RA 5835 – Production Organizations (MRP Part 21 Subpart G)

Rationale

Although the MAA does not currently require the specific approval of Production Organizations (PO)[1], it is essential that the engineering process link between design and production is established. Without adequate Assurance that the engineering processes between design and PO are linked, there is potential for PO to manufacture Products, Parts, Appliances, Airborne Equipment and Air Launched Weapons that do not meet the designs produced by the Design Organization(s) (DO). This RA ensures that a level of Assurance is identified and that Air Systems (and related Products, Parts and Appliances) are produced by competent organizations and show conformity to the applicable design data and are in a condition for safe operation.

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Regulation 5835(1)

Production Organizations

5835(1) The Type Airworthiness Authority (TAA)[2] or Commodity Chief Engineer (CE) **shall** ensure that 'prime'[3] PO hold a recognized Part 21 Subpart G approval or comply with a recognized Quality System.

Acceptable Means of Compliance 5835(1)

Production Organizations

Common Acceptable Means of Compliance (AMC)

1. If a 'prime' PO has a European Union Aviation Safety Agency (EASA) Part 21 Subpart G approval, a Federal Aviation Administration (FAA)[4] Part 21 Subpart G approval, a UK Part 21 Subpart G approval or a European Military Airworthiness Requirements (EMAR) 21 Subpart G approval from an Authority that the MAA has formally accepted under the Recognition process, they **should** submit their Production Organization Exposition (POE) to the TAA or Commodity CE to confirm that its scope is appropriate for the production tasks.

2. If the 'prime' PO does not hold a recognized Part 21 Subpart G approval, or the approval held does not cover the scope of the production tasks, the TAA or Commodity CE **should** assure themselves that the 'prime' PO:

   a. Hold AS/EN 9100 certification and comply with Allied Quality Assurance Publication (AQAP) 2310 covering the scope of production tasks. The certification **should** be issued by a Certification Body holding suitable accreditation, with the right scope, from a National Accreditation Body (NAB)[8] who is a signatory to the International Accreditation Forum (IAF) or IAF Accredited Regional Multi-Lateral Agreements (MLA). The Quality system **should** contain:

      (1) Control procedures for traceability including a definition of clear criteria of which Parts or Appliances need such traceability eg Critical Parts.

   b. Submit their POE to the TAA or Commodity CE, as appropriate, to enable assessment of competency[1].

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[1] Refer to RA 1005 – Contracting with Competent Organizations.
[2] Where the Air System is ►not UK owned, Type Airworthiness (TAw) management◄ regulatory responsibility by either the TAA or Type Airworthiness Manager (TAM) needs to be agreed within the Sponsor's approved model ►◄ ; refer to RA 1162 – Air Safety Governance Arrangements for Civilian Operated (Development) and (In-Service) Air Systems or refer to RA 1163 – Air Safety Governance Arrangements for Special Case Flying Air Systems. Dependant on the agreed delegation of TAw responsibilities TAM may be read in place of TAA as appropriate throughout this RA.
[3] 'Prime' refers to the highest level of Air System, Product, Part or Appliance procured by the DO or Delivery Team within an arrangement / contract.
[4] FAA Production Approval Regulations are a subset of the Title 14 Code of Federal Regulations (CFR) known as 14 CFR Part 21 Subpart G.

Acceptable Means of Compliance 5835(1)

3. The TAA or Commodity CE **should** assure themselves that the 'prime' PO can demonstrate that it has established and is able to maintain a Quality Management System to ensure that each Product, Part and Appliance produced by the organization 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.

4. The TAA or Commodity CE **should** assure themselves that the 'prime' PO has a documented arrangement in place with the appropriate DO describing in detail how to reliably use the applicable design data to manufacture a Product, Part or Appliance.

5. This arrangement **should** detail as a minimum:

a. The responsibilities of the PO and DO with respect to the arrangement.

b. The procedures to deal adequately with production deviations and non-conforming Parts[5].

c. The procedures and associated responsibilities to achieve adequate configuration control of manufactured Parts (ie traceability).

d. The procedure for requesting and managing changes in manufacturing methods or materials.

6. The TAA or Commodity CE **should** assure themselves that the 'prime' PO has the facilities and processes to:

a. Keep full records of all work carried out[6].

b. Maintain an auditable trail of approved concessions and deviations.

c. Ensure that their Products, Parts and Appliances conform to the approved type design.

