STANDARDS RELATED DOCUMENT

AQAP-2110-SRD.3.1

TRAINING MATERIAL TO SUPPORT AQAP-2110 EDITION D - PRESENTATION

Edition A Version 1

NOVEMBER 2020

NORTH ATLANTIC TREATY ORGANIZATION

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NATO STANDARDIZATION OFFICE (NSO)

NATO LETTER OF PROMULGATION

16 November 2020

1. The enclosed Standards Related Document, AQAP-2110-SRD.3.1, Edition A, Version 1, TRAINING MATERIAL TO SUPPORT AQAP-2110 EDITION D - PRESENTATION, which has been approved in conjunction with AQAP-2110 by the nations in the Life Cycle Management Group, is promulgated herewith.

2. AQAP-2110-SRD.3.1, Edition A, Version 1, is effective upon receipt.

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4. This publication shall be handled in accordance with C-M(2002)60.

[Signature]
Zoltán Gulyás
Brigadier General, HUNAF
Director, NATO Standardization Office
AQAP 211O Edition D Training

Venue  dd-mmm-yyyy

• Presenters
AQAP 2110 Ed D Training: Content

1. Introduction to AQAPs
2. Applicability to Contract and Supplier QMS
3. Structure and Overview of AQAP 2110
4. Requirements, Definitions and Interpretation
5. Further guidance
6. Acquirer and/or GQAR Responsibilities
7. Quiz
AQAP 2110 Edition D Training

Training Aims:

• To provide an awareness of the new requirements of AQAP 2110 Edition D

• To promote a consistent interpretation based on NATO guidance

• To explore what you can do as the Acquirer/GQAR in relation to the requirements of AQAP 2110 Ed D
AQAP 2110 Ed D Training: Format

• Slides detailing REQUIREMENTS and GUIDANCE
• Interactive - ask questions, offer comment
• Quiz
AQAP 2110 Edition D Training

1. Introduction to AQAPs
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AQAP Training Introduction

Why do we use Allied Quality Assurance Publications (AQAPs)?

• Common definition of NATO requirements for quality that can be used in global supply chains
• Supports Government Quality Assurance between nations and agencies
• Provide defence context to ISO 9001:2015 requirements
  – ISO 9001 defines a set of generic requirements for a QMS
  – AQAPs define additional NATO requirements to be applied to specific contracts
• Makes provision for GQAR and/or Acquirer access and assistance
• GQAR and/or Acquirer right to reject product, QMS and plans without penalties
Contractual Quality Requirements

**AQAPs**
Use AQAP Selection Guidance

- **GQA***
- **No GQA**

**No AQAPs**
Consider other QA requirements:
- Certification or Compliance with International QMS Standards e.g. ISO 9001, AS9100, AS9110, etc.
- Specific clauses in Contract/SOW

*Note: A Primary AQAP must be invoked in the contract if GQA is required.*
Government Quality Assurance (GQA)

- The decision to request GQA needs to be based on risk.
- STANAG 4107 is the overarching agreement for Mutual GQA between NATO nations and the usage of AQAPs.
- Link to STANAG 4107 Edition 11:
  - [https://nso.nato.int/nso/nsdd/stanagdetails.html?idCover=9184&LA=EN](https://nso.nato.int/nso/nsdd/stanagdetails.html?idCover=9184&LA=EN)
- **Note:** RGQA can be rejected (by exception) under the provisions of AQAP 2070.
Government Quality Assurance (GQA)

AQAP 2070 defines the process for NATO Mutual Government Quality Assurance (GQA).

- AQAP 2070 is not a contractual document
- It describes the processes that should be followed by staff (delegators and delegates) involved in Government to Government GQA activities
- Activation of GQA services is dependant on the conditions and process steps defined in AQAP 2070
- Link to AQAP 2070 Edition B: https://nso.nato.int/nso/nsdd/apdetails.html?APNo=2980
Government Quality Assurance (GQA)

- Where GQA is a requirement, it is important that there is synergy between the contractual requirements and the Request for Government Quality Assurance (RGQA) requirements.
- e.g. If the RGQA requires the GQAR to sign a statement of GQA on a CofC for partial or full shipments, a corresponding condition or statement should be included in the contract.
Government Quality Assurance (GQA)

- GQA provides confidence that the Supplier has met contractual requirements relating to quality.
- The GQAR does **not** accept, inspect or test the product.
- The Supplier is solely responsible for the conformance to requirements, of products provided to the Acquirer.
- GQA surveillance is risk-based and primarily process-oriented.
Risk Identification: Risk Factors

Exercise:

For each of the topics below, please give examples of risk factors or sources of data which will inform the contract risk identification process.

