



EUROPEAN AVIATION SAFETY AGENCY  
AGENCE EUROPÉENNE DE LA SÉCURITÉ AÉRIENNE  
EUROPÄISCHE AGENTUR FÜR FLUGSICHERHEIT

# RMT.0018 & 0571

## Installation of parts released without an EASA Form 1

Name Boudewijn Deuss

Title Product Safety- Initial Airworthiness

Date 3 June 2014

Your safety is our mission.



- Current regulation (Design/Production)
- How Standard parts fit in the regulations
- Rulemaking task line of development



## **Subpart K Parts and appliances**

21.A.307 Release of parts and appliances for installation.

A part or appliance shall be eligible for installation in a type-certificated product when it is in a condition for safe operation, and it is:

- (a) accompanied by an authorised release certificate (EASA Form 1), certifying that the item was manufactured in conformity to approved design data and is marked in accordance with Subpart Q; or



## **Subpart K Parts and appliances**

(b) a standard part; or

(c) in the case of ELA1 or ELA2 aircraft, a part or appliance that is:

1. not life-limited, nor part of the primary structure, nor part of the flight controls;
2. manufactured in conformity to applicable design;
3. marked in accordance with Subpart Q;
4. identified for installation in the specific aircraft;
5. to be installed in an aircraft for which the owner has verified compliance with the conditions 1 through 4 and has accepted responsibility for this compliance.



## **AMC 21.A.303(c) Standard parts**

1. In this context a part is considered as a 'standard part' where it is designated as such by the design approval holder responsible for the product, part or appliance, in which the part is intended to be used. In order to be considered a 'standard part', all design, manufacturing, inspection data and marking requirements necessary to demonstrate conformity of that part should be in the public domain and published or established as part of officially recognised Standards, or
2. For sailplanes and powered sailplanes, where it is a non-required instrument and/or equipment ....



# Current situation

Part-21 provides only 3 options for acceptance of parts for installation

1. EASA Form 1
2. Standard parts
3. ELA1/ELA2 parts if not “critical” when accepted by the owner



# Part-M Subpart E Components

## M.A.501 Installation *(not regulatory text)*:

- (a) No component may be fitted unless it is in a satisfactory condition, has been appropriately released to service on an EASA Form 1 or equivalent*
- (b) The component must be eligible for installation (Check configuration and AD prior to installation)*
- (c) Standard parts shall only be fitted when identified as such in the maintenance data and coming with evidence of conformity to the standard*
- (d) Materials, either raw material or consumables ...*
- (e) For ELA1 and ELA2 aircraft, components that are:*



High level view on the rules show the following:

Initial Airworthiness (part-21) regulates:

**Design**

Who is responsible: Design approval holder

For what: The design meets the certification basis

Evidence by: Approval Certificate (e.g. Type-certificate)





# Regulations (continued)

High level view on the rules show the following:  
Initial Airworthiness (part-21) regulates:

## Production

Who is responsible: Production Approval Holder

For what: The product or parts are  
manufactured in  
conformity to the design

Evidence by: EASA Form 1 or Form 52



# Standard parts

## Design

Who is responsible: Design approval holder

For what: Determination that a part qualifies as a Standard Part and meets the type design (!)

Evidence by: Standard parts need to be specified in the maintenance data (M.A.501(c))



## 21.A.31 Type design

(a) The type design shall consist of:

1. the drawings and specifications, and a listing of those drawings and specifications, necessary to define the configuration and the design features of the product shown to comply with the applicable type-certification basis and environmental protection requirements;
2. information on materials and **processes and on methods of manufacture and assembly of the product necessary to ensure the conformity of the product;**



## Production

Who is responsible: Manufacturer

For what: The Standard part is  
manufactured in  
conformity to the standard

Evidence by: statement of conformity



## Observations for Standard parts

The difference in respect of the aviation rules for standard parts or other parts is not in the design

From the production side there is a difference  
End-users don't need an EASA Form 1, so no need for POA?

Production and oversight not embedded in the rules

However, when a POA does release standard parts with an EASA Form 1, the POA takes responsibility for conformity with the design



# Rulemaking task

The line of thought and current development of discussions

- Acceptance of replacement parts should be regulated within the continuing airworthiness rules (2042/2003)
- Reality is that parts are not all produced by a POA and come without an EASA Form 1
- The rulemaking activity is therefore reviewing how various production control mechanism could still result in acceptable production control and release processes



