

**AQAP 2110
(Edition 1)**

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

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(Edition 1)**

(June 2003)

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**NORTH ATLANTIC TREATY ORGANIZATION
NATO STANDARDISATION AGENCY (NSA)
NATO LETTER OF PROMULGATION**

June 2003

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Jan H ERIKSEN
Rear Admiral, NONA
Chairman NSA

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Table of Contents

Section	Page number
1.0 General	1
1.1 Introduction.....	1
1.2 Purpose.....	1
1.3 Applicability.....	1
2.0 Compliance with this Publication	1
2.1 Organisational compliance.....	1
2.2 Contractual compliance.....	1
3.0 Composition of requirements in AQAP 2110	2
3.1 Composition.....	2
3.2 References.....	2
3.3 Definitions.....	3
4.0 Quality Management System	4
4.1 General requirements.....	4
4.2 Documentation requirements.....	4
5.0 Management responsibility	4
5.1 Management commitment.....	4
5.2 Customer focus.....	5
5.3 Quality Policy.....	5
5.4 Planning.....	5
5.5 Responsibility, authority and communication.....	5
5.6 Management review.....	6
6.0 Resource management	6
6.1 Provision of resources.....	6
6.2 Human resources.....	7
6.3 Infrastructure.....	7
6.4 Work environment.....	7
7.0 Product realisation	7
7.1 Planning of product realisation.....	7
7.2 Customer-related processes.....	7
7.3 Design and development.....	7
7.4 Purchasing.....	8
7.5 Production and service provision.....	9
7.6 Control of monitoring and measuring devices.....	10
7.7 Configuration Management.....	10
7.8 Reliability and Maintainability (R&M).....	10
8.0 Measurement, analysis and improvement	11
8.1 General.....	11
8.2 Monitoring and measurement.....	11
8.3 Control of non-conforming product.....	12
8.4 Analysis of data.....	12
8.5 Improvement.....	12
9.0 NATO additional requirements	12
9.1 Access to Supplier and Sub-suppliers and support for GQA activities.....	12
9.2 Products for release to the Acquirer.....	13

1.0 General

1.1 Introduction

1.1.1 AQAP 2110 contains the NATO requirements for Quality. A system needs to be established, documented, applied, maintained, assessed and improved, and/or evaluated, in accordance with requirements contained in the subsequent sections.

1.2 Purpose

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

1.3 Applicability

1.3.1 This publication is primarily intended for use in a contract between two or more parties.

1.3.2 When referenced in a contract, this publication shall apply to all of the processes necessary for the Supplier to fulfil the contractual requirements.

1.3.3 This publication may also be used internally by a Supplier or a potential Supplier to cover the Quality aspects of the Management System (MS).

1.3.4 Where identified by the Acquirer this publication can be used in conjunction with other appropriate standards to manage processes of the MS.

1.3.5 If inconsistencies exist between the contract requirements and this publication, the contract requirements shall prevail.

2.0 Compliance with this Publication

2.1 Organisational compliance

2.1.1 Compliance with AQAP 2110 at Supplier organisational level is defined as:
The fulfilment of the requirements of AQAP 2110, sections 4 to 9.

2.2 Contractual compliance

2.2.1 Compliance with this publication for a contract is defined as the fulfilment of the requirements in sections 4 to 9.

2.2.2 In this publication NOTES are not contractual requirements.

3.0 Composition of requirements in AQAP 2110

3.1 Composition

3.1.1 A requirement in this publication is composed as follows:

- a. A title.
- b. A NATO requirement or an ISO requirement. Each ISO-requirement may have one or more NATO supplements. The supplements are grouped under the ISO-requirement. A supplement is characterised as follows:
 - (1) “Change”: a change to one or more words, a sentence and/or section of the ISO-requirement(s).
 - (2) “Delete”: a deletion of one or more words, a sentence and/or section of the ISO-requirement(s).
 - (3) “Add”: an addition of one or more words, a sentence and/or section to the ISO-requirement(s). The addition can be of the following types:
 - (a) An addition of a NATO specific requirement
 - (b) A link to other AQAPs

3.1.2. Whenever the ISO requirement refers to “this international standard” it should be read as “this publication”.

3.2 References

3.2.1 Normative references:

ISO 9001:2000	Quality Management Systems – Requirements
ISO 9000:2000	Quality Management Systems – Fundamentals and Vocabulary
ISO 10012-1	Quality Assurance Requirements for measuring equipment

3.2.2 Informative references:

AQAP 2000	Policy on an Integrated Systems Approach to Quality through the Life Cycle
AQAP 2009	NATO Guidance on the use of the AQAP 2000 series
AQAP 2105	NATO Requirements for Deliverable Quality Plans
AQAP 2070	NATO Mutual Government Quality Assurance(GQA) process
ACMP	Allied Configuration Management Publications
ARMP	Allied Reliability and Maintainability Publications
STANAG 4159	NATO Materiel Configuration Management Policy and procedure for multinational joint projects

3.3 Definitions

Unless stated otherwise, ISO 9000:2000 definitions shall apply.

Acquirer	Governmental and/or NATO Organisations, that enter into a contractual relationship with a Supplier, defining the product and quality requirements
Certificate of Conformity	A document, signed by the Supplier, which states that the product conforms with contractual requirements
Government Quality Assurance	Government Quality Assurance is the process by which the appropriate National Authorities establish confidence that the contractual requirements relating to quality are met
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
Product	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 processes materials) or intangible (e.g. knowledge or concepts), or a combination thereof. A product can be either intended (e.g. offering to customers) or unintended (e.g. pollutant or unwanted effects)
Government Quality Assurance Representative	Government Quality Assurance Representatives are the Personnel with responsibility for Government Quality Assurance (GQA), acting on behalf of the Acquirer
Quality Plan	A Quality Plan is a 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
Supplier	Organisation that acts in a contract as the provider of products to the Acquirer
Sub-supplier	Provider of products to the Supplier

4.0 Quality Management System

4.1 General requirements

ISO 9001:2000 4.1 “General requirements” shall apply

NATO specific requirement:

Add:

The Supplier shall establish, document, implement, assess and improve an effective and economical system in accordance with this document, which includes the requirements of ISO 9001:2000 as necessary to satisfy the contract requirements.

The Acquirer and/or Government Quality Assurance Representative (GQAR) reserves the right to reject this system as it applies to the contract.

Objective evidence, which may include documentation from first, second and/or third party assessment/certification processes that this system is compliant with this Publication and is effective shall be readily available to the GQAR and/or Acquirer.

4.2 Documentation requirements

4.2.1 General

ISO 9001:2000 4.2.1 “General requirements” shall apply

4.2.2 Quality manual

ISO 9001:2000 4.2.2 “Quality Manual” requirements shall apply

NATO specific requirement:

Delete:

Last part of the sentence a): “including details of and justification for any exclusions (see 1.2)”.

4.2.3 Control of documents

ISO 9001:2000 4.2.3 “Control of documents” requirements shall apply

4.2.4 Control of records

ISO 9001:2000 4.2.4 “Control of records” requirements shall apply

NATO specific requirement:

Add:

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

5.0 Management responsibility

5.1 Management commitment

ISO 9001:2000 5.1 “Management commitment” requirements shall apply.

5.2 Customer focus

ISO 9001:2000 5.2 “Customer focus” requirements shall apply.

5.3 Quality Policy

ISO 9001:2000 5.3 “Quality Policy” requirements shall apply.

5.4 Planning

NATO specific requirement:

Add:

The Supplier shall submit a Quality Plan (QP) which addresses the contractual requirements to the GQAR and/or the Acquirer prior to the start of the activities. The QP shall be a clearly identified discrete document or part of another document that is prepared under the contract.

The QP shall play two complementary roles:

1. 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);
2. 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.

The Supplier and Sub-supplier shall provide objective evidence, that 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 updated thereafter in a timely manner. The Acquirer and/or GQAR reserve the right to reject QPs, Risk Plans and their revisions.

NOTE:

The QP requirements for role 1 relate to clause 5.4, while the QP requirements for role 2 relate to clause 7.1.

5.4.1 Quality objectives

ISO 9001:2000 5.4.1 “Quality Objectives” requirements shall apply.

5.4.2 Quality Management system planning

ISO 9001:2000 5.4.2 “Quality Management system planning” requirements shall apply.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

ISO 9001:2000 5.5.1 “Responsibility and authority” requirements shall apply.

5.5.2 Management representative

ISO 9001:2000 5.5.2 "Management representative" requirements shall apply.

NATO specific requirement:

Add:

The management representative shall have the necessary organisational authority and freedom to resolve matters pertaining to quality. The management representative shall report directly to top management.

5.5.3 Internal communication

ISO 9001:2000 5.5.3 "Internal communication" requirements shall apply.

NATO specific requirement:

Add:

The Supplier shall ensure that lines of communication are established with the GQAR and/or Acquirer.

5.6 Management review

5.6.1 General

ISO 9001:2000 5.6.1 "General" requirements shall apply.

5.6.2 Review input

ISO 9001:2000 5.6.2 "Review input" requirements shall apply.

NATO specific requirement:

Add:

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

5.6.3 Review output

ISO 9001:2000 5.6.3 "Review output" requirements shall apply.

NATO specific requirement:

Add:

Records of the review output, related to the contract, shall be available to the GQAR and/or Acquirer. The Supplier shall notify the GQAR and/or Acquirer prior to making significant changes to its organisation that affect product quality or the Quality Management System.

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).