- Product
- Contract
- Supplier
- Defects & Issues
- Customer

Note: Supplier risk should not drive selection of AQAPs in contracts, but may influence the decision to invoke GQA.
# Risk Identification: Risk Factors

## Product
- Design maturity e.g. new design, modifications, upgrades
- Complexity
- Software
- Lifecycle
- Risk of counterfeit
- Critical Safety Item
- Operational Environment

## Contract
- Timescales e.g. Urgent Operational Requirement?
- Cost/value
- Duration
- Requirements e.g. clear, defined, realistic
- Legislation

## Supplier
- Performance e.g. quality, OTD
- QMS Certification
- QMS Scope
- Capability
- Supply Chain
- Stability
- Single Source
- Engagement with customers
- Pre Contract Award Evaluation

## Defects and Issues
- Defect Reports
- QDRs
- RIACs
- In-Service Issues
- Platform Issues e.g. integration
- Lessons Learned

## Customer
- Risks
- Requirements
- Concerns
- Delegated responsibilities
- Feedback
- Priorities
- Stakeholder engagement
## Contractual AQAPs @ November 2017

<table>
<thead>
<tr>
<th>AQAP 2110</th>
<th>AQAP 2120</th>
<th>AQAP 2130</th>
<th>AQAP 2131</th>
<th>AQAP 2310</th>
<th>AQAP 2210</th>
<th>AQAP 2105</th>
</tr>
</thead>
</table>
| • NATO Quality Assurance Requirements for Design, Development & Production  
• Ed 3 aligns with ISO 9001:2008  
• Ed D aligns with ISO 9001:2015 | • NATO Quality Assurance Requirements for Production  
• Ed 3 aligns with ISO 9001:2008 | • NATO Quality Assurance Requirements for Inspection & Test  
• Ed 3 aligns with ISO 9001:2008 | • NATO Quality Assurance Requirements for Final Inspection  
• Relates to all inspection and testing  
• Standalone publication  
• No link to ISO 9001  
• Ed 2 | • NATO QMS Requirements for Aviation, Space & Defence Suppliers  
• Ed A Ver 1 aligns with AS9100:2009 | • NATO Supplementary Software QA Requirements to AQAP 2110 or AQAP 2310  
• Ed A Ver 2 aligns with AQAP 2110 Ed 3 and AQAP 2310 Ed A Ver 1 | • NATO Requirements for Deliverable Quality Plans  
• Ed 2 aligns with AQAP 2110/2120/2130 Ed 3 |

### Primary QA Conditions

### Supplementary QA Conditions
<table>
<thead>
<tr>
<th>AQAP 2110</th>
<th>AQAP 2131</th>
<th>AQAP 2310</th>
<th>AQAP 2210</th>
<th>AQAP 2105</th>
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• New Edition B aligns with AS 9100:2016 | • NATO Supplementary Software QA Requirements to AQAP 2110 or AQAP 2310  
• New Edition A aligns with AQAP 2110 Ed D and AQAP 2310 Ed B | • NATO Requirements for Deliverable Quality Plans  
• New Edition C aligns with AQAP 2110 Ed D, AQAP 2310 Ed B and AQAP 2210 |

**Primary QA Conditions**

**Supplementary QA Conditions**
AQAP Selection Guidance

START

Design or Production risk?

- Yes
  - Supplier to comply with AS/EN9100?
    - Yes
      - AQAP 2310
    - No
      - AQAP 2110

- No
  - Final Inspection or Test?
    - Yes
      - AQAP 2131
    - No

PRIMARY AQAPs

Select one only

- AQAP 2310
- AQAP 2110
- AQAP 2131

Software Development?

- Yes
  - AQAP 2210
- No

Standardised Quality Plan?

- Yes
  - AQAP 2105
- No

Provenance?

- Yes
  - Request CoC
- No

FINISH
Contractual AQAPs

Exercise:

Q. A contract is to be placed for an upgrade to a batch (Qty 30) of electronic cryptographic units. The upgrade involves hardware and software modifications. What AQAPs should be invoked in the contract?

   a) No AQAPs
   b) AQAP 2131
   c) AQAP 2110
   d) AQAP 2110 and AQAP 2210
Reason for update:
- to reflect changes in ISO 9001:2015 standard
- inclusion of new requirements based on Acquirer and GQAR experience

Link to AQAP 2110 Edition D:
- [http://nso.nato.int/nso/nsdd/apdetails.html?APN=o=2286](http://nso.nato.int/nso/nsdd/apdetails.html?APN=o=2286)
AQAP 2110 Edition D Introduction

• AQAP 2110 Edition 3 invoked ISO 9001:2008 requirements plus additional NATO specific requirements and was withdrawn in September 2018

• AQAP 2120 and 2130 have also been withdrawn

• Expected that AQAP 2110 Ed D will now be used

• AQAP 2110 Ed D invokes ISO 9001:2015 requirements plus additional NATO specific requirements
AQAP 2110 Edition D Introduction

