Eligibiliy 21.A.133

Link between design and production organisations

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- What must be fulfilled betwen design organisations and production? Why?

- **21.A.133 Eligibility**
- Any natural or legal person (‘organisation’) shall be eligible as an applicant for an approval under this Subpart. The applicant shall:
- (a) justify that, for a defined scope of work, an approval under this Subpart is *appropriate* for the purpose of showing conformity with a specific design; and
- (b) *hold or have applied for an approval of that specific design*; or
- *(the design holder is within the same legal entity (company))*
- (c) *have ensured, through an appropriate arrangement* with the applicant for, or holder of, an approval of that specific design, *satisfactory coordination between production and design.*
  (the design holder is a separate legal entity (company))

21.A.4

- **21.A.4 Coordination between design and production**
- Each holder of a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, approval of a change to type design or approval of a repair design, *shall collaborate with the production organisation as necessary to ensure:*
- (a) *the satisfactory coordination* of design and production required by point 21.A.122 or point 21.A.133 or point 21.A.165(c)(2) as appropriate; and
- (b) the proper support of the continued airworthiness of the product, part or appliance.

Part 21 subpart J

- Part 21 Subpart J (Design organisation approvals) does NOT state anything saying there need to be a arrangement in place between POA-DOA.
- In the DOH Design organistion handbook, Part 9.1 is a section adressing this matter.

What does the AMC say?

- **AMC No. 1 to 21.A.133(b) and (c) Eligibility – Link between design and production organisations**
- An arrangement is considered appropriate if it is documented and satisfies the competent authority that co-ordination is satisfactory.
- To achieve satisfactory coordination *the documented arrangements must at least define the following aspects* irrespective of whether the two organisations are separate legal entities or not: *(9 bullets to come... What you can ask yourself is : does MY arrangements cover this.....)*

Timely transfer of design data to POA
POA:s prodcedures for developing manufactiring data.

- • The responsibilities of a design organisation which assure correct and timely transfer of up-to-date airworthiness data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.);
- • The responsibilities and *procedures* of a POA holder/applicant *for developing, where applicable, its own manufacturing data in compliance with the airworthiness data package;*

POA:s responsibility towards DOA
The scope of the arranfement

- • The responsibilities of a POA holder/applicant to assist the design organisation in dealing with continuing airworthiness matters and for required actions (e.g., *traceability of parts in case of direct delivery to users*, retrofitting of modifications, traceability of processes' outputs and *approved deviations for individual parts as applicable*, technical information and assistance, etc.);
- • The scope of the arrangements must cover Part 21 Subpart G requirements and associated AMC and GM, in particular: 21.A.145(b), 21.A.165(c), (f) and (g);

Prior to type certification, testing prototype models and test specimen
Handling of production deviations an non conforming parts.

- • The responsibilities of a POA holder/applicant, in case of *products prior to type certification* to assist a design organisation in demonstrating compliance with CS (access and suitability of production and test facilities for *manufacturing and testing of prototype models and test specimen*);
- • The *procedures* to deal adequately with *production deviations* and *non-conforming parts*;

Configuration control , identification for conformity Responsible persons for the control…..

- • The *procedures* and associated responsibilities to achieve adequate *configuration control of manufactured parts*, to enable the *production organisation to make the final determination (CS)* and identification for *conformity* or *airworthiness release* and eligibility status;
- • The identification of the responsible persons/offices who control the above;

