



**European Aviation Safety Agency
Rulemaking Directorate**

EXPLANATORY NOTE

AMC/GM to Part-21

1. GENERAL

Executive Director Decision 2010/016/R amends Decision No 2003/01/RM of 17 October 2003 (AMC/GM to Part-21 Initial Issue) as last amended by the Executive Director Decision 2010/001/R of 30 March 2010. It represents output from the following EASA rulemaking tasks:

Rulemaking Task No	TITLE	NPA No
MDM.001	Extended Range Operations with Two-Engined Aeroplanes ETOPS Certification and Operation	2008-01
ETSO.007	Systematic review and transposition of existing FAA TSO standards for parts and appliances into EASA ETSO	2009-11
21.042	Other party supplier control	2010-01

Each Notice of Proposed Amendment (NPA) has been subject to consultation in accordance with Article 52(1)(c) of the Basic Regulation¹ and articles 5(3) and 6 of the Rulemaking Procedure established by the Management Board².

2. RULEMAKING TASK MDM.001

For detailed information on the proposed change of task MDM.001 and the justification please consult the NPA 2008-01 'Extended Range Operations with Two-Engined Aeroplanes ETOPS Certification and Operation' which is available on the Agency's website. The Agency has addressed and responded to the comments received on this NPA in a Comment Response Document (CRD 2008-01) which is also available on the Agency's website³.

2.1 CRD REACTIONS

The Agency received no substantive reactions in response to the CRD 2008-01 that impact on the amendment of AMC/GM to Part-21.

¹ Regulation (EC) No 690/2009 of the European Parliament and of the Council of 30 July 2009 amending Regulation (EC) No 216/2008 of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 199, 31.7.2009, p. 6).

² Management Board decision concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications and guidance material ('Rulemaking Procedure'), EASA MB 08-2007-03, 13.6.2007.

³ http://www.easa.europa.eu/ws_prod/r/r_archives.php.

3. RULEMAKING TASK ETSO.007

For detailed information on the proposed change of task ETSO.007 and the justification please consult the NPA 2009-11 'Systematic review and transposition of existing FAA TSO standards for parts and appliances into EASA ETSO' which is available on the Agency's website. The Agency has addressed and responded to the comments received on this NPA in a Comment Response Document (CRD 2009-11) which is also available on the Agency's website⁴.

3.1 CRD REACTIONS

The Agency received no substantive reactions in response to the CRD 2007-06 that impact on the amendment of AMC & GM to Part-21.

4. RULEMAKING TASK 21.042

For detailed information on the proposed change of task 21.042 and the justification please consult the NPA 2010-01 'Other party supplier control' which is available on the Agency's website. The Agency has addressed and responded to the comments received on this NPA in a Comment Response Document (CRD 2010-01) which is also available on the Agency's website⁵.

4.1 CRD REACTIONS

In response to the CRD 2010-01, the Agency received the following substantive comments, which are reproduced below together with the Agency's position.

⁴ http://www.easa.europa.eu/ws_prod/r/r_archives.php.

⁵ http://www.easa.europa.eu/ws_prod/r/r_archives.php.

CRD comment no.	Commenter	Reaction	EASA response
1	Swiss International Airlines/ Bruno Pfister	SWISS Intl air Lines does not hold a Part 21 Approval and therefore has no comments on the CRD to NPA 2010-01 "Other Party Supplier Control".	Noted. The Agency thanks the commenter for the reaction.
2	UK CAA	<p>Page 3 - Paragraph No: IV. 8 Comment: Further clarity is required in order to ensure that organisations clearly understand that the intent of the NPA is to reduce duplication of audits of the <i>quality system</i> but does not address product conformity. The example quoted in the second paragraph of 8 is a good case in point. Just because a supplier is "well organised" is not a guarantee of product conformity (See RLD comment 24.4). A judgement on whether to accept incoming material on the basis of supplier documentation and data must be made on the basis of <i>risk</i> – primarily the risk to airworthiness of the part and the risk posed by the quality system of the supplying organisation. The example states that full-scale incoming inspection by the POA holder could be necessary when there is no adequate control of that supplier. If there was no adequate control of the supplier, then complete conformity checks by the POA holder would be the only way to meet 21A.139(b)(1). Proposed Text: It is recommended that specific wording be included to make it clear that the NPA applies only to demonstration of the working of the quality system as part of a risk based approach to supplier control which must also include the demonstration of product conformity.</p>	Noted The Agency agrees that the new AMCs relate to the possible reduction of quality audits of suppliers and that they do not address product conformity. However the Agency is of the opinion that this is already clear enough in the text of the existing GM No. 2 to 21A.139(a). Moreover this should also be clear because the AMCs are linked to 21A.139(b)(1)(ii) which deals with subcontractor audit and control only and not to 21A.139(b)(1)(iii) regarding conformity of incoming products.
3	UK CAA	<p>Page 4 - Comment 25 (Embraer) Comment: It's noted that Embraer supports the</p>	Not accepted The redirection of resources that could become