• It is expected that Suppliers will have transitioned to ISO 9001:2015 by September 2018

• Revised AQAP selection guidance issued in November 2018. Link to AQAP 4107 SRD.2 Edition A Version 1:
  • https://nso.nato.int/nso/nsdd/SRDdetails.html?SRDNo=141&LA=EN

• Note: AQAP 2310 Edition B NATO QMS Requirements for Aviation, Space and Defence Suppliers aligns with AS/EN 9100:2016
AQAP 2110 Ed D Training

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AQAP 2110 Ed D & Supplier QMS

• AQAP 2110 Ed D does not require Suppliers to have a certified management system to ISO 9001:2015
• Ed D requires the Supplier’s QMS, as it applies to the contract, to comply with the requirements of ISO 9001:2015
• Ed D also requires that the Supplier must be able to readily provide evidence of such compliance
  – Suppliers generally use third party certification to demonstrate that they meet the ISO 9001 requirements contained within AQAP 2110.
AQAP 2110 Ed D & Supplier QMS

• ISO 9001:2015 certification does **not** equate to AQAP compliance

• ISO 9001:2015 certification may support demonstration of compliance with Chapter 4 requirements of the AQAP

• Suppliers must also demonstrate compliance with the NATO-specific requirements contained in AQAP 2110 Ed D Chapter 5
AQAP 2110 Ed D & Supplier QMS

- AQAP 2110 Ed D is not supported by tailored versions (i.e. AQAP 2120 and AQAP 2130)

- For all contracts, the Supplier shall have a QMS appropriate for the products or services being acquired
  - Applicable QMS processes can be captured in a contract quality plan

- NATO-specific requirements of AQAP 2110 can be addressed in contract-specific quality plans, where appropriate
Where mandated in a contract (e.g. for high risk projects, etc.), **appropriate certification** is:-

- QMS certified to a recognised European [EN] standard e.g. BS EN ISO 9001:2015
- Certification Body must hold suitable accreditation from a National Accreditation Body (NAB) who is a signatory to the International Accreditation Forum (IAF)
- Supplier registered scope of work must cover intended acquisition

Link to IAF website: [https://www.iaf.nu/articles/IAF_MEMBERS_SIGNATORIES/4](https://www.iaf.nu/articles/IAF_MEMBERS_SIGNATORIES/4)
AQAP 2110 Ed D & Supplier QMS

- AQAP 2110 Chapter 4.1 establishes the applicability of ISO 9001:2015 requirements as necessary to satisfy the contract.

- ISO 9001:2015 Para 4.4.1 requires that the Supplier implement and maintain a QMS, and to the extent necessary maintain documented information (4.4.2). Para 5.1.2 requires that customer requirements are considered.

- The above establishes that the Supplier must maintain a QMS with the processes necessary to achieve the contractual requirements.
Example:

A Supplier has a QMS certified to ISO 9001:2015 and the scope of certification includes the design, manufacture and repair of Printed Circuit Boards (PCBs).

A defence contract is placed with the Supplier for the manufacture of a batch of “build-to-print” PCBs.

- The requirements of AQAP 2110 Ed D Chapter 5.4.3 and ISO 9001:2015 Paragraph 8.3 will not apply to this contract
- The Supplier’s quality planning would address any MOD specific requirements such as part numbers, labelling, etc., but the core activity is within the scope of the QMS.
AQAP 2110 Edition D Training

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AQAP 2110 Ed D and ISO 9001:2015
Structure of AQAP 2110 Edition D

• AQAP 2110 Ed D adopts a revised format
• Previous version referenced all ISO 9001 sub-headings
• AQAP 2110 Ed D:
  – invokes ISO 9001:2015 requirements as necessary in Chapter 4
  – groups NATO requirements in Chapter 5
  – AQAP sub-headings X-refer to related ISO paragraphs
Overview of AQAP 2110 Ed D

• Maintains focus on risk management & quality planning.
  – Extends these concepts to the supply chain
• Increased focus on requirements management:
  – Identification of how they are to be achieved
  – Evidence to be presented to support product release
• Supplier to establish and maintain knowledge of the supply chain and external provider assurance activities
AQAP 2110 Edition D Training

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AQAP 2110 Ed D: Key Concepts

• Management representative
• Risk Management
• Infrastructure
• Planning
• Customer communication
• Critical characteristic

• Dependability
• Supply chain
• Purchasing
• Counterfeit material
• Traceability
• Customer satisfaction
• Improvement
AQAP 2110 Chapter 3.3.7 Definitions

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.
Access to Supplier and External Providers and Support for GQA Activities.

