or Acquirer when it can be shown that they do not provide the necessary controls.
3. The Supplier shall notify the GQAR and/or Acquirer of non-conformities and corrective actions required, unless otherwise agreed with the GQAR and/or Acquirer. The GQAR and/or Acquirer reserve the right to reject all rework, repair and use as is dispositions.
4. Where the Supplier proposes to raise a concession for the use, release or acceptance of a nonconforming product appropriate authorisations shall be obtained from the GQAR and/or Acquirer unless otherwise agreed.

5. The Acquirer requirements for concessions apply equally to outsourced processes or purchased products. The Supplier shall review any request from External Providers before submission to the GQAR and/or Acquirer.

6. The Supplier shall retain documented information of quantity authorized and/or expiration date for concessions or deviation permits. The Supplier shall ensure compliance with the contract requirements when the authorization expires.

7. The Supplier shall notify the GQAR and/or the Acquirer of nonconforming product received from an External Provider that has been subject to Government Quality Assurance.

5.5 Performance Evaluation

5.5.1 Customer satisfaction [9.1.2]

1. Any complaints or deficiencies relevant to the contract, reported by the GQAR and/or Acquirer, shall be recorded as customer complaints.

2. The Supplier shall provide a response to the originator of the complaint or deficiency that shall include information on root cause analysis and corrective action.

Note: Customer complaints could be in the form of quality non-conformance, deficiency or occurrence reports or another format but regardless will be identified by the GQAR and/or Acquirer as 'customer complaints'.

5.5.2 Internal audit [9.2]

1. During the planning of internal audits the Supplier shall ensure that their audit programme covers all contract related critical processes and activities on an annual basis and includes contractual requirements and NATO supplements. The Supplier shall also consider the output from the actions to address risk and opportunities assessment.

2. Unless otherwise agreed, the Supplier shall inform the GQAR and/or Acquirer of deficiencies or findings identified during internal audit.

3. The Supplier shall retain documented information that demonstrates auditor training and experience.

5.5.3 Management review [9.3]

5.5.3.1 Management Review Input [9.3.2]

Documented information of review input, related to the contract, shall be available to the GQAR and/or Acquirer.

5.5.3.2 Management Review Output [9.3.3]

1. Documented information of the review output, related to the contract, shall be available to the GQAR and/or Acquirer.
2. The Supplier shall notify the GQAR and/or Acquirer of proposed action, resulting from Review Output that will affect compliance with contractual requirements. Review output shall, where action item(s) are identified, specify the responsible person/function and due date of the action item(s).

5.6 Improvement

5.6.1 Nonconformity and corrective action [10.2]

The Supplier shall define their process, including tools and techniques, used to support root cause analysis for nonconformities.

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