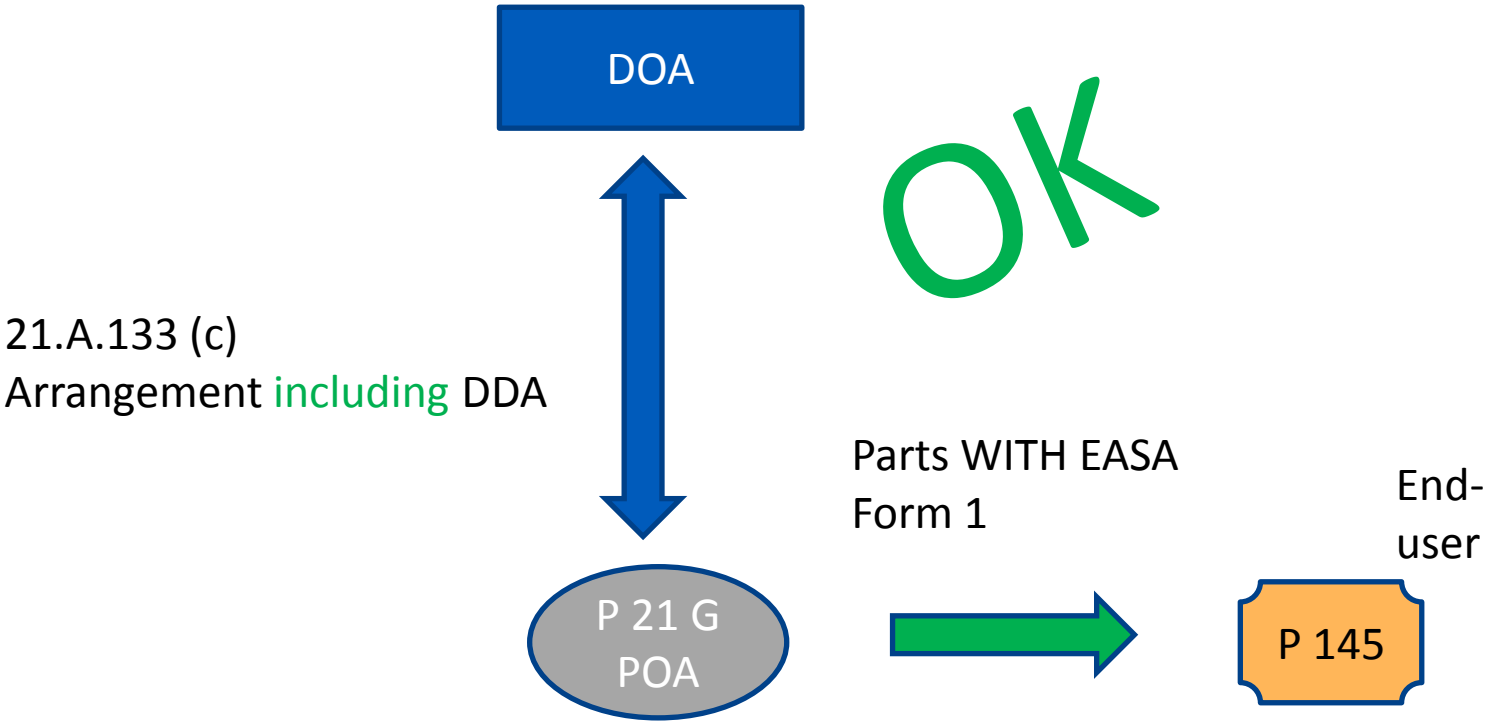
Acknowledgement from DOA of design data as approved. When an IPOA is in between POA and DOA

- • The acknowledgment by the holder of the TC/STC/repair or change approval/ETSO authorisation that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved.
- In many cases the production organisation may receive the approved design data through an *intermediate production organisation*. This is acceptable provided an effective link between the design approval holder and the production organisation can be maintained to satisfy the intent of 21.A.133.

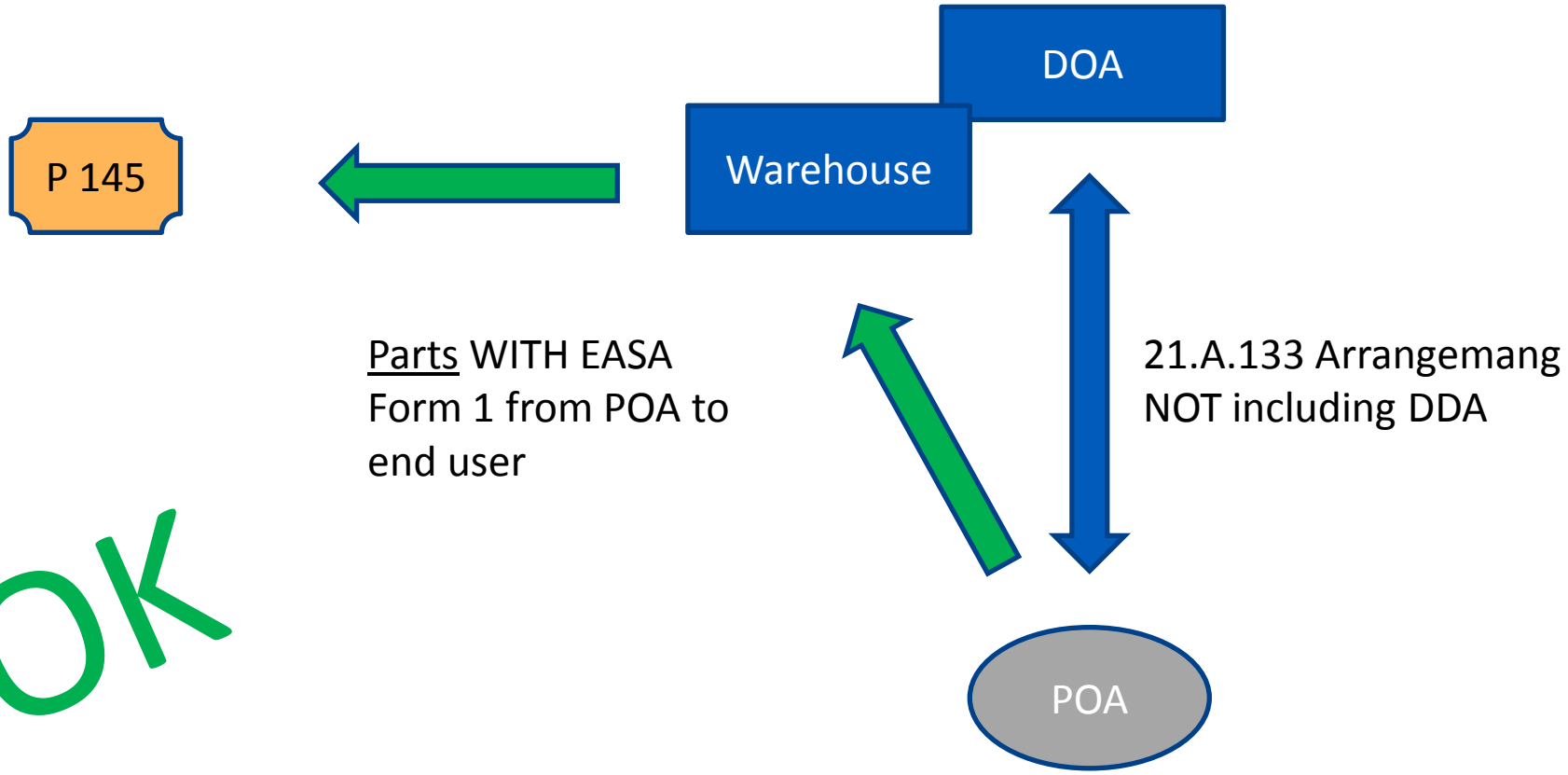
DDA, direct delivery authorisation, delivery to EASA Part 145.

- When the design and production organisations are two separate legal entities a *Direct Delivery Authorisation* must be available for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.
- Where there is no general agreement for Direct Delivery Authorisation, specific permissions may be granted (refer to AMC 21.A.4).

Text book example of arrangements including DDA (two different companies)



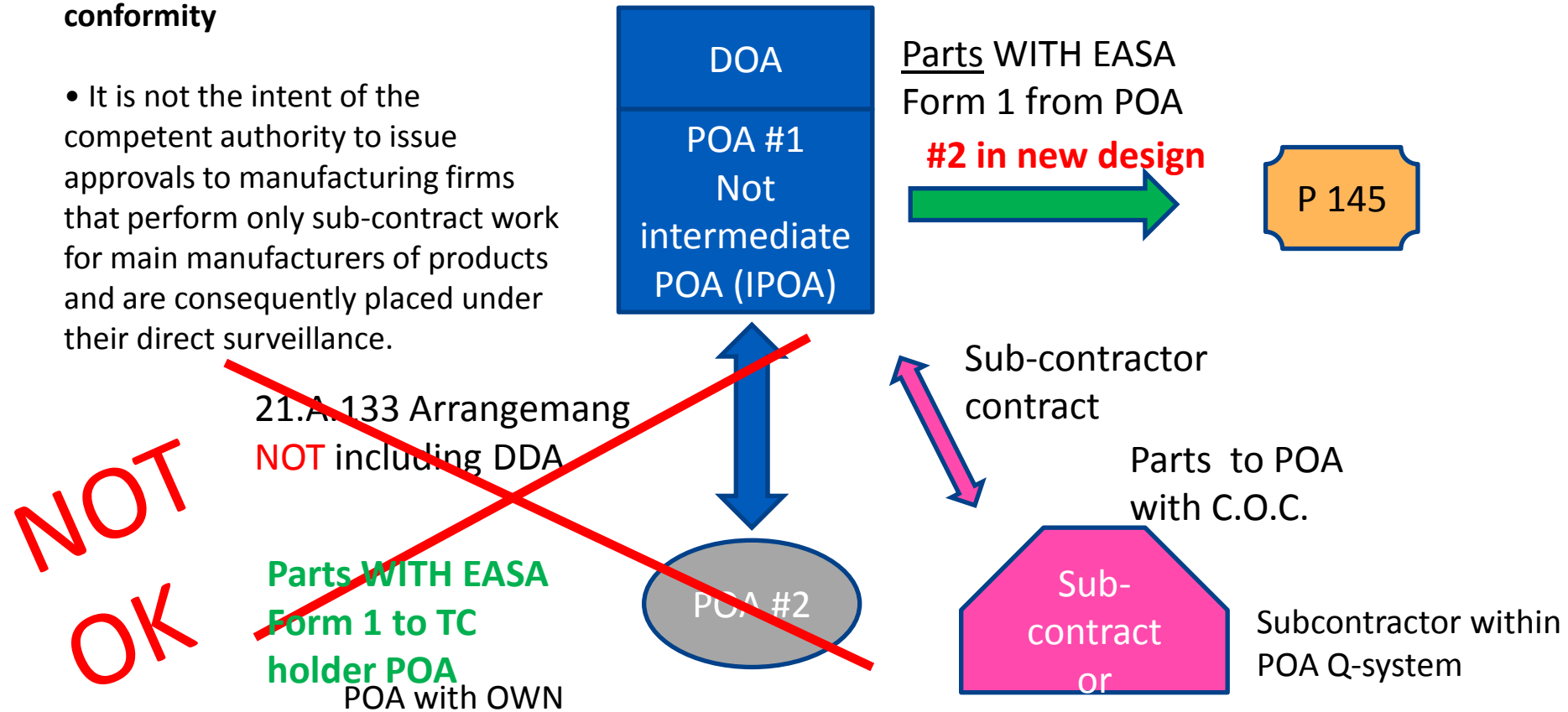
Arrangement NOT including DDA



Typically TC-holder NOT the same company (POA DOA arrangement NOT including DDA)

GM 21.A.133(a) Eligibility – Approval appropriate for showing conformity

• It is not the intent of the competent authority to issue approvals to manufacturing firms that perform only sub-contract work for main manufacturers of products and are consequently placed under their direct surveillance.



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POA-DOA Arrangement

- **AMC No. 2 to 21.A.133(b) and (c) Eligibility – Link between design and production organisations**
- In accordance with AMC No.1 to 21.A.133(b) and (c) the POA holder must demonstrate to the competent authority that it has entered into an arrangement with the design organisation.
  The arrangement must be documented irrespective of whether the two organisations are separate legal entities or not.