- These requirements emphasise the Supplier’s responsibility to provide unrestricted access and assistance for the GQAR and/or Acquirer where any parts of the contracted work are being performed.
AQAP 2110: Management Representative

Management representative

• The appointment of a management representative is critical to ensuring that the GQAR and/or Acquirer can perform their duties effectively.

• AQAP 2110 Ed 3 required that a management representative be appointed with the necessary authority and freedom to resolve matters pertaining to quality.

• The management representative is responsible for liaison with the GQAR and/or Acquirer for all quality-related aspects.

• Edition D extends the above to include a requirement related to the competence of the management representative.
Competence of management representative

5.1.1 Organisational roles, responsibilities and authorities [5.3]

3. The management representative shall have the appropriate competence related to Quality Management.
Guidance:

• It is reasonable to confirm that the management representative is suitably qualified and experienced regarding Quality Management (QM).

• Currency of QM knowledge should be maintained through training and professional development.
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.
AQAP 2110 Ed D: Risk Management

• ISO 31000:2009 defines the principles, framework and process for risk management.
• The framework assists the organisation to embed risk management into its overall management system.
• The process requires the organisation to:-
  – establish its context
  – identify, analyse, evaluate and treat risks
  – continuously monitor and review the process
  – communicate and consult with internal and external stakeholders
AQAP 2110 Ed D: Risk Management

• AQAP 2110 Ed D invokes ISO 31000:2009

• **Note:** ISO 31000:2009 has been superseded by ISO 31000:2018

• If Supplier is required to comply with the latest version of ISO 31000, the Acquirer should consider inclusion of suitable statement in the contract.
AQAP 2110 Ed D: Risk Management

Guidance:

• The risk information/plan can be included in another document but risks must be relevant to the contract. There should be evidence that:
  – risks are being actively reviewed and, where appropriate, mitigation actions are being pursued and are effective.
  – senior managers use risk information as part of their decision making process and at the QMS review.
  – Supplier and Acquirer are sharing risk information.
AQAP 2110 Ed D: Risk Management

Exercise:

Q. Give 3 reasons why the Acquirer and/or GQAR might reject a Risk Plan.
AQAP 2110 Ed D: Risk Management

Example:

GQAR analysis of performance metrics identifies that the performance of an External Provider of a critical item for a defence contract has fallen significantly during the last two quarters. It is expected that:

- The Supplier risk management plan identifies how External Provider risks are to be managed
- External Provider poor performance has been identified as a risk in the Project/Supplier risk register and risk information is regularly reviewed
- Mitigation actions have been identified and are being pursued
- The risk has been communicated to senior management to inform their decision making process and QMS review
- The Supplier has informed the GQAR and/or Acquirer of the risk
Segregation

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).
Guidance: Segregation

• Wherever possible, an area should be set aside for nonconforming parts and the level of control / access for this area should be appropriate for the type of product.

• Where NC parts cannot be segregated or it would not be cost effective to do so; positive materiel control and identification should be confirmed both in stock management systems and through physical identification or ‘locking’.
5.4.1.1 Quality Plan (QP)

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).
AQAP 2110 Ed D: Planning

Guidance: Quality Plan

- The Quality Plan should be developed in conjunction with other project-related planning, e.g. as a sub-set of the Project Management Plan.

- Where functions and processes are clearly defined in the Supplier’s QMS, a cross-reference is recommended.

- AQAP 2105 may be used as a framework for the Quality Plan, but other standards can be invoked e.g. ISO 10005, AS/EN9145, etc.
Guidance: Quality Plan

• If activity is being undertaken out with the Supplier’s QMS scope or usual location, theQP should detail how activity is to be controlled. The plan should also consider how the Supplier will interface with other organisations.
  
  – E.g. where a Supplier is performing work at another Supplier’s location or military site and does not have access to their normal infrastructure for tool control, storage of consumables, etc.
AQAP 2110 Ed D: Planning

**Guidance:** Quality Plan

- Traceability of requirements can be included in another document or for complex products the supplier can refer to a requirements management software tool.

- Traceability of requirements to be maintained throughout the product lifecycle.

- Linkage and configuration control between requirements, analysis, architecture, design, verification and validation, etc.
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.
Guidance: Post Award GQA Meeting

• Purpose: To organize the practicalities for performing GQA during the contract between Supplier (and/or External Providers) and Acquirer and/or GQAR by for example:
  – Appointing the points of contact for GQA;
  – Agreeing of the composition of evidence and elements of evidence;
  – Planning the provision of evidence and elements of evidence;
  – Defining conditions for Acquirer and/or GQAR to get visibility over processes.
The Post Contract Award GQA meeting provides an opportunity for the Supplier and Acquirer and/or GQAR to establish lines of communication, how the GQAR will interface with the Supplier during the contract including sharing and transmission of information and what QA activities are planned for the product and the supply chain.

