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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The Type Airworthiness Authority (TAA)² or Commodity Chief Engineer (CE) shall ensure that 'prime'3 PO hold a ► Part 21 Subpart G Approval ► that is accepted by the MAA or have a nationally accredited Quality Management System (QMS) with an appropriate scope for Production. ◀

Acceptable Means of Compliance 5835(1)

Production Organizations

Common Acceptable Means of Compliance (AMC)

- ▶ Part 21 Subpart G Approvals from one of the following organizations are categorized as accepted by the MAA. If a 'prime' PO holds any of these Approvals, 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:
 - European Union Aviation Safety Agency (EASA). a.
 - b. Federal Aviation Administration (FAA)4.
 - UK Civil Aviation Authority (CAA). C.
 - A National Military Airworthiness Authority that the MAA has a Recognition in place with and that Recognition specifically enables the use of their Part 21 Production Organization Approvals (as detailed on the MAA Recognition webpage⁵). ◀
- If the 'prime' PO does not hold a recognized Part 21 Subpart G Approval ►accepted by the MAA <, or the Approval held does not cover the scope of the</p> production tasks, the TAA or Commodity CE should assure themselves that the 'prime' PO:
 - 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)9 who is a signatory to the International Accreditation Forum (IAF) or IAF

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

⁵ ►MAA Recognition – <u>www.gov.uk/government/publications/maa-recognition</u>. ◀

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Accredited Regional Multi-Lateral Agreements (MLA). The QMS should contain:

- Control procedures for traceability including a definition of clear (1) criteria of which Parts or Appliances need such traceability eg Critical Parts.
- Submit their POE to the TAA or Commodity CE, as appropriate, to enable b. assessment of competency1.
- 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 QMS 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.
- 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:
 - The responsibilities of the PO and DO with respect to the arrangement. a.
 - The procedures to deal adequately with production deviations and nonconforming Parts⁶.
 - C. The procedures and associated responsibilities to achieve adequate configuration control of manufactured Parts (ie traceability).
 - The procedure for requesting and managing changes in manufacturing methods or materials.
- 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 out7.
 - b. Maintain an auditable trail of approved concessions and deviations.
 - Ensure that their Products, Parts and Appliances conform to the approved type design.
- 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.
- 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

- In addition to the requirements of paragraph 2, the TAA should ensure that the 'prime' PO is subject to Defence Quality Assurance – Field Force (DQA-FF) surveillance.
- 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 CDO8.

Additional AMC - Commodity CE only

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.

⁶ Refer to RA 5825 – Fault Reporting and Investigation.

Refer to RA 1225 – Air Safety Documentation Audit Trail.
 Refer to RA 1014 – Design Organizations and Co-ordinating Design Organizations – Airworthiness Responsibilities.

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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.

Guidance **Material** 5835(1)

Production Organizations

Common Guidance Material (GM)

- The POE may follow the format as defined in EASA Part 21 Subpart G detailing as a minimum:
 - 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.
 - A list of certifying staff. C.
 - d. A general description of the facilities located at each address.
 - A description of the PO's scope of work. e.
 - The procedure for the notification of organizational changes to the TAA or Commodity CE.
 - The amendment procedure for the POE.
 - A description of the QMS 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.
- The documented arrangement between the PO and DO may follow the sample format defined in EASA Part 21 Subpart G.
- 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.
- 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 QMS 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.
- A PO ▶(that is not the Prime PO) who does not hold ▶a Part 21 Subpart G Approval ▶that is accepted by the MAA (see paragraph 1) ◀ is considered ▶ ◀ a sub-contractor under the direct control of the 'prime' PO's Management System.
- 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).
- Quality Assurance of FMS procurement may follow the processes detailed in the Knowledge in Defence9.
- 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 advice¹⁰.

Additional GM – TAA / TAM only

Where the TAM is delegated to deliver Type Airworthiness responsibility¹¹, the tasking of DQA-FF will be through the TAA.

https://www.gov.uk/guidance/knowledge-in-defence-kid.

¹⁰ Refer to Regulation DSA 02.OME(2) – Appointment of an independent OME safety advisor.

¹¹ Refer to RA 1162 – Air Safety Governance Arrangements for Civilian Operated (Development) and (In-Service) Air Systems.

Guidance Material 5835(1) Additional GM – Commodity CE only

22. Nil.