7. Where a 'prime' PO uses Parts or Appliances from a sub-contractor, the TAA or Commodity CE **should** assure themselves that the 'prime' PO has an auditable process to demonstrate design conformity, Safety for operation and that full records of work carried out are retained.

8. If the TAA or Commodity CE is procuring through a Foreign Military Sales (FMS) contract, they **should** assure themselves of the design conformity and Assurance for operation of the Product, Part or Appliance.

Additional AMC – TAA only

9. In addition to the requirements of paragraph 2, the TAA **should** ensure that the 'prime' PO is subject to Defence Quality Assurance – Field Force surveillance.

10. The collaboration between the 'prime' PO and DO **should** be agreed by the TAA, irrespective of whether the DO is acting as a Co-ordinating Design Organization (CDO) or Air System CDO[7].

Additional AMC – Commodity CE only

11. In derogation to paragraph 4, where Products, Parts and Appliances are procured to prescribed technical specifications without reach back to the DO (eg standard Parts, Commercial Off the Shelf parts etc) the Commodity CE **should** assure themselves of the design conformity and Assurance for operation of the Product, Part or Appliance.

12. The Commodity CE **should** assure themselves of the governance and Assurance management systems in place for / within POs to ensure the design conformity and Assurance for operation of the procured Product, Part of Appliance. Additionally, the Commodity CE **should** have right of access / investigation of production arrangements to ensure Quality and traceability of Products, Parts and Appliance is maintained.

[5] Refer to RA 5825 – Fault Reporting and Investigation.
[6] Refer to RA 1225 – Air Safety Documentation Audit Trail.
[7] Refer to RA 1014 – Design Organizations and Co-ordinating Design Organizations – Airworthiness Responsibilities.

Guidance Material 5835(1)

Production Organizations

Common Guidance Material (GM)

13. The POE may follow the format as defined in EASA Part 21 Subpart G detailing as a minimum:

a. A statement confirming that the POE and any associated manuals which define production processes will be complied with.

b. The organizational structure showing associated chains of responsibility.

c. A list of certifying staff.

d. A general description of the facilities located at each address.

e. A description of the PO's scope of work.

f. The procedure for the notification of organizational changes to the TAA or Commodity CE.

g. The amendment procedure for the POE.

h. A description of the Quality Management System and the procedures necessary to demonstrate that the Products, Parts and Appliances conform to the relevant design and are in a condition for the safe operation.

14. The documented arrangement between the PO and DO may follow the sample format defined in EASA Part 21 Subpart G.

15. The 'prime' PO is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity of supplied Products, Parts and Appliances, whether to be used in production or delivered to customers as spare Parts.

16. The control of POs holding an EASA Part 21 Subpart G approval for the Parts or Appliances to be supplied can be reduced to a level at which a satisfactory interface between the two Quality Management Systems can be demonstrated. Thus, the 'prime' PO can rely upon documentation for Parts or Appliances released under a supplier's EASA 21.A.163 privileges.

17. A PO who does not hold an EASA Part 21 Subpart G, FAA Part 21 Subpart G or EMAR 21 Subpart G approval is considered as a sub-contractor under the direct control of the 'prime' PO's Management System.

18. If several TAAs are relying on the same division of an organization as a PO, they might decide to co-ordinate work to achieve compliance with RA 5835(1).

19. Quality Assurance of FMS procurement may follow the processes detailed in the Knowledge in Defence[8].

20. A change in place or method of manufacture or a change of explosive material or source of explosive material will require Independent Ordnance, Munitions and Explosives Safety Advisor advice[9].

Additional GM – TAA / TAM only

21. Where the TAM is delegated to deliver Type Airworthiness responsibility[10], the tasking of Defence Quality Assurance Field Force (DQA-FF) will be through the TAA.

Additional GM – Commodity CE only

22. Nil.

[8] https://www.gov.uk/guidance/knowledge-in-defence-kid.
[9] Refer to Regulation DSA 02.OME(2) – Appointment of an independent OME safety advisor.
[10] Refer to RA 1162 – Air Safety Governance Arrangements for Civilian Operated (Development) and (In-Service) Air Systems.

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