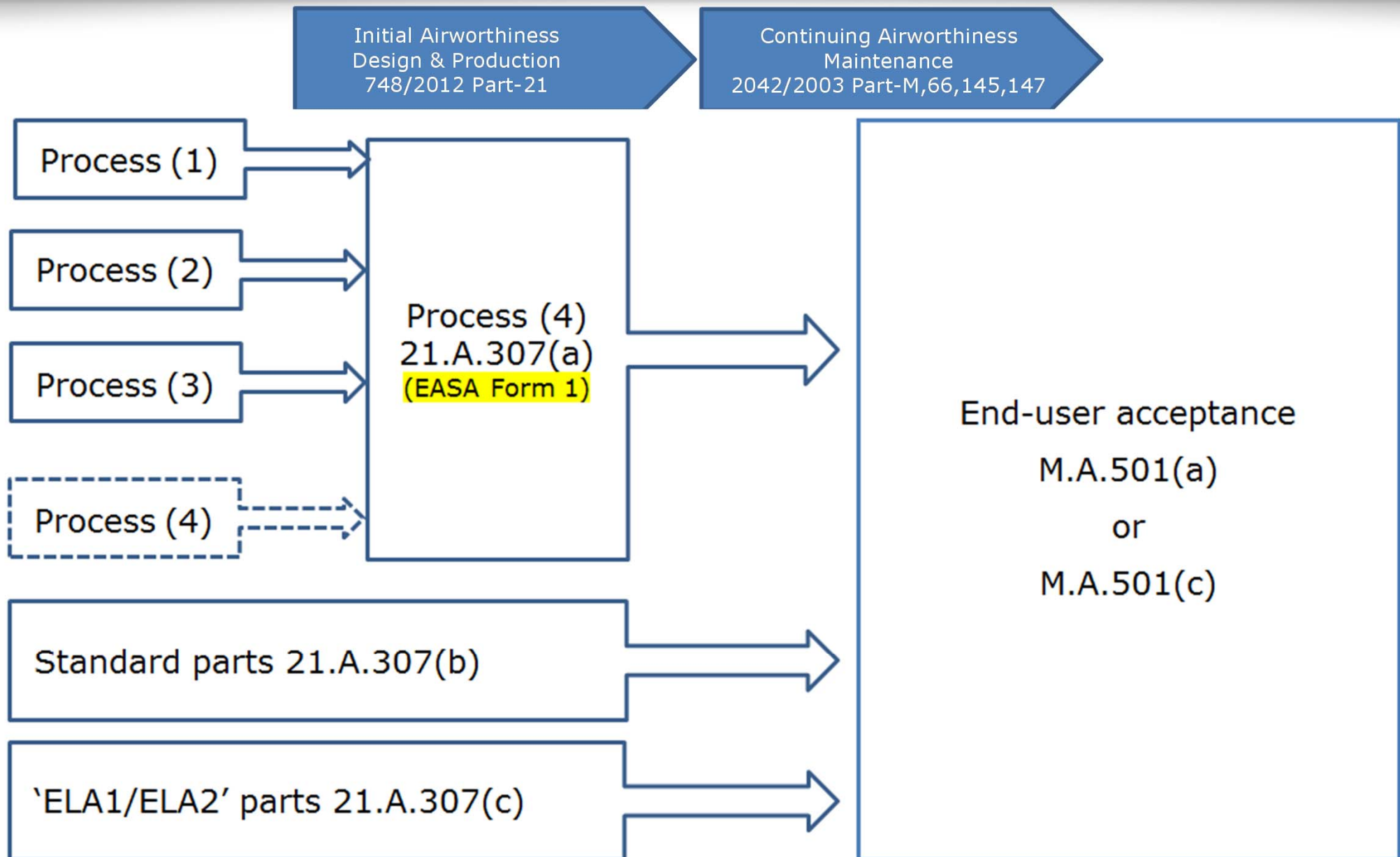
# Existing production processes

## Design and Production principle process

Design	Production standard	Other party control & release	Evidence/Form
<b>Part-21</b> <b>Subpart B</b> (TC/RTC) <b>Subpart D</b> (changes to TC/RTC) <b>Subpart E</b> (STC) <b>Subpart M</b> Repairs <b>Subpart O</b> ETSO	<b>1</b> <b>Unknown</b>	No other party control, industry 'self'-release	Statement of conformity
	<b>2</b> <b>Non-aviation</b>	Other party (non-aviation) e.g. ISO	CofC & proof of producer qualification
	<b>3</b> <b>Aviation</b> ASTM/IAQG/SAE etc.	Other party (aviation) e.g. IAQG 9100 series	CofC & proof of producer qualification
	<b>4</b> <b>Aviation (Part-21)</b> Section A Subpart F/G	<b>Aviation Authority (Part-21)</b> Section B Subpart F/G	Acceptance with EASA Form 1 or equivalent



# Part 21 Production/ Part M acceptance







# Rulemaking task

A new concept is being explored in the rulemaking group that:

- Introduces acceptance of parts coming from multiple path for production/control/release
- Introducing a rigor in the rules that is proportionate with the safety risks
- Introducing a rigor in the rules that takes the safety level of the type of aviation into account



# Rulemaking task

The main questions are here:

- Who decides **how** to establish conformity with the type design?
- Answer: The design approval holder
- What level of proof/confidence is required
- Answer: Depending on the function and design margins of the part
- Who establishes that the actual parts conform with the design?
- Answer: The producer or end-user, using the designers input



# Summary of Design & Production

## **Design** (21.A.31 Type design)

2. information on materials and processes and on methods of manufacture and assembly of the product necessary to ensure the conformity of the product;

## **Production** (21.A.126 & 21.A.139)

The Competent Authority (Subpart F) or POA (Subpart G) are responsible for determining and applying acceptance standards (processes, manufacturing techniques and methods of assembly affecting the quality and safety)



# Not only Part-21!

## ISO 9001/EN9100 (7 Product realization)

- In planning product realization, the organization shall determine the following, as appropriate:
- a) quality objectives and requirements for the product;
- b) the need to establish processes and documents, and to provide resources specific to the product;
- c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements. (See 4.2.4).



# Rulemaking objectives

- Strengthen in type design:  
..... information on materials **and processes**  
**and on methods of manufacture** and  
assembly of the product necessary to ensure  
the conformity of the product;
- Create a link between this type design data  
and the acceptable manufacturing process



# How to link design & production

## Design and Production principle process

Design	Production standard	Other party control & release	Evidence/Form
<b>Part-21</b> <b>Subpart B</b> (TC/RTC) <b>Subpart D</b> (changes to TC/RTC) <b>Subpart E</b> (STC) <b>Subpart M</b> Repairs <b>Subpart O</b> ETSO	<b>1 Unknown</b>	No other party control, industry 'self'-release	Statement of conformity
	<b>2 Non-aviation</b>	Other party (non-aviation) e.g. ISO	CofC & proof of producer qualification
	<b>3 Aviation</b> ASTM/IAQG/SAE etc.	Other party (aviation) e.g. IAQG 9100 series	CofC & proof of producer qualification
	<b>4 Aviation (Part-21)</b> Section A Subpart F/G	<b>Aviation Authority (Part-21)</b> Section B Subpart F/G	Acceptance with EASA Form 1 or equivalent



# Introducing proportionality in the process

"Criticality" level	Production Standard	production control	Part acceptance Part-M
Level I	Unknown	Unknown	Owner
Level II	Non-aviation	Other party	CofC
Level III	Aviation (not Part-21)	Other party	CofC
Level IV	Aviation (Part-21)	Aviation Authority	Form 1



# “Criticality”

The “criticality” is a function of several elements that affect the failure/hazard relation

From the design:

- Function and failure hazard assessment
- Design margins
- Aircraft safety levels

From Production

- Complexity and risks in the production process





# Rulemaking Concept

Design defines in the type design data a criticality level for the parts (e.g. from FAA SMS pilot project report):

**Level I** for parts where a failure would:

- (i) have no effect on the aircraft operational capabilities or safety, or
- (ii) cause no inconvenience for passengers, or
- (iii) have no effect on flight crew.

**Level II** for parts where a failure would:

- (i) cause a slight reduction in functional capabilities or safety margin, or
- (ii) cause physical discomfort for passengers, or
- (iii) for the flight crew cause a slight increase in workload or use of emergency procedures.

**Level III** for parts where a failure would:

- (i) cause a significant reduction in functional capabilities or safety margin, or
- (ii) cause physical distress to passengers possibly including injuries, or
- (iii) for the flight crew cause a physical discomfort or significant increase in workload.

**Level IV** for parts where a failure would:

- (i) cause a large reduction in functional capabilities or safety margin, or
- (ii) cause serious or fatal injury to an occupant, or
- (iii) for the flight crew cause physical distress or excessive workload impairs ability to perform tasks



# What could the rules look like?

## Part-21:

- The design approval holder needs to establish the functional (and if applicable production/conformity-) criticality level of parts. I.e. the approved design data identifies for the parts if they are level I, II, III or IV.



# What could the rules look like?

## Part-M:

The end-user shall ensure that installed replacement parts are in conformity with the approved design.

## AMC

conformity to the design can be shown:

1. by an EASA Form 1 or equivalent for parts of Level IV or lower
2. by a CofC issued by the manufacturer or an approved maintenance organisation for parts of Level III or lower
3. by the end-user for aircraft in the ELA1 or ELA2 category for parts of level III or lower
4. etc.



# Conclusion

The rulemaking task is further developing this theoretical approach in order to:

- Make it practically apply able
- Check that it solves most of the current problems in respect of acceptance of parts
- Develop a regulatory impact assessment
- Respect or embed the existing classification (e.g. standard parts) in the concept
- Seek harmonisation/ global acceptance



EUROPEAN AVIATION SAFETY AGENCY  
AGENCE EUROPÉENNE DE LA SÉCURITÉ AÉRIENNE  
EUROPÄISCHE AGENTUR FÜR FLUGSICHERHEIT

# Questions/Comments ??

Your safety is our mission.