For your specific contract scenario, which of the following information would you expect to be available at the Post Contract Award GQA Meeting?
### AQAP 2110 Edition D Training

**Syndicate Exercise:** Post Contract Award GQA Meeting

<table>
<thead>
<tr>
<th>Information</th>
<th>AQAP Chapter/Paragraph</th>
<th>Available Y/N?</th>
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<tr>
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<td>Quality Plan</td>
<td>5.4.1.1</td>
<td></td>
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<tr>
<td>Risk Management Plan</td>
<td>5.2.1</td>
<td></td>
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<td>Configuration Management Plan</td>
<td>5.4.1.2.2</td>
<td></td>
</tr>
<tr>
<td>Customer Communication strategy</td>
<td>5.4.2</td>
<td></td>
</tr>
<tr>
<td>Dependability</td>
<td>5.4.5</td>
<td></td>
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<tr>
<td>Critical Product Characteristics</td>
<td>5.4.3</td>
<td></td>
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<tr>
<td>Knowledge of the Supply Chain</td>
<td>5.4.6.1</td>
<td></td>
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<tr>
<td>Knowledge of Sub-Supplier Quality Assurance Activities</td>
<td>5.4.6.1</td>
<td></td>
</tr>
<tr>
<td>Counterfeit Material avoidance, detection and mitigation process</td>
<td>5.4.6.2.(2)</td>
<td></td>
</tr>
</tbody>
</table>
Scenario 1:

- A new Defence Contract has been awarded to a Supplier and the GQAR and/or Acquirer has been invited to attend a Post Contract Award GQA Meeting. The contract is for the development of a one-off prototype model of a new laser weapon, utilising innovative cutting-edge technology. The estimated contract duration is 28 months.
Scenario 2:

- A new Defence Contract has been awarded to a Supplier and the GQAR and/or Acquirer has been invited to attend a Post Contract Award GQA Meeting. The contract is for the manufacture and supply of hull valves for in-service warships. The estimated contract duration is 12 months.
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.

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.
AQAP 2110 Ed D: Critical Characteristic

Guidance:

• Supplier should have an understanding of how the product relates to the critical characteristics
  – This may be difficult for sub tier suppliers who may not be aware of where their product is used.

• This will ensure that resources are used appropriately and that decisions affecting product conformity are made by the right people in the organisation
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.
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).
Guidance:

• The dependability characteristics of any item are inherent in its design.

• Dependability should be considered from the very beginning of the pre-concept stage and be continued, in a disciplined manner, throughout the whole life cycle by the implementation of dependability disciplines as described in the IEC 60300 series standards.
5.4.6 Control of externally provided processes, products & services

1. 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.
AQAP 2110 Ed D: Supply Chain

Guidance:

• The Supplier should be able to demonstrate to the GQAR and/or Acquirer that the resulting products and services meet the requirements for the specified application or intended use.

• This includes traceability and corrective action e.g. inspection and test records and results of the activities.
5.4.6.1 Control of externally provided processes, products & services

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.

4. 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.
Guidance:

• Supplier should focus QA resource and sub supplier controls based on the level of risk as it applies to the contract.

• Sub supplier controls are usually influenced by past performance. Ed D extends these controls to reflect the criticality of the supplier in relation to the product/contract and deliberately focuses on areas of potential risk such as design.

• Criteria provided will inform the Supplier’s risk based thinking.
AQAP 2110 Ed D: Supply Chain Linkages

GQAR and/or Acquirer

SUPPLIER

5.4.6.3

5.4.1

5.4.6

5.4.6.2

5.4.6.1

Product Approval & Production Process Approval

Verification & Validation of Products

Implementation of procedures & processes to fulfil requirements

Quality Assurance Activities

EXTERNAL PROVIDER

EXTERNAL PROVIDER

EXTERNAL PROVIDER

KEY

Maintains Knowledge

Ensures

Documented Information

Communicates

SUPPLY CHAIN

SUPPLY CHAIN

SUPPLY CHAIN

SUPPLY CHAIN

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AQAP 2110 Ed D: Purchasing Pt. 1

Documented information for external providers

5.4.6.1 General

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.
Guidance: Documented information for external providers

• It is important that the Supplier clearly identifies the process and criteria to be applied to assess whether:-
  – contractual conditions are ‘flowed down’ to the supply chain.
  – purchasing documentation fully identifies the product and applicable contractual conditions.

