

European Union Aviation Safety Agency

Comment-Response Document 2017-10

Related NPA 2017-10 — RMT.0469 — 29.10.2019

Table of contents

1.	Summary of the outcome of the consultation	2
2.	Individual comments and responses	4
3.	Attachments	140



1. Summary of the outcome of the consultation

The public consultation period was prolonged, following the request of stakeholders, and ended on 8 December 2017. As a result of the public consultation, EASA received 315 comments, whose distribution is shown in Figure 1 below.



Figure 1: Percentage of comments per type of stakeholder

The nature of the comments received varies from comments regarding the applicability of the software assurance AMC & GM to certain service providers (e.g. MET providers) until proposals for stricter implementing measures.

Furthermore, after the closure of the public consultation, EASA carried out a focused consultation and held a thematic meeting in October 2017 purposed to review the main topics commented on the proposed acceptable means of compliance (AMC) and guidance material (GM). The thematic meeting involved experts who contributed actively to the NPA consultation. The purpose of the meeting was to gather advice on specific subjects that would facilitate EASA in taking informed decisions for the CRD publication and the final ED Decision.

The thematic meeting covered the following subjects:

- Legal responsibility for suppliers of EATMN systems and components;
- Extension and transition period for service providers not currently regulated by Regulation (EC) No 482/2008;
- Terminology;
- Software aspects in the context of safety (support) assessment;
- Coordination between the competent authority and the service provider(s);
- The use of industry standards as AMC & GM, including cyber security standards;
- (Possible) extension of the AMC & GM to hardware, people and procedures; and
- Reporting and assessment of service occurrences.



As regards the applicability of this set of AMC & GM, EASA considers that some of the service providers other than the ones that apply today Regulation (EC) No 482/2008 (e.g. MET, FPD, DAT providers) are more and more influenced by the software. Therefore, it was concluded that the features of these providers' systems are affected by the current regulatory requirements, which also supports the approach that the proposed set of AMC & GM should apply to all service providers of ATM/ANS, incl. AIS and MET providers towards software assurance level standardisation.

Following the NPA 2017-10 consultation, as regards hardware assurance, it is concluded that a further consideration is required and this element should be further discussed via a separate rulemaking activity.

EASA reviewed all the comments and, based on them, adjusted the AMC & GM that are annexed to Decision 2019/022/R.



Figure 2: Percentage of comments that have been accepted, partially accepted, noted, or not accepted



(Conoral Commonts)

2. Individual comments and responses

In responding to comments, a standard terminology has been applied to attest EASA's position. This terminology is as follows:

- (a) **Accepted** EASA agrees with the comment and any proposed amendment is wholly transferred to the revised text.
- (b) **Partially accepted** EASA either partially agrees with the comment, or agrees with it but the proposed amendment is only partially transferred to the revised text.
- (c) **Noted** EASA acknowledges the comment, but no change to the existing text is considered to be necessary.
- (d) Not accepted The comment or proposed amendment is not agreed by EASA.

comment	1 comment by: DFS Deutsche Flugsicherung Gr
	There is high probability that the felt "potential safety weakness as regards software assurance aspects" is a result of the complexity of the Comm Requirements in this particular context. Adding more AMC, which do rather serve new IR requirements than as means for implementation of existing ones, is not right way to solve the complexity.
	These AMC represent a hurdle too high for the creation of any AltMoC.
	Instead, the provisions on safety management for ATM/ANS providers includ changes to their functional systems should be revisited in applying the principles Better Regulation, finding the right balance between IR and AMC and ensuring a le playing field.
response	Noted
	The comment is duly noted.
	The aim of the proposed set of AMC is not to trigger a development/managemen AltMoC, but rather to provide AMC for the software assurance we introducing changes to the functional system. The need for this additional mate regarding software assurance was expressed by several stakeholders, especi authorities during the Comitology process that resulted in Regulation (EU) 2017/3
	39 comment by: CAN



Requirements in this particular context. Adding more AMC, which do rather serve as

new IR requirements than as means for implementation of existing ones, is not the right way to solve the complexity.

These AMC represent a hurdle too high for the creation of any AltMoC.

Instead, the provisions on safety management for ATM/ANS providers including changes to their functional systems should be revisited in applying the principles for Better Regulation, finding the right balance between IR and AMC and ensuring a level playing field.

Noted response

The comment is duly noted.

The aim of the proposed set of AMC is not to trigger a development/management of AltMoC, but rather to provide AMC for the software assurance when introducing changes to the functional system. The need for this additional material regarding software assurance was expressed by several stakeholders, especially authorities during the Comitology process that resulted in Regulation (EU) 2017/373.

comment 80 comment by: EUROCONTROL

The EUROCONTROL Agency welcomes the publication of EASA Notice of Proposed Amendment 2017-10. It also thanks EASA for the opportunity that has been given to submit comments. In addition, the EUROCONTROL Agency would like to confirm that it will read with interest the other comments on the NPA which will be received from the stakeholders and the responses given to them by EASA in its future commentresponse document (CRD). It is hoped that the CRD will be published before it is annexed to the decision amending the AMC/GM to Regulation (EU) 2017/373 in order to give stakeholders some time for analysing the responses to comments and, if need be, further reflection.

In general, the EUROCONTROL Agency feels that the amendments proposed under NPA 2017-10 are almost the same as the requirements under EC482/2008, which will be repealed once EU 2017/373 comes in force. The EUROCONTROL Agency therefore does not make any comments on NPA content, with the exception of those made concerning ATS.OR.205(a)(2) and ATM/ANS.OR.C.005(a)(2). In addition, since the requirements proposed in the NPA are almost exclusively found at the level of Guidance Material only, and not at the level of Acceptable Means of Compliance, it seems that the NPA content could weaken the case for software assurance.

response Noted

EASA duly noted the comment.

On the other hand, the commentator is invited to note that Article 9 of MB Decision No 18-2015 ('Rulemaking procedure') applies. It regulates that the Executive Director shall issue his or her decision in respect of the rule in question together with the CRD.



comment	84 comment by: EASA Focal Point for AustroControl ