TERMS OF REFERENCE

Task Nr:	21.046
Issue:	1
Date:	03 December 2009
Regulatory reference:	- Regulation EC 1702/2003, provisions of Subparts D, E, F, J, K, and Q) of the annexed Part 21 which are applicable to approval of a subset of parts designed and/or produced as "replacement parts" - Associated AMCs/GMs to Part-21;
Reference documents:	- Pre-RIA for task 21.046 (06.03.2009) - FAR Part 21, provisions applicable to replacement and modification parts (Subpart K, sec. 21.303) - FAA Order 8110.42C

1. Subject: Replacement parts

2. Problem / Statement of issue and justification; reason for regulatory evolution (regulatory tasks):

The vast majority of non-TC holder replacement or modification parts in the world are produced in the US under the Parts Manufacturer Approval (PMA). The implementing rules for airworthiness (Part-21) allow for approval of design and production of those parts but the applicable rules are hardly utilised in the EU by candidate manufacturers of those parts. This might be the result of a difference in regulatory or certification procedural burden on the manufacturers of replacement parts. It might also be the result of misunderstanding of the EASA rules, missing guidance or it may have other (e.g. commercial market, historical) reasons.

A. Design

The processes used for the design approval of replacement or modification parts are indeed different in Part-21 and FAR 21, mainly due to the different basic principles that were used to draft JAR 21, and which are still valid in Part-21. The EU basic principles are:

- Clear separation of regulations dealing with a change design (Subparts D or E) and production (Subparts F or G);
- Demonstration of design capability required (see 21A.112B), except for minor design changes (21A.92 (b));
- An arrangement with the TC Holder is necessary for those applicants proposing major design changes who cannot show they are able to produce all the required information (design change identification and compliance data) from their own resources but they need for that a support from the TC Holder to get access to the product design or certification data (see 21A.113 (b));

Replacement parts, i.e. parts the design of which is controlled by someone else than the holder of the approved design data for the original part (the TC holder or a part supplier who has obtained those approved design data through an appropriate licensing agreement), require to be approved under Part-21 as minor or major changes to the type design of the product. This is also the case when a replacement part designer/manufacturer has no intention to introduce any changes into the design of the replacement part compare to the original part intending just to "copy" the original part by creating the replacement part design data through "reverse engineering").

These EU rules seem to be more demanding than the equivalent US regulations which require/allow:

- no need for the PMA organisation to show design capability;
- acceptance of showing "identicality" of the replacement part and the original part as an acceptable alternative to a full showing of compliance that the design of the replacement part meets the airworthiness requirements applicable to the product (see FAR Part 21.303 (c)(4));
- no link with the TC holder required.

B. Production

The processes used to be able to produce replacement or modification parts and release them for installation on a type-certificated product are also different in Part-21 and FAR 21:

EU:

- a Production Organisation Approval (POA), issued under Subpart G of Part-21, to a manufacturer with a satisfactory quality assurance system, is mandatory for the manufacturer to have a privilege to issue without further showing an EASA Form 1, or
- a letter of agreement, issued under Subpart F of Part-21, to a manufacturer with a suitable production inspection system in place, to be eligible to issue an EASA Form 1 for its validation by the Competent Authority.

The EASA form 1 is required to accompany all the parts, except standard parts, to be eligible for installation in a type-certificated product (21A.307 (a)).

US:

- fabrication inspection system is only required (a quality system without quality assurance and quality management)

General concerns were voiced by some EU stakeholders as regards the above differences between the US and EU systems for approval of replacement and modifications parts, pointing out that:

- the US design approval methods do not sufficiently assure that products with PMA parts installed fully comply with the airworthiness requirements;
- the EU system seems to put more demanding conditions on potential EU designers and manufacturers of those parts compared to the US systems. This consequently puts the EU manufacturers into a competitive disadvantage with US PMA producers.

3. Objective:

The objective of the rulemaking task is to revisit if a better balance could be created between the conditions for PMA approval in the US and the rules for approving design and manufacturing of replacement parts in the EU without compromising safety of those parts and the product on which they are installed.

Any solution proposed to achieve the above objective must assure that the design of those parts meets all the airworthiness requirements applicable to the product on which they are to be installed, and that they are produced in conformity with the approved design data.

Any solution should respect as far as possible the above mentioned basic principles of the EU certification system while considering the existing flexibility in Part-21 allowing to take a different approach in different (more or less safety critical) cases (e.g. minor vs. major changes, critical parts vs. non-critical parts etc).

4. Specific tasks and interface issues (Deliverables):

The following specific task and interface issues should be accomplished:

a. Compare the EU system for approval of replacement parts with the US system for PMA parts, in particular the applicable provisions of FAR 21 and EASA Part-21, including the related guidance material, and confirm whether the perceived unbalance between both systems exists or not.

b. Check if any identified unbalance is justified by safety reasons.

c. Investigate if the range of showing of compliance methods currently available in Part-21 for acceptance of design of replacement parts is adequate and complete or if it could be extended in certain (safety less critical) cases by accepting some of the methods used by the FAA for PMA parts (namely the “identicality” method).

d. Investigate whether amending the Part-21 implementing rules is necessary or whether the objective of the task could be achieved by developing a guidance material for EU designers/manufactures of replacement parts to facilitate their development, certification, testing and production processes.

e. Co-ordinate with the FAA and TCCA using the applicable rulemaking co-operation procedures.

When a rulemaking action is justified, draft an NPA proposing and justifying amendments to the implementing rules in Part-21 and/or related AMC/GM to Part-21.

5. Working Methods (in addition to the applicable Agency procedures):

The Agency

6. Time scale, milestones:

NPA: 2010/Q2

CRD: 2010/Q4

Opinion: 2011/Q2