• The process must offer assurance that a consistent rationale is applied and any associated supply chain risks are documented and addressed.
Exercise:


Contract Conditions:
- AQAP 2110: NATO Quality Assurance Requirements for Design, Development and Production.
- AQAP 2210: NATO Supplementary Software QA Requirements to AQAP 2110 and AQAP 2310
- IEC 60034: Rotating Electrical Machines

Which of the contract conditions would be most appropriate to flow down in the following sub-contracts?
1. Acquisition of programmable Control Panel.
2. Supply of COTS manual emergency Start/Stop button.
3. Overhaul and modification of electric motor.
AQAP 2110 Ed D: Counterfeit Material

• Counterfeit materiel may have unpredictable performance and failure modes which could compromise capability and equipment safety.

• Additional measures have been implemented to reduce the contractual risk of counterfeit material, including:-
  – AQAP 2110 Ed D includes a definition for Counterfeit Material and a new requirement relating to Counterfeit Material.
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.
5.4.6.2 Counterfeit

2. The Supplier shall establish and implement a process for the avoidance, detection, mitigation, and disposition of Counterfeit Materiel.
# AQAP 2110 Ed D: Counterfeit Modes

<table>
<thead>
<tr>
<th>COUNTERFEIT TYPES</th>
<th>Source of Origin</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>False Trade Mark, False Manufacturer’s Name</td>
<td>False Extended Expiry Date, Recycled</td>
</tr>
<tr>
<td>Composition</td>
<td>Misrepresentation of Material (e.g. Lead vs Lead Free)</td>
<td></td>
</tr>
<tr>
<td>Configuration</td>
<td>Incorrect Marking/Identification</td>
<td></td>
</tr>
<tr>
<td>Certification</td>
<td>False Certification, False Documents</td>
<td></td>
</tr>
<tr>
<td>Material Characteristics</td>
<td>False Specification Claims (e.g. Military vs Industrial), False Material Strength Claim</td>
<td></td>
</tr>
<tr>
<td>Misrepresentation</td>
<td>Lesser Quality, Repackaged to look like new</td>
<td></td>
</tr>
</tbody>
</table>
Guidance:

• Increased probability of counterfeit materiel where:
  – components or raw material are of a type known to be vulnerable to counterfeiting
  – design requires sourcing of parts that are obsolescent, or are foreseen to become obsolescent during the lifecycle of the equipment
  – likely to be multiple tiers in the supply chain
  – traceability of the materiel is not otherwise mandated
  – design includes Electrical, Electronic and Electro-mechanical (EEE) Parts
  – counterfeiting of test results enables the product to be accepted by an organisation
  – counterfeiting of certificates enables an organisation to benefit from that certification without achieving the required standard or output
## AQAP 2110 Ed D: Counterfeit Material

### Counterfeit risk identification table

<table>
<thead>
<tr>
<th>Source of Supply</th>
<th>Product and Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Supplier</td>
<td>Safety Critical Application</td>
</tr>
<tr>
<td>Supplier</td>
<td>Mission Critical Application</td>
</tr>
<tr>
<td>Full Traceability of Materiel</td>
<td>Parts Obsolescence</td>
</tr>
<tr>
<td>Multiple Tier Supplier</td>
<td>Complex Equipment</td>
</tr>
<tr>
<td>Limited Traceability</td>
<td>Non Critical Application</td>
</tr>
<tr>
<td>On-line Sales</td>
<td>Lower Risk</td>
</tr>
</tbody>
</table>

Legend:
- **Highest Risk**: Safety Critical Application
- **Intermediate Risk**: Mission Critical Application, Parts Obsolescence, Complex Equipment
- **Lowest Risk**: Non Critical Application, Full Traceability of Materiel, Limited Traceability, New Supplier, Supplier, Trading history ascertained

Source:
- AQAP 2110 Ed D
- NATO OTAN
5.4.6.3 Communication

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.
Guidance:

- AQAP 2110 Ed 3 required that the Supplier inform the GQAR/Acquirer ‘if a subcontract or order has been identified as constituting or involving risk.’
- Ed D focuses on specific characteristics/ risk areas that the Supplier has decided to subcontract which will enable the GQAR and/or Acquirer to determine appropriate levels of GQA activity.
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.
AQAP 2110 Ed D: Traceability

Guidance:

• ISO 9001 defines the actions to be taken when traceability is a requirement.

• AQAP 2110 Ed D provides criteria for when traceability must be maintained.

• The Supplier is required to maintain build records during manufacture where components and materials have been used.

• Records should be able to support product recall in the event that batches of material are subsequently found to be suspect or nonconforming.
AQAP 2110 Ed D: Control of Shelf Life

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.
Guidance:

• Defence product can be in the manufacturing process for a considerable time, e.g. pumps on a ship. A maintenance regime exists within the manufacturing process.

