Supplier/ sub-contractor/ partners audit and control.

NAA Level of involvement.

The production approval holder is strictly responsible for manufacture according to design data.

21.A.165 Obligations of the holder

The holder of a production organisation approval shall:

(b) maintain the production organisation in conformity with the data and procedures approved for the production organisation approval

2. Determine that other **products, parts or appliances** are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1 to certify conformity to approved design data and condition for safe operation;

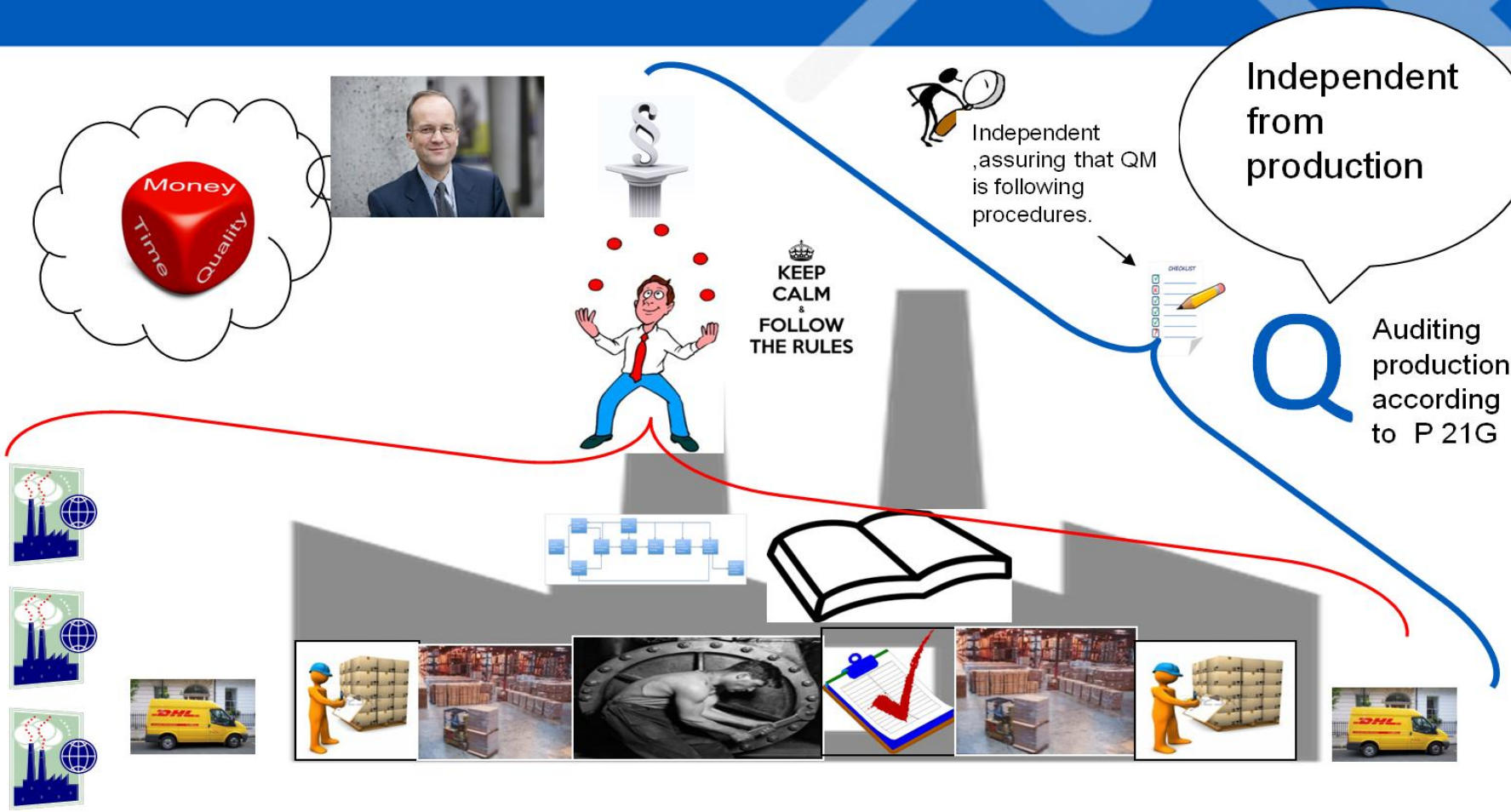
4. Determine that other products, parts or appliances conform to the *applicable data* before issuing an EASA Form 1 as a conformity certificate.

Supplier classifications (suggestion)

Classification of suppliers:

Type	Definition	Category	Level	Document to be delivered
Contractor	Has its own manufacturing approval (within EASA or a bilateral BASA country) and exercises its previleges to issue a EASA Form 1 or equal for this design.	Within own approval and quality system.	B	EASA Form 1 Or equal.
Sub-contractor	Manufactures products, parts or appliances from deseign data provided by the POA.(Minor change, TC, STC) . Controlled strictly under the POA quality system.	FLIGHT CRITICAL PARTS.	F	Certificate Of Conformance (conformity) C.O.C. and other requested documentation from POA. Material certificates, test protocols e.t.c
		CRITICAL OR SPECIAL PROCESSES.	E	
		COMPLEX OR APPLIANCES	D	
		SIMPLE	C	
Vendor	Delivers standard parts manifactured to a approved industry standard. Even raw material.	STANDARD PARTS, COTS, RAW MATERIAL	A	Certificate of contformance (conformity) C.O.C. and other requested documentation from POA. Material certificates, test protocols e.t.c.

Roles in POA. Who is responsible for all suppliers/sub-contractors/partners?



