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<b>Title</b>	Additional acceptable means of compliance and guidance material for the safety/safety support assessment of changes to the air traffic management/air navigation services functional systems
<b>NPA Number</b>	NPA 2019-04

**UK CAA** (European.Affairs@caa.co.uk) has placed **11** unique comments on this NPA:

<b>Cmt:</b>	<b>Segment description</b>	<b>Page</b>	<b>Comment</b>	<b>Attachments</b>
181	2. In summary — why and what	4 - 7	<p><b>Page No:</b> 4</p> <p><b>Paragraph No:</b> 2.1 and proposed AMC/GM.</p> <p><b>Comment:</b> The UK CAA considers that the proposed AMC/GM signals a change of philosophy by EASA in that the current methodology of how safety assessments of change are undertaken is maintained, as opposed to the progressive and flexible approach previously developed in support of Regulation (EU) 2017/373 that to date has not been adopted by the Agency.</p> <p>EASA is invited to clarify its current position regarding methodology to be applied when undertaking safety assessments of change and to provide an indication as to whether any of the previously developed (but to date unpublished) AMC/GM will be considered for adoption. This material provides more comprehensive guidance in a number respects when compared to the proposed NPA 2019-04 content. It is contended that it is more fully aligned with the intent and requirements of Regulation (EU) 2017/373.</p> <p><b>Justification:</b> The aim of Regulation (EU) 2017/373 is to set objective criteria for the outcomes of the safety assessment and assurance of changes to functional systems. To this end the requirements do not include specific requirements for methods or processes. This is highlighted in GM2 ATS.OR.205(b) and in section 2.1 of NPA 2014-13.</p> <p>SESAR JU was involved in RMG.0469 throughout its life. While their views on the outcomes of development and assurance processes and methods were taken into account, their wishes to include specific SRM material were rejected on the basis that they were too method oriented. This can be confirmed by referring to the records of RMG.0469 meetings. Whilst elements of the SRM may indeed complement existing AMC/GM, we believe the NPA is insufficiently explicit in identifying what may be applied without contradicting extant Regulation (EU) 2017/373 rule/AMC/GM content.</p> <p>Regulation (EU) 2017/373 recognises the need for guidance on methods and processes; we recommend an appropriate approach to be taken is to encourage ANSPs to use or promote the further development general or domain specific standards (see GM2 ATS.OR.205(b), GM2 ATM/ANS.OR.C.005(b)(1), GM1 ATM/ANS.OR.C.005(b)(1).</p>	

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182	2. In summary – why and what	4 - 7	<p><b>Page No:</b> 4-6</p> <p><b>Paragraph No:</b> 2.1 and 2.3.2</p> <p><b>Comment:</b> We believe the focus on the success/failure approach as described in Section 2.1 and 2.3.2 is unnecessary and probably counterproductive.</p> <p><b>Justification:</b> The focus on the success/failure approach was originally proposed in RMG.0469 meetings and rejected because the approach described in Regulation (EU) 2017/373 is already a broader approach. This is a total risk approach (see ATS.OR.210 (c)(2)) and requires success to be taken into account as well as failure in order to be practical – a functional system cannot be as safe as it was before the change if only failure is taken into account – see AMC1 ATS.OR.205(b)(4), AMC2 ATS.OR.205(b)(4), GM1 to AMC1 ATS.OR.205(b)(4) and GM1 ATS.OR.210(b)(2).</p> <p>Scoping activities are already well documented and NPA 2019-04's additional material is considered unnecessary. The criteria and activities surrounding establishing the necessary scope for a change can be found in:</p> <ul style="list-style-type: none"> <li>· AMC1 ATM/ANS.OR.C.005(b)(1)</li> <li>· GM1 ATM/ANS.OR.A.045(c) and (d)</li> <li>· GM1 ATM/ANS.OR.A.045(f)</li> <li>· GM1 ATM/ANS.OR.B.010(a)</li> <li>· GM3 ATM/ANS.OR.C.005(a)(1)</li> <li>· GM4 ATM/ANS.OR.C.005(a)(1)</li> <li>· GM6 ATM/ANS.OR.C.005(a)(1)</li> <li>· GM3 ATM/ANS.OR.C.005(a)(2)</li> <li>· GM1 ATM/ANS.OR.C.005(b)(1)</li> <li>· AMC1 ATS.OR.205(b)(5)</li> <li>· GM2 ATS.OR.205(a)(1)</li> <li>· GM4 ATS.OR.205(a)(1)</li> <li>· GM1 ATS.OR.205(a)(1)(iii)</li> <li>· GM3 ATS.OR.205(a)(2)</li> <li>· GM1 to AMC2 ATS.OR.205(a)(2)</li> </ul> <p><b>Proposed Text:</b> It is recommended that the proposed GM1 ATS.OR.205(b)(3) Safety assessment and assurance of changes to the functional system is removed.</p>	

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183	2. In summary — why and what	4 - 7	<p><b>Page No:</b> 5</p> <p><b>Paragraph No:</b> 2.3.1</p> <p><b>Comment:</b> We believe the new GM proposed for ATM/ANS.OR.C.005(a)(1) (i);(ii);(iii);(iv) Safety support assessment and assurance of changes to the functional system is not required.</p> <p><b>Justification:</b> The new GM1 ATM/ANS.OR.C.005(a)(1)(i);(ii);(iii);(iv) details what needs to be done at an early stage of the process; however, the requirement in Regulation (EU) 2017/373 does not cover merely the early stages. The proposed GM is therefore incomplete but does not explain this. The current GM GM4 ATM/ANS.OR.C.005(a)(1) already covers iterative development. Safety support assessment requirements are contained in ATM/ANS.OR.C.005(b) and associated GM.</p> <p>In addition, we believe there is inadequate definition of the word 'scoping', which is the identification of the scope of the change in accordance with the requirements determining the need for change.</p> <p><b>Proposed Text:</b> It is recommended that the proposed <u>GM1 ATM/ANS.OR.C.005(a)(1)(i);(ii);(iii);(iv)</u> is removed.</p>	
184	2. In summary — why and what	4 - 7	<p><b>Page No:</b> 6</p> <p><b>Paragraph No:</b> 2.3.2</p> <p><b>Comment:</b> We believe proposed GM1 ATS.OR.205(b)(3) and new AMC3 ATS.OR.205(b)(4) are unnecessary and should be deleted.</p> <p><b>Justification:</b> The allocation of safety requirements is adequately covered in GM3 ATS.OR.205(a)(2) and GM1 to AMC2 ATS.OR.205(a)(2). How they may be derived is not addressed by the proposed NPA text and provision of guidance in this respect should be considered.</p> <p>In addition, the original intent of the regulation regarding safety assessment of changes was to provide a process-free regulation. This allows flexibility around the processes to be used by service providers.</p> <p><b>Proposed Text:</b> It is recommended that the proposed text at GM1 ATS.OR.205(b)(3) and AMC3 ATS.OR.205(b)(4) is removed.</p>	

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186	3. Proposed amendments — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision)	8 - 18	<p><b>Page No:</b> 9</p> <p><b>Paragraph No:</b> GM1 ATM/ANS.OR.C.005(a)(1)(v) Safety support assessment and assurance of changes to the functional system, subparagraph (b)</p> <p><b>Comment:</b> The text describes how one can enter a degraded state. The assessment and risk evaluation of a degraded mode is described at GM1 ATM/ANS.OR.C.005(a)(1)(v) and at GM2 to AMC3 ATS.OR.205(b)(4) which should be referenced in the subject paragraph for clarity. In addition, the need for additional GM is unclear. It is much less than that currently provided at GM1 to AMC2 ATM/ANS.OR.C.005(a)(2) and GM2 ATM/ANS.OR.C.005(b)(1).</p> <p><b>Justification:</b> Need for clarity on assessing the safety of a degraded state.</p> <p><b>Proposed Text:</b> Amend to read:</p> <p>'Abnormal conditions are those external changes in the context (operational environment) that the functional system may exceptionally encounter (e.g. severe weather conditions, ionosphere, interferences, supplier or utility failure, etc.) under which the functional system may be allowed to enter a degraded state provided that it can easily be recovered when the abnormal condition passes and the risk during the period of the degraded state is shown to be tolerable. See GM1 ATM/ANS.OR.C.005(a)(1)(v) and GM2 to AMC3 ATS.OR.205(b)(4).'</p>	
187	3. Proposed amendments — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision)	8 - 18	<p><b>Page No:</b> 12</p> <p><b>Paragraph No:</b> GM1 ATS.OR.205(a)(1)(v) Safety assessment and assurance of changes to the functional system, subparagraph (b)</p> <p><b>Comment:</b> The text describes how one can enter a degraded state. The assessment and risk evaluation of a degraded mode is described at GM1 ATM/ANS.OR.C.005(a)(1)(v) and at GM2 to AMC3 ATS.OR.205(b)(4) which should be referenced in the subject paragraph for clarity.</p> <p><b>Justification:</b> Clarity on assessing the safety of a degraded state.</p> <p><b>Proposed Text:</b> Amend to read:</p> <p>'Abnormal conditions are those external changes in the context (operational environment) that the functional system may exceptionally encounter (e.g. severe weather conditions, ionosphere, interferences, supplier or utility failure, etc.) under which the functional system may be allowed to enter a degraded state provided that it can easily be recovered when the abnormal condition passes and the risk during the period of the degraded state is shown to be tolerable. See GM1 ATM/ANS.OR.C.005(a)(1)(v) and GM2 to AMC3 ATS.OR.205(b)(4).'</p>	

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188	3. Proposed amendments — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision)	8 - 18	<p><b>Page No:</b> 12/13</p> <p><b>Paragraph No:</b> GM1 ATS.OR.205(b)(3) RISK ANALYSIS</p> <p><b>Comment:</b> GM1 sees the first use of the term “integrated risk model” (note that this term is not defined nor cited within the IR) with points (b)(1), (2) and (3) stating what an integrated risk model should contain. However, neither GM1, nor the remainder of the text proposed within NPA 2019-04, appears to contain sufficient detail to describe how such an “integrated risk model” should be developed by ATS providers.</p> <p><b>Justification:</b> Need for completeness and clarity.</p> <p><b>Proposed Text:</b> EASA is requested to explain the term “integrated risk model” more fully.</p>	
189	3. Proposed amendments — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision)	8 - 18	<p><b>Page No:</b> 13</p> <p><b>Paragraph No:</b> AMC3 ATS.OR.205(b)(4), subparagraph (a)</p> <p><b>Comment:</b> We believe that AMC3 ATS.OR.205(b)(4) subparagraph (a) is not required.</p> <p><b>Justification:</b> ATS.OR.205(b)(4) is about safety <i>criteria</i> not safety <i>requirements</i>. The relationship between safety criteria and safety retirements is already explained in GM1 to AMC2 ATS.OR.205(a)(2)..</p> <p><b>Proposed Text:</b> We recommend that the proposed AMC3 ATS.OR.205(b)(4) subparagraph (a) is removed.</p>	
190	3. Proposed amendments — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision)	8 - 18	<p><b>Page No:</b> 13</p> <p><b>Paragraph No:</b> AMC3 ATS.OR.205(b)(4), subparagraph (b)</p> <p><b>Comment:</b> The UK CAA does not support the contention that the risk evaluation and mitigation process is considered complete when all the stages of the life cycle of the change have been assessed.</p> <p><b>Justification:</b> As no processes are required by the regulation (only objectives are to be met) then there can be no compliance with processes. In addition, the risk evaluation and mitigation process can only be considered complete when a valid safety argument is produced.</p> <p><b>Proposed Text:</b> It is recommended that the proposed AMC3 ATS.OR.205(b)(4) subparagraph (b) is removed.</p>	
191	3. Proposed amendments — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision)	8 - 18	<p><b>Page No:</b> 15</p> <p><b>Paragraph No:</b> AMC1 ATS.OR.210(b)</p> <p><b>Comment:</b> The term “accident precursors” is not defined.</p> <p><b>Justification:</b> This appears to be the first time that this term appears in the IR/AMC/GM and needs to be explained (without recourse to a fixed definition). It does not appear in any other context within the rule package.</p> <p><b>Proposed Text:</b> EASA are requested to define the term “accident precursors”.</p>	

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192	3. Proposed amendments — 3.1. Draft acceptable means of compliance and guidance material (Draft EASA decision)	8 - 18	<p><b>Page No:</b> 15</p> <p><b>Paragraph No:</b> AMC1 ATS.OR.210(b)</p> <p><b>Comment:</b> The sentence appears to contain a typographical error in that it mixes use of singular and plural terms.</p> <p><b>Justification:</b> Accuracy of EU Regulatory materials</p> <p><b>Proposed Text:</b> Two options are proposed, either:</p> <p>“The accident precursors within the integrated risk model should be used to define safety criteria in terms of explicit, quantitative levels of <del>the</del> safety risk”;</p> <p>or,</p> <p>“The accident precursors within the integrated risk model should be used to define safety criteria in terms of an explicit, quantitative level of <del>the</del> safety risk”.</p>	