CRD comment no.	Commenter	Reaction	EASA response
		<p>proposal as eliminating duplication of effort <i>thus saving resources that can be redirected to other safety matters</i>. CAA wholeheartedly concurs with this sentiment, but this objective – i.e. to release resource to other areas such as product conformity issues and technical capability checks of supplier competence does not seem to be reflected in the current NPA. This was a stated objective of the prior JAA arrangements to obtain NAA support.</p> <p>Justification: Previously stated CAA concern has been that organisations will reduce numbers of supplier QA personnel rather than redirect to areas of safety improvements such as product audits.</p> <p>Proposed Text: The intent to redirect resource to seek improved product conformity should be restated as a specific objective.</p>	<p>available when oversight activities are performed by other parties is not the objective of this AMC. This is a possible beneficial effect from a more efficient oversight of suppliers.</p>
4	UK CAA	<p>Page 9 - Comment 24 (RLD) 4. (+ 29 FOCA) Comment: CAA UK has similar experience regarding varying standards of compliance of those organisations holding EN/AS9100 certification to that of RLD and has passed this to Industry via the National Certification Management Body on which it sits. The Agency should consider a qualification audit of the functioning of the ICOP system with the results available to NAAs as part of their decision-making process. Consideration should be given to the use of NAA personnel to support Agency resource. Justification: To reduce possible inconsistencies between implementation of the certification schemes within member states (as noted in the FOCA comment).</p>	<p>Noted The Agency agrees that it is important for competent authorities to share experience on applied standards, systems and implementation. This is also required in accordance with article 15(1) of the Basic regulation. A qualification audit on the ICOP system as such is however outside the remit of the Agency as described in article 20 of the Basic Regulation, because the ICOP system is not eligible for an EASA certificate. It is even to be determined if such a system audit would provide added value when it is performed outside the context of oversight of a specific production organisation and its suppliers.</p>
5	UK CAA	<p>Page 20 - Response to Comment 33 (Claude Mas) Comment: Mention is made of EASA plans to organise a workshop shortly after publication to discuss</p>	<p>Noted</p>

CRD comment no.	Commenter	Reaction	EASA response
		<p>consistent implementation. CAA UK considers this essential in order to ensure standardisation and common understanding between NAAs and the Agency.</p> <p>Justification: Standardisation.</p>	
6	UK CAA	<p>Page 26 - Comment 22 (UK CAA) Comment: CRD response states that AMC No. 2 lists the criteria used such that oversight by an other party scheme “can be used to substitute the assessment, audit and control of the POA Holder.” Other party oversight cannot substitute for the control of the POA Holder, which remains their legal obligation under 21A.139. Such a comment gives CAA concern that there is not a clear understanding of exactly what the intent of this NPA is. It is <u>not</u> to replace the assessment, audit and control of the POA Holder, it is to allow an element (i.e. the assessment of the quality system) to be delegated to another organisation under controlled conditions). CAA remains concerned that this NPA will be commonly misinterpreted as simply meaning that a supplier with EN/AS9100 needs no oversight at all – hence the other comments regarding clarity of purpose.</p> <p>Justification: Lack of clear statement of intent of NPA will lead to inconsistent application and confusion.</p>	<p>Accepted</p> <p>The Agency accepts that the wording of the response in the CRD does not correctly reflect the intent of the AMCs. Therefore the Agency agrees to add a statement to the AMCs clarifying their purpose.</p> <p>In addition the planned workshop is a tool to address possible misinterpretations.</p>
7	UK CAA	<p>Page 33/34 - Resulting text to AMC No. 2 to 21A.139(b)(1)(ii) paragraph 3(c)(3)(i) Comment: If this paragraph is intended to make sure that no gaps will occur between the assessment, audit and control performed by the OP and the POA holder, then clear guidance may be beneficial. A similar comment may be applied to the corresponding text in</p>	<p>Not accepted</p> <p>The comment and proposal show that the commentor presumes that the Part-21 Subpart G requirements apply to suppliers of a POAH. This is however not the case.</p> <p>Subpart G requirements are applicable to the POAH, who must have a quality system ensuring that each</p>

CRD comment no.	Commenter	Reaction	EASA response
		<p>AMC No. 1 to 21A.139(b)(1)(ii).</p> <p>Justification: Clear guidance to make sure that no gaps will occur between the assessment, audit and control performed by the OP and the POA holder.</p> <p>Proposed Text: Replace existing text with the following:</p> <p>“(i) Verification that certification standards and checklists are acceptable and applied to the applicable scope, and include all applicable elements of Part 21 Subpart G e.g.</p> <ul style="list-style-type: none"> ▪ Mandatory Occurrence Reporting and continued airworthiness, ▪ Co-ordination with the POA or holder of, an approved design ▪ Issue of certifications within the scope of approval. ▪ Incorporation of airworthiness data in production and inspection data ▪ When applicable, ground test products in accordance with procedures defined by the POA, or holder of, the design approval ▪ Procedures for traceability including a definition of clear criteria of which items need such traceability. ” 	<p>product, part or appliance produced by the organisation or its partners conforms to the applicable design data and is in condition for safe operation.</p> <p>GM No. 2 to 21A.139(a) provides a list of techniques that can be used to control conformity of supplied parts.</p>