SWEDISH TRANSPORT AGENCY

Quality system

- **21.A.139 Quality System**
- (a) The production organisation shall demonstrate that it has established and is able to maintain a quality system. The quality system shall be documented. This quality system shall be such as to enable the organisation to ensure that each product, part or appliance produced by the organisation *or by its partners, or supplied from or subcontracted to outside parties, conforms to the applicable design data* and is in condition for safe operation, and thus exercise the privileges set forth in point 21.A.163.

Quality system

- (b) The quality system shall contain:
- 1. as applicable within the scope of approval, *control procedures* for:
- (ii) *vendor and subcontractor assessment audit and control*;
- (iii) verification that *incoming products, parts, materials, and equipment*, including items supplied new or used by buyers of products, *are as specified in the applicable design data;*

GM No. 2 to 21.A.139(a) Quality System – Conformity of supplied parts or appliances

- The POA holder is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity of supplied products, parts or appliances, whether to be used in production or delivered to customers as spare parts. This responsibility also includes BFE (Buyer Furnished Equipment) items.
- To discharge this responsibility the quality system needs an organisational structure and procedures to adequately control suppliers. Elements of the quality system for the control of suppliers may be performed by other parties provided that the conditions of AMC No. 1 or No. 2 to 21.A.139(b)(1)(ii) are met.

GM No. 2 to 21.A.139(a) Quality System – Conformity of supplied parts or appliances

- Control **can** be based upon use of the following techniques (as appropriate to the system or product orientation necessary to ensure conformity):
- qualification and auditing of supplier's quality system,
- evaluation of supplier capability in performing all manufacturing activities, inspections and tests necessary to establish conformity of parts or appliances to type design,
- FAI first article inspection (EN 9102, common requirement within FAA), including destruction if necessary, to verify that the article conforms to the applicable data for new production line or new supplier,
- incoming inspections and tests of supplied parts or appliances that can be satisfactorily inspected on receipt,

GM No. 2 to 21.A.139(a) Quality System – Conformity of supplied parts or appliances

- identification of incoming documentation and data relevant to the showing of conformity to be included in the certification documents,
- a vendor rating system which gives confidence in the performance and reliability of this supplier,
- any additional work, tests or inspection which may be needed for parts or appliances which are to be delivered as spare parts and which are not subjected to the checks normally provided by subsequent production or inspection stages.

GM No. 2 to 21.A.139(a) Quality System – Conformity of supplied parts or appliances

- The POA holder may rely on inspection/tests performed by supplier if it can establish that:
- □ personnel responsible in charge of these tasks satisfy the competency standards of the POA quality system,
- □ quality measurements are clearly identified,
- □ the records or reports showing evidence of conformity are available for review and audit.

- All this text ends up to that the POA has strictly responsibility to control its production up to a level that enabels the POA to certify products, parts and appliances ,issuing an EASA Form 1, stating that it is produced according to approved design data, in a approved production enviroment.

Vendor and sub-contractor assessment audit and control.

- What does it mean?
  - ***Assessment***
    - A few of the questions to be answered by the PM (not QM):
      - How can I ensure that the parts or work I ask for, are up to the POA(DOA) requirements?
      - Can I rely on other approvals and certification? Are they up to date?
      - Is a questionare enough to approve the supplier in the POA enviroment?
      - How do I seperate suppliers from each other, can I use an risk based approach?
      - Do I need to perform an on-site audit, or is it enough with an desk-top to assess a sub-contractor ?

Suggestion of classification table.

Classification of suppliers:

Type	Definition	Category	Level	Document to be delivered
Contractor	Has its own manufacturing approval (within EASA or a bilateral BASA country) and exercises its previleges to issue a EASA Form 1 or equal for this design.	Within own approval and quality system.	B	EASA Form 1 Or equal.
Sub-contractor	Manufactures products, parts or appliances from deseign data provided by the POA.(Minor change, TC, STC) . Controlled strictly under the POA quality system.	FLIGHT CRITICAL PARTS.	F	Certificate Of Conformance (conformity) C.O.C. and other requested documentation from POA. Material certificates, test protocols e.t.c
		CRITICAL OR SPECIAL PROCESSES.	E	
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Vendor	Delivers standard parts manifactured to a approved industry standard. Even raw material.	STANDARD PARTS, COTS, RAW MATERIAL	A	Certificate of contformance (conformity) C.O.C. and other requested documentation from POA. Material certificates, test protocols e.t.c.

Vendor and sub-contractor assessment audit and control.

- ***Audit***
  - Desk top audit:
  - What should it include as a minimum? …….

  - On-site audit:
  - It should be a production conformity audit, NOT anything else!
  - It should be performed by an adequatly trained auditor, to be able to audit the production techniques/standards/conformity required by the POA(DOA).
  - If any tests are performed at the sub-contractor, it should be audited!

Control

SWEDISH TRANSPORT AGENCY

Vendor and sub-contractor assessment audit and control.

- ***Control***:
  - First approval, continuation approval
  - When is the supplier considered void?
  - Re-instating supplier
  - Monitoring deviations and performance
  - Arrival inspections at POA?
  - Supplier history?

NAA LOI (Level of involvement)

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- In B section of P 21 , requirements on NAA, states that the NAA needs a clear procedure to assess when an audit needs to be performed on a POA holders supplier, sub-contractor and partners location.
- The Swedish NAA uses a risk based system, trying to establish what risk different POA:s poses. Three levels are used, LOW, NORMAL and HIGH.
- LOW risk POA:s are not subject for any on-site audits at vendors or sub-contractors.
- NORMAL are subject to a minimum of involvement from NAA, HIGH risk POA:s are more thourough audited, including suppliers.

Questions?