• Installed equipment should be entered in a maintenance process with the OEM from the time of issue to the time of receipt, including sub-assemblies.
5.4.11 Release of products [8.6]

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.
Guidance:

- Suppliers are required to conduct effective planning for final inspection and formal acceptance activities.
- This requirement encourages Suppliers to communicate key events to the GQAR and/or Acquirer.
- The aim is to ensure that appropriate stakeholders are afforded the opportunity to be involved in product release activities where required.
5.4.12 Control of nonconforming products [8.7]

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.
Guidance:

• ISO 9001:2015 requires that the Supplier informs the customer of nonconforming outputs and can obtain authorisation for acceptance under concession.

• Suppliers often interpret the customer to be a prime supplier.

• This requirement explicitly states that authorisations must be obtained from the GQAR and/or Acquirer (unless otherwise agreed).
5.4.12 Control of nonconforming products [8.7]

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.
Guidance:

• The use of concessions should not be encouraged and only by exception.

• In the event that a concession is deemed necessary, authorisation should be limited to a specified time-bound period.

• This requirement aims to ensure that Suppliers implement timely corrective actions to prevent recurrence of nonconformities and thus negate the need for any further concessions.
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'.
AQAP 2110 Ed D: Customer satisfaction

Guidance:

• AQAP 2110 Ed D requires that information on root cause analysis is also detailed in the Supplier response.

• The note in Chapter 5.5.1 clarifies that the GQAR and/or Acquirer will explicitly identify to the Supplier when deficiencies are to be treated as customer complaints.
A collective term that describes a wide range of approaches, tools and techniques used to identify causes of nonconformity.

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

• Suppliers will adopt tools and techniques appropriate for the nature and complexity of the business and be able to manage root cause analysis as a business process.

• Root cause analysis process, tools and techniques applied to the contract shall be included in, or referred to, in the contract quality plan and made available to GQAR and/or Acquirer.

• Suppliers should have competent personnel to support the techniques identified in their process.
AQAP 2110 Edition D Training

1. Introduction to AQAPs
2. Applicability to Contract and Supplier QMS
3. Structure and Overview of AQAP 2110
4. Requirements, Definitions and Interpretation
5. Further guidance
6. Acquirer and/or GQAR Responsibilities
7. Quiz
Guidance on the use of AQAP 2110 Edition D

- AQAP 2110 SRD.1 Ed B
  - https://nso.nato.int/nso/nsdd/SRDdetails.html?SRDNo=177

- Annex A of SRD.1 contains a list of documented information requested by AQAP 2110 Ed D and ISO 9001:2015
AQAP 2110 Ed D Guidance

- Guidance on the application of AQAP 2110 Ed D within an AS9100 Quality Management System
  - AQAP 2110 SRD.2 Ed A
    - https://nso.nato.int/nso/nsdd/SRDdetails.html?SRDNo=139&LA=EN
    - Released in November 2018
Standards Related Document AQAP-2110-SRD.3

• Training Material to Support AQAP-2110 Edition D
  – This presentation is AQAP-2110-SRD.3.1

• Annex A of AQAP-2110-SRD-3 contains a table which provides a direct comparison of the requirements of AQAP 2110 Edition 3 and AQAP 2110 Edition D Version 1
AQAP 2110 Edition D Training

1. Introduction to AQAPs
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6. Acquirer and/or GQAR Responsibilities
7. Quiz
Acquirer and/or GQAR Responsibilities

• The following slides detail some of the potential responsibilities of the Acquirer and/or GQAR with respect to contracting and use of AQAP 2110 both pre and post contract award
• The list is not exhaustive
• Note: not all responsibilities will apply to every contract; however, it is recommended that these areas are considered during planning.
Responsibilities: Pre Contract Award

1. Understand the AQAP 2000 series in order to invoke appropriate AQAPs and other standards in contracts.

2. Identify, record, review and monitor risks throughout the contract duration [5.2.1] [5.4.6.3] [5.5.3.2]

3. Determine if the contract is to be subject to GQA. If yes, invoke one primary AQAP and include a statement in the contract.
Responsibilities: Pre Contract Award

4. Determine any regulatory requirements e.g. airworthiness and invoke in contract (if applicable)

5. Ensure that contractual requirements for dealing with concessions are clearly defined in the contract \[5.4.12\]

6. Specify Certificate of Conformity requirements \[5.4.11.(2)\]

7. Invoke appropriate Configuration Management standards in the contract \[5.4.1.2\]
Responsibilities: Pre Contract Award

8. Review evidence of Supplier’s QMS suitability e.g. 3rd party certification, QMS scope [4.2]

9. Consider documented information to be provided by the Supplier, and timescales [4.3] [5.4.1]

10. Establish and define contractual dependability requirements (if applicable) [5.4.5]
Responsibilities: Pre Contract Award