6.0 Resource management

6.1 Provision of resources

ISO 9001:2000 6.1 "Provision of resources" requirements shall apply.

6.2 Human resources

6.2.1 General

ISO 9001:2000 6.2.1 “General” requirements shall apply.

6.2.2 Competence, awareness and training

ISO 9001:2000 6.2.2 “Competence, awareness and training” requirements shall apply.

6.3 Infrastructure

ISO 9001:2000 6.3 “Infrastructure” requirements shall apply.

6.4 Work environment

ISO 9001:2000 6.4 “Work environment” requirements shall apply.

7.0 Product realisation

7.1 Planning of product realisation

ISO 9001:2000 7.1 “Planning of product realisation” shall apply.

NATO specific requirement:

Add:

For details, see this publication clause 5.4.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product.

ISO 9001:2000 7.2.1 “Determination of requirements related to the product” shall apply.

7.2.2 Review of requirements related to the product

ISO 9001:2000 7.2.2 “Review of requirements related to the product” shall apply.

7.2.3 Customer communication

ISO 9001:2000 7.2.3 “Customer communication” shall apply.

NATO specific requirement:

Add:

The Supplier shall ensure that lines of communication are established with the GQAR and/or Acquirer.

7.3 Design and development

7.3.1 Design and development planning

ISO 9001:2000 7.3.1 “Design and development planning” shall apply.

7.3.2 Design and development inputs

ISO 9001:2000 7.3.2 "Design and development inputs" shall apply.

7.3.3 Design and development outputs

ISO 9001:2000 7.3.3 "Design and development outputs" shall apply.

7.3.4 Design and development review

ISO 9001:2000 7.3.4 "Design and development review" shall apply.

7.3.5 Design and development verification

ISO 9001:2000 7.3.5 "Design and development verification" shall apply.

NATO specific requirement:

Add:

Unless invoked in the contract, the Supplier shall determine the test methods required and perform the tests to demonstrate conformity with the corresponding requirements at appropriate stages up to and including the final product.

7.3.6 Design and development validation

ISO 9001:2000 7.3.6 "Design and development validation" shall apply.

7.3.7 Control of design and development changes

ISO 9001:2000 7.3.7 "Control of design and development changes" shall apply.

7.4 Purchasing

7.4.1 Purchasing process

ISO 9001:2000 7.4.1 "Purchasing process" shall apply.

NATO specific requirement:

Add:

The Supplier shall on request provide the GQAR and/or Acquirer with a copy of any subcontracts or orders for products related to the contract. The Supplier shall notify the GQAR and/or Acquirer if a subcontract or order has been identified as constituting or involving risk. This shall be documented in accordance with 5.4 of this publication.

7.4.2 Purchasing information

ISO 9001:2000 7.4.2 "Purchasing information" shall apply.

NATO specific requirement:

Add:

The Supplier shall flow down the applicable contractual requirements to Sub-suppliers 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."

Only the Supplier placing the purchasing documents with a Sub-supplier will issue consequential instructions to that Sub-supplier. It is the Supplier's responsibility to ensure that the procedures and processes required to fulfil contract requirements are fully implemented at the Sub-supplier's facilities.

GQA activities at Sub-supplier'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 Sub-supplier's facilities can only be requested by the GQAR and/or Acquirer.

7.4.3 Verification of purchased product

ISO 9001:2000 7.4.3 "Verification of purchased product" shall apply.

NATO specific requirement:

Add:

Suppliers shall notify the GQAR and/or Acquirer if a sub-supplied product is rejected or repaired which has been identified as involving risk or supplied by a Sub-supplier whose selection or subsequent performance has been identified as involving risk.

7.5 Production and service provision

7.5.1 Control of production and service provision

ISO 9001:2000 7.5.1 "Control of production and service provision" shall apply.

7.5.2 Validation of processes for production and service provision

ISO 9001:2000 7.5.2 "Validation of processes for production and service provision" shall apply.

7.5.3 Identification and traceability

ISO 9001:2000 7.5.3 "Identification and traceability" shall apply.

7.5.4 Customer property

ISO 9001:2000 7.5.4 "Customer property" shall apply.

NATO specific requirement:

Add:

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.

7.5.5 Preservation of product

ISO 9001:2000 7.5.5 "Preservation of product" shall apply.

7.6 Control of monitoring and measuring devices

ISO 9001:2000 7.6 "Control of monitoring and measuring devices" shall apply.

NATO specific requirement:

Delete NOTE

Add:

The measurement and calibration system applied to this contract shall be in accordance with the requirement of ISO 10012-1.

When an item of measuring equipment is found to fail re-calibration or is not in calibration, and when there are affected products, the GQAR and/or Acquirer is to be informed and presented with details of affected products, including products already delivered.

7.7 Configuration Management

No ISO requirement available

NATO specific requirement:

Add:

7.7.1 Configuration Management (CM) requirements

As a minimum, the Supplier shall describe and document the CM procedures for:

- Configuration Identification
- Configuration Control
- Configuration Status Accounting
- Configuration Audit

7.7.2 Configuration Management Plan (CMP)

The Supplier shall prepare a CMP, which describes the application of CM to the contract.

NOTE:

The CMP may form part of another plan if appropriate.

NATO Configuration Management Policy is established in STANAG 4159 while detailed contractual requirements for CM are contained within STANAG 4427 and associated Allied Configuration Management Publications (ACMP).

7.8 Reliability and Maintainability (R&M)

No ISO requirement available

NATO specific requirement:

Add:

- 7.8.1 If stated in the contract, the Supplier's R&M system, appropriate to the design of the product, shall ensure that R&M issues and related documents, including those from associated Sub-suppliers, are controlled.

NOTE:

NATO Reliability and Maintainability Policy is established in STANAG 4174 while detailed contractual requirements for Reliability and Maintainability Management are contained within Allied Reliability and Maintainability Publications (ARMP).

8.0 Measurement, analysis and improvement

8.1 General

ISO 9001:2000 8.1 "General" requirements shall apply.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

ISO 9001:2000 8.2 "Customer satisfaction" requirements shall apply.

NOTE:

Any complaints or deficiencies relevant to the contract, reported by the GQAR will be recorded as customer complaints.

8.2.2 Internal audit

ISO 9001:2000 8.2.2 "Internal audit" requirements shall apply.

NATO specific requirement:

Add:

The Supplier shall ensure that all contractual requirements, including NATO supplements, are included in internal audits.

The Supplier shall inform the GQAR and/or Acquirer of deficiencies identified during internal audit unless otherwise agreed between the GQAR and/or Acquirer and the Supplier.

8.2.3 Monitoring and measurement of processes

ISO 9001:2000 8.2.3 "Monitoring and measurement of processes" requirements shall apply.

8.2.4 Monitoring and measurement of product

ISO 9001:2000 8.2.4 "Monitoring and measurement of product" requirements shall apply.

NATO specific requirement:

Add:

The Supplier shall provide a Certificate of Conformity at release of product to the GQAR and/or Acquirer unless otherwise instructed.

The Supplier is solely responsible for the quality of all products he provides to the Acquirer.

8.3 Control of non-conforming product

ISO 9001:2000 8.3 “Control of non-conforming product” requirements shall apply.

NATO specific requirement:

Add:

The Supplier shall issue and implement procedures which identify, control and segregate non-conforming products.

Procedures for the disposition of non-conforming product are subject to disapproval by the GQAR and/or Acquirer when it can be shown that they do not provide the necessary controls.

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.

All rework, repair and use-as-is dispositions must be acceptable to the GQAR and/or Acquirer. When the Supplier establishes that an acquirer-supplied product is unsuitable for its intended use, he shall immediately report to and coordinate with the Acquirer the remedial actions to be taken. The Supplier shall also inform the GQAR.

The Supplier shall notify the GQAR and/or the Acquirer of non-conforming product received from a Sub-supplier that has been subject to Government Quality Assurance.

8.4 Analysis of data

ISO 9001:2000 8.4 “Analysis of data” requirements shall apply.

8.5 Improvement

8.5.1 Continual improvement

ISO 9001:2000 8.5.1 “Continual improvement” requirements shall apply.

NOTE:

The application of this section is intended to be limited to the scope of the contract.

8.5.2 Corrective action

ISO 9001:2000 8.5.2 “Corrective action” requirements shall apply.

8.5.3. Preventive action

ISO 9001:2000 8.5.3 “Preventive action” requirements shall apply.

9.0 NATO additional requirements

9.1 Access to Supplier and Sub-suppliers and support for GQA activities

9.1.1 The Supplier and/or Sub-suppliers shall provide the GQAR and/or Acquirer:

- The right of access to facilities where parts of the contracted activities are being performed.
- Information pertaining to the fulfilment of requirements in the contract.

- Unrestricted opportunity to evaluate Supplier compliance with this Publication.
- Unrestricted opportunity to conduct verification of product conformity with the contract requirements.
- Required assistance for evaluation, verification, validation, testing, inspection or release of the product for the accomplishment of GQA to contract requirements.
- Accommodation and facilities.
- The necessary equipment available for reasonable use for performing GQA.
- Supplier and or Sub-suppliers personnel for operation of such equipment as required.
- Access to information and communication facilities.
- The necessary Supplier documentation, to confirm product conformance to specification.
- Copies of necessary documents, including those on electronic media.

9.2 Products for release to the Acquirer

9.2.1 The Supplier shall ensure that only acceptable products, intended for delivery, are released. GQAR and or Acquirer reserve the right to reject non-conforming products.