Ex

ARRANGEMENT

in accordance with 21.A.133(b) and (c)

The undersigned agree on the following commitments:	Relevant interface procedures
The design organisation *EASA.21J.0263 Finnair Technical Services, Ltd.* takes responsibility to • assure correct and timely transfer of up-to-date applicable design data (e.g.), drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.) to the production organisation approval holder *NO.21G.0002 Heli-One Norway AS* • provide visible statement(s) of approved design data.	DOH Part 9.1.
The production organisation approval holder *NO.21G.0002 Heli-One Norway AS* takes responsibility to • assist the design organisation *EASA.21J.0263 Finnair Technical Services, Ltd.* in dealing with continuing airworthiness matter and for required actions • assist the design organisation *EASA.21J.0263 Finnair Technical Services, Ltd.* in case of products prior to type certification in demonstrating compliance with certification specifications • develop, where applicable, its	POE Ch 2.3.12 DOH Part 9.1.
The design organisation *EASA.21J.0263 Finnair Technical Services, Ltd.* and the POA holder *NO.21G.0002 Heli-One Norway AS* take joint responsibility to • deal adequately with production deviations and non-conforming parts in accordance with the applicable procedures of the design organisation and the production organisation approval holder • achieve adequate configuration control of manufactured parts, to enable the POA holder to make the final determination and identification for conformity.	DOH Part 9.1. POE Ch 2.3.12
The scope of production covered by this arrangement is detailed in *CAPABILITY LIST , doc ID CL-01.*	

When the design organisation is not the same legal entity as the production organisation approval holder]

Transfer of approved design data:

The TC/STC/ETSO holder *EASA.21J.0263 Finnair Technical Services* acknowledges that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved by the competent authority and therefore the parts and appliances manufactured in accordance with these data and found in a condition for safe operation may be released certifying

[When the design organisation is not the same legal entity as the production organisation approval holder]

Direct Delivery Authorisation:

This acknowledgment *includes* also the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

For the *EASA.21J.0263 Finnair Technical Services, Ltd.*	For the *NO.21G.0002 Heli-One Norway AS*
Date: 2016-11-03	Date: 2016-11-03
Signature: Tom-Inge Fygle Hansen	Signature: Jukka Salo
TOM-INGE FYGLE HANSEN	JUKKA SALO

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What is a ”design approval holder” within EASA?

- Each holder of a EASA type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, approval of a change to type design or approval of a repair design.

How about foreign designs?

- Other regulatory systems that an EASA POA can use for arrangement/licencing agreement, and issuing an EASA Form 1 to a EASA approved/non approved design (with a special statement in block 12 for non EASA approved designs), are the bilateral countries, holding a Bilateral Aviation Safety Agreement

Bilateral Agreements and Working Arrangements

EASA works at facilitating the free movement of European products and services worldwide. It assists non-European authorities when they certify European products and services. Reciprocally, it issues European certificates for non-European products. The legal tools to do so are bilateral agreements and Working Arrangements.

A Bilateral Aviation Safety Agreement (BASA) is signed between the EU (and its Member States) and a non-EU country. It is used when the cooperation between the two sides aims at the mutual acceptance of certificates. EASA supports the European Commission during the negotiation and implementation of such agreements. So far, the EU has concluded a BASA with the US, Canada and Brazil.

Suggestions to have the contact information fresh:

- In the POE or referenced document there should be a list of contact information of the arranged designholders.
- The list should be audited (checked for correct information) in QM:s audit planning.

- Example:
  Contact information to arranged design holders:
- 1) Arangement with Focke Wulf, EASA.21J.0666:
  Kurt.Tank@FockeWulf.de
- 2) Arangement with Supermarine, EASA.21J.0007:
  Reginald.J.Mitchell@Supermarine.uk
- 3) Licencing agreement with North American Aviation,
  FAA DO Approval No: PQ1383CE-D :
  James.H.Kindelberger@NorthAmericanAviation.com

Questions?