Annex 13

Manufacturing Organisations

Introduction

This annex is an integral part of the CASA Surveillance Manual (CSM), which should be referenced at all times. To allow for more frequent revisions, this annex can be updated independent of the CSM and other annexes. The process of updating this annex requires verification and approval from its owners and sponsors, as well as from Coordination and Safety Systems (CSS). An updated version can only be published once CSS has finalised the format, with the latest revision history data included in the revision table.

Revision history

Revisions to this annex are recorded below in order of the most recent first.

Version Nº.	Date	Parts / sections	Details
5.0	July 2021	Section 2	Added Quality to Safety Management System title
4.0	April 2019	Inclusion of Introduction and Revision history.	These inclusions allow for updates and revisions independent of the CSM and other annexes.
4.0	April 2019	Section 2.1	Removal of recommended Health Check timeframes.
4.0	April 2019	Section 3	Removal of recommended surveillance intervals.
4.0	April 2019	Section 4	Addition of third-party audits.

1 Overview

This Annex provides instructions for conducting surveillance of CASR Part 21 Manufacturing Organisations and contains information relating to the following:

- Systems and Elements
- Systems and Elements – Health Checks
- Surveillance Currency Guide
- Information Sources.

2 Systems and Elements: Manufacturing Organisations

The audit technique involves assessing the documented system, comparing it against the actual system processes. The system is assessed for compliance and sampling conducted as appropriate. The assessment of the system is achieved by a questioning technique using the four attributes (12 components) of the Management System Model (MSM), see CSM Sections 3.3.3 System attributes – Management System Model and Section 3.3.3.1 – Systems attributes (table).

The CASA description of a Manufacturing Organisation authorisation holder consists of four systems incorporating 15 elements.

Table 1: Systems and Elements

Systems	Elements
Manufacturing Operations	Manufacturing Administration
	Tooling and Equipment
	Supplier Control
	Data and Documents
Personnel	Personnel Standards
Activity	Certification and Release
	Storage and Distribution
	Material Review
	Manufacturing Activity
Quality and Safety Management	Quality Policy and Objectives
	Quality Assurance
	Safety Policy and Objectives
	Safety Risk Management
	Safety Assurance
	Safety Promotion

Table 2: Manufacturing Operations Elements

SYSTEM: Manufacturing Operations	
ELEMENT: Manufacturing Administration	
The Manufacturing Administration element addresses the systems and processes that an authorisation holder must have to ensure the services and or products it provides meets regulatory standards and addresses the systems that ensure the Authorisation holder contains and controls its operations to those authorised. This is primarily achieved through the use of a properly structured organisation with appropriate communication channels. Appropriate key personnel are a key link in ensuring ATS operations are not only contained but are appropriate controlled. Examples include the Senior Supervisor (however named) and Safety Officer.	
Prompts:	
Organisation structure	Supervisory personnel
Operational staff	Appropriate communication channels
Appropriate key personnel	Operations contained to those authorised
Appropriate facilities	Operations controlled to those authorised.
Consistency of policy	DAMP supervision
ELEMENT: Tooling and Equipment	
This element consists of the systems that make up the control of aspects associated with any tooling and equipment utilised in the production of the authorisation holder's product. The documented system should address, but is not limited to, all tooling and equipment held, used, contracted, loaned or borrowed by the organisation for the purpose of manufacturing aircraft or aircraft components.	
Prompts:	
Availability/Adequacy	Parts pooling
Identification	Calibration
Protection and storage	Maintenance
Borrowing/lending arrangements	Contracting
Disposal	Testing
ELEMENT: Supplier Control	
This element describes the systems that make up the control of materials and products received from external suppliers. The documented system should address acquisition, storage and handling of all parts, components, materials, and consumable goods used, kept, loaned, or borrowed in the course of manufacturing aircraft or aircraft component maintenance.	
Prompts:	
Purchasing	Receipt
Storage	Handling
Borrowing/Lending	Dispatch/Issue
Quarantine/Rejection	Traceability

SYSTEM: Manufacturing Operations	
Tracking	Quality
ELEMENT: Data and Documents	
This element addresses all technical data, design drawings; regulatory documentation and quality/procedures manuals used in the course of manufacturing aircraft or aircraft components.	
Prompts:	
Availability	Identification
Storage	Handling
Document control	Change management
Borrowing/Lending	Back up of data
Records management	DAMP documentation

Table 3: Personnel Elements

SYSTEM: Personnel	
ELEMENT: Personnel Standards	
The manufacturing authorisation holder is required to establish and maintain an appropriate organisation, with sound and effective management structure. The standards of personnel, including third party providers is required to be documented detailing induction training, periodic recurrent training/checking (if applicable) and any required upgrade training. A process for dealing with unsatisfactory performance should also be documented.	
Prompts:	
Induction training	Recurrent checking program
Upgrade training	Poor performance aspects
Recurrent training program	Training and performance
Checking and training	Qualifications
Licensing	DAMP education and testing
DAMP supervision	

