## **Production Under TSO**

## **Manufacturing Considerations**



## **Overview**

- TSO / TSOA process
- Quality System Requirements
- Quality Manual / Coordination
- Facilities / Transfer

## **TSO / TSOA Process**

- FAA Order 8150.1D
  - TSO / TSOA / LODA
- Applications
  - Certification Branch (CB) and Certificate Management (CM) Sections
- Applicant status
  - Current production approval holder (PAH) or new applicant?
- Requirements under § 21.137(h)
  - Material review board (MRB)
- Facility Relocation
- Transfers



## **Quality System Requirements**

## § 21.137 Quality System Requirements

## References

- AC 21-43, Production Under 14 CFR Part 21, Subparts F, G, K, and O
- Order 8120.22A, Production Approval Procedures Chapter 5
- Order 8150.1D, Technical Standard Order Program
- CM Section Audit

# **Quality Manual / Coordination**

- Involve CM Section early
- Communicate (cc:) other offices on all dialogue
- Marking
- MRB
- Major/Minor Change Agreement
- Audits

## **Transfer / Relocation**

- § 21.609 Location of or change to manufacturing facilities
  - Guidance: 8150.1D references 8120.22A
- Coordination required with both CB(s) and CM Section(s)
- Timing / Shipping of Parts
- Marking requirements
  - Company name change?
  - § 45.15(b)
- Separation of Design and Manufacturing



# **Questions?**

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# **Backup Slides**

### **FAA Order 8150.1D**

- **5-5. Processing TSOA Transfers.** As stated in 14 CFR 21.614, TSOA holders may not transfer TSOAs. However, they may submit a request to the FAA for a transfer. Effective on the date of this order, ACO personnel may process and approve TSOA transfer requests without further involvement from AIR-100.
- a. Transfer. A TSOA holder's transfer request must be approved by the FAA prior to the FAA reissuing the TSOA to another legal entity. This process may occur as the result of a change of the legal status of a company that holds TSOA(s) through sale or liquidation, the sale of TSOA design data from one company to another, an agreement between companies within a corporation, or other means. For example, the acquisition of a company with a TSOA by a holding company would be considered a transfer if the acquired company is disbanded or absorbed into the purchasing corporation. In this case, the legal entity that currently holds the TSOA will no longer exist so the original holder would be required to request a transfer of the TSOA to the purchasing corporation before being disbanded or absorbed. The term "transfer" applies only to the TSO design approval. The production approval process that the MIDO accomplishes during a transfer is the same process for a new applicant or an applicant that is adding additional capability to an existing facility. TSOA transfer requests must be made by the current holder of the TSOA.

### FAA Order 8150.1D

- **b.** Name Changes or Facility Relocations. A company changing its name or relocating its facilities is not considered a transfer. Under the following conditions, the acquisition of a company with a TSOA by a holding company would not be considered a transfer if the acquired company continued to exist as the same legal entity to which the original TSOA was issued:
  - (1) The acquired company retains possession of the TSOA.
  - (2) The acquired company retains the same quality system.
- (3) The acquired company continues to operate at the same location with the same core management for manufacturing and design.
- (4) The TSOA holder provides written confirmation that its legal status remains unchanged after an acquisition.

### **FAA Order 8120.22A**

#### c. Transfer Process.

- (1) A company that wishes to transfer its TSOA may do so by submitting a transfer request to its issuing ACO.
- (2) The ACO must instruct the TSOA holder to provide the relevant details of the transfer request, including the TSOA(s) and the name and address of the company that will receive the transferred authorization.
- (3) The ACO must inform the TSOA holder that the new holder may not ship any articles until the MIDO has approved the new quality manual and notified the ACO that the new holder is approved for production, and the ACO has reissued the TSOA in the new holder's name and address.

**Note:** Re-issued TSOA letters should have the current date of the re-issue and also reference the original approval date and revision levels of the TSOs.

- (4) The ACO receiving a transfer request must send a copy of the request to the responsible MIDO/MISO, as they will need to coordinate during the transfer process.
- (5) The ACO must consider the following, as appropriate, and include them as conditions in the transfer approval letter stating the transfer is contingent on the applicant meeting/accepting all the conditions. Any contingencies must be met before the ACO responsible for the new holder can reissue the TSOA letter to the new holder.

### **FAA Order 8120.22A**

- **5-7. Preliminary MIDO Audit.** At the request of the ACO, the MIDO/CMO should make arrangements to conduct a MIDO audit, within the deadline established by the ACO. This audit will be conducted as follows:
- a. Evaluate the applicant's quality manual for compliance with § 21.607. Additional guidance is provided in AC 21-43. The manual must include an acceptable test procedure to which each production article will be tested. Any inadequacies in the quality manual submitted must be identified to the applicant for corrective action. After the quality manual has been reviewed, and any applicable corrective actions taken, the MIDO/CMO will approve the quality manual submitted by the applicant. The approved quality manual may be retained in the MIDO/CMO files.
- **b.** Evaluate the applicant's production facilities in accordance with the pertinent 14 CFR, the FAA-approved design data, and the quality manual approved in paragraph 5-7a of this order. The cognizant MIDO/CMO manager will select either an individual or a team to conduct this audit. The team may consist of the cognizant PI and at least one other manufacturing inspector or the MIDO/CMO manager. It is also recommended that an engineer be selected for the team when deemed necessary by the type and complexity of processes and procedures being used at the facility. The standardized evaluation criteria may be used as an aid to evaluate compliance, as discussed in FAA Order 8120.23. Team members should be advised, however, that some of the evaluation criteria contained therein may not be related to 14 CFR, and therefore may only be evaluated as a best practice. This audit is not considered to be a QSA. Record all noncompliances on FAA Form(s) 8100-6 and 8120-14.

## § 21.607 – References § 21.137

#### § 21.137

### Quality system.

Each applicant for or holder of a production certificate must establish and describe in writing a quality system that ensures that each product and article conforms to its approved design and is in a condition for safe operation. This quality system must include:

- (a) Design data control.
- (b) Document control.
- (c) Supplier control.
- (d) Manufacturing process control.
- (e) Inspecting and testing.
- (f) Inspection, measuring, and test equipment control.
- (g) Inspection and test status.
- **(h)** Nonconforming product and article control.
- (i) Corrective and preventive actions.
- (j) Handling and storage.
- (k) Control of quality records.
- (I) Internal audits.
- (m) In-service feedback.
- (n) Quality escapes.
- (o) Issuing authorized release documents.