11. Establish if there is a requirement for the supply of customer property to the Supplier [5.4.9]

12. Request a Post Award GQA meeting (if required) [5.4.2.(1)]

13. Specify requirements for Acquirer and/or GQAR attendance at final inspection or formal acceptance activities [5.4.11.(4)]
Responsibilities: Post Contract Award

1. Where considered appropriate: raise Requests for Government Quality Assurance (RGQA) to mitigate risks

2. Ensure synergy between contractual and RGQA requirements

3. Liaise with the GQAR and/or Acquirer or Supplier management representative on quality matters

4. Review plans (Quality, Risk Management, Configuration Management) and comment on acceptability/non-acceptability of plans. [5.2.1] [5.4.1.1] [5.4.1.2.2]
Responsibilities: Post Contract Award

5. Review requirements and solution compliance matrices [5.4.1.1.(2)]

6. Review acceptability of objective evidence of product conformance with requirements [5.4.1.1.(1)] [5.4.1.1.(2)]

7. Where necessary, comment on the acceptability of the Supplier’s QMS as it applies to the contract [4.2]

8. Establish requirements and methodology for dealing with non-conforming product e.g. warranty claims, defects [5.4.11.(1)], dispositions (rework, repair or use as is), concessions [5.4.12]
Responsibilities: Post Contract Award

9. Review proposals by the Supplier to change its organisation that will affect product quality or the QMS [5.4.2.(3)]

10. Approve/disapprove Supplier documented procedures for the identification, control and segregation of nonconforming product [5.4.12.(2)]

11. Raise customer complaints when necessary [5.5.1]
Responsibilities: Post Contract Award

12. Where applicable, review Supplier corrective action proposals [4.2] [5.4.12] [5.5.1.(2)]

13. Where applicable, review risks notified by the Supplier relating to External Providers or externally-provided product [5.4.6.3]

14. Continue to identify, record, review and monitor risks throughout the contract duration [5.2.1] [5.4.6.3] [5.5.3.2]
Responsibilities: Post Contract Award

15. Review Supplier notifications of lost, damaged or unsuitable customer property and advise on suitability of remedial actions [5.4.9]

16. Advise on acceptability of remaining shelf life of product [5.4.10.(3)]

17. Review details of products affected by out of calibration measuring equipment [5.3.2.(2)]
Responsibilities: Post Contract Award

18. Review deficiencies identified during supplier internal audits [5.5.2.(2)]

19. Where applicable, identify the need for contract amendment as a result of non-conformities and corrective actions
Thank you for listening.

Any questions?

Quiz
AQAP 2110 Edition D Training

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Primary Contractual AQAPs:

- AQAP 2110: NATO Quality Assurance Requirements for Design, Development and Production.
- AQAP 2131: NATO Quality Assurance Requirements for Final Inspection and Test.
- AQAP 2310: NATO Quality Assurance Requirements for Aviation, Space and Defence Suppliers

Supplementary Contractual AQAPs:

- AQAP 2210: NATO Supplementary Software QA Requirements to AQAP 2110 and AQAP 2310
- AQAP 2105: NATO Requirements for Deliverable Quality Plans

Guidance AQAP:

- AQAP 2070: NATO Mutual Government Quality Assurance (GQA)
Q1. What is the meaning of dependability?
QUIZ

Q2. Which one of the following statements is false?

a. AQAP 2070 is not a contractual AQAP
b. AQAPs should only be included in contracts when GQA is required
c. AQAP 2131 relates to all inspection and test
d. AQAP 2210 is not a primary AQAP
Q3. Define root cause analysis.
Q4. In general, which primary AQAP(s) should be invoked in aerospace sector contracts?

a. AQAP 2131
b. AQAP 2110
c. AQAP 2310
d. All of the above
Q5. Give two reasons why we have AQAPs?
Q6. Which of the following sections of AQAP 2110 Ed D was subject to the highest number of new requirements?

a. 5.4.1. Operational planning and control
b. 5.4.6. Control of externally provided processes, products and services
c. 5.4.11. Release of products
d. 5.4.12. Control of nonconforming products
Q7. AQAP 2110 Ed D states that the Acquirer and/or GQAR reserve the right to reject which of the following Supplier plans?

a. Quality Plan
b. Risk Management Plan
c. Both of the above
d. None of the above
Q8. Which of the following statements is false?

a. AQAP 2210 must be used in conjunction with either AQAP 2110 or AQAP 2310.

b. AQAP 2110 Ed D should be included in contracts where there is a risk in the manufacturing process.

c. AQAP 2110 Ed D should be included in contracts where there is a risk in the design process.

d. AQAP 2110 Ed D requires Suppliers to have a certified management system to ISO 9001:2015
Q9. Which one of the following options are considered to present the highest risk in terms of counterfeit material?

a. On-line Sales  
b. Original Equipment Manufacturer  
c. Multiple Tier Supplier  
d. New Supplier