Table 4: Activity Elements

SYSTEM: Activity	
ELEMENT: Certification and Release	
This element addresses the systems and processes that ensure proper release of products is obtained. Documented process should exist but not be limited to supervision, certification, release and internal audit.	
Prompts:	
Supervision	Initial certification
Non-conformity	Final certification
Product release	Internal audit
Supervision	Housekeeping (work in progress control and cleanliness)
ELEMENT: Storage and Distribution	
This element contains the systems and processes associated with the storage and distribution of items being prepared for freight forwarding. This includes the acquisition, storage and handling of all items and consumable goods used, kept, loaned, or borrowed in the course of carrying out the manufacture of products.	
Prompts:	
Identification	Tracking
Quarantine	Shelf life
Purchasing	Receipt
Dispatch	
ELEMENT: Material Review	
This element contains the systems and processes associated with the review of material likely to be re-used in manufacturing items. This includes but is not limited to the Material Review Board (MRB), correct MRB representation and record keeping.	
Prompts:	
MRB representation	MRB exists
MRB utilised	Documentation
Decisions recorded correctly	
ELEMENT: Manufacturing Activity	
This element addresses the systems and processes that apply to the outputs of the manufacturing authorisation holder. Documented process should exist but not be limited to individually or collective manufacturing activity undertaken, including general and specialised activities.	
Prompts:	
Current Data	Current standards
Contractors	Supervision

SYSTEM: Activity	
Specialised data	Obsolete or conflicting data
Interpretation of data	Conformance to procedures

Table 5: Quality and Safety Management Elements

SYSTEM: Quality and Safety Management	
ELEMENT: Quality Policy and Objectives	
The element contains the systems and processes that ensure effective governance to support the quality system are in place, this will include processes for the review and update of the authorisation holder's management and commitment (through quality policy and objectives), the appointment of key personnel, the accountabilities of management and quality documentation.	
Prompts:	
Management commitment and responsibility – quality policy	Appointment of key personnel
Management commitment and responsibility – communication of policy	Quality system is adopted by personnel
Quality accountabilities of managers	
ELEMENT: Quality Assurance	
This element contains the systems and processes for setting, recording and evaluating system performance, conformance with regulations and company procedures, a process for the conduct of internal quality investigations, effectively manage change across the activities conducted and drive continuous improvement of the quality system.	
Prompts:	
Quality performance monitoring and assessment – system performance	Internal investigation
Quality performance monitoring and assessment – assurance	Management of change
Safety performance monitoring and assessment	Continuous improvement of quality system
ELEMENT: Safety Policy and Objectives	
This element contains the systems and processes that ensure effective governance to support the safety management system is in place including processes for the review and update of the authorisation holder's management and commitment (through Safety Policy, Just Culture and Safety Objectives), the appointment of key personnel, the accountabilities of management, the Emergency Response Plan and SMS documentation.	
Prompts:	
Management commitment and responsibility – safety policy	Appointment of key personnel
Management commitment and responsibility – just culture	Relevant third-party relationships and interactions
Management commitment and responsibility – safety objectives	Coordination of emergency response plan
Safety accountabilities of managers	SMS documentation

SYSTEM: Quality and Safety Management	
ELEMENT: Safety Risk Management	
This element contains the systems and processes to ensure investigation and analysis of the safety risks associated with identified hazards resulting in the implementation of effective safety risk controls.	
Prompts:	
Hazard identification processes – reactive	Risk assessment and mitigation
Hazard identification processes – proactive	DAMP supervision
ELEMENT: Safety Assurance	
This element contains the systems and processes for setting, recording and evaluating system performance, conformance with regulations and company procedures, a process for the conduct of internal safety investigations, effectively manage change across the aviation activities conducted and drive continuous improvement of the SMS.	
Prompts:	
Safety performance monitoring and assessment – system performance	Internal safety investigation
Safety performance monitoring and assessment – assurance	Management of change
Safety performance monitoring and assessment – flight data analysis (if applicable)	Continuous improvement of SMS
DAMP supervision	
ELEMENT: Safety Promotion	
This element contains the systems and processes for ensuring personnel are appropriately trained, are aware of the SMS to a degree commensurate with their positions that conveys safety-critical information, explains why particular safety actions are taken and explains why safety procedures are introduced or changed must be evident.	
Prompts:	
Training and education	Safety communication
DAMP education and testing	

2.1 Health Check

Health Check mandatory elements are current for a financial year and are reviewed and updated by the Safety Systems Branch (SSB) each year for the following year. Details of the current mandatory elements for each authorisation type are published separately to the CASA website.

3 Surveillance Currency Guide: Manufacturing Organisations

Surveillance level	Type	Elements
Level 1	Systems Audit	Systems and Compliance
	Health Check	Specific Elements and Compliance
	Post-authorisation Review	Entry Control Elements
Level 2	Operational Check	Selected elements of the Production/Fabrication Inspection System (FIS/PIS Check)

Note: Surveillance intervals are determined by the National Surveillance Selection Process (NSSP). Refer to the NSSP planned surveillance schedule for further information regarding surveillance intervals.

4 Information Sources

The following is a non-exhaustive list of information sources that can be accessed to support an assessment:

- previous Manufacturing surveillance reports, including Safety Findings and Safety Observations and history of non-compliance
- related surveillance reports i.e. CAR30/CASR Part 145 and CASR Part 42
- industry report and information received during workshops and seminars
- surveys
- third-party audits
- Defect Report Service (DRS)
- information gathered by the authorisation holder
- external information gathered from industry or other government agencies including foreign NAAs
- Enforcement action
- past accident/Incident history
- risk management plans provided by the authorisation holder
- information received from CASA Authorised Persons.

A large portion of this information is available to the surveillance team and authorisation management team via the Data Warehouse using the BusinessObjects application.

Note: For advice on where and how to access required information, refer to CSM Chapter 5 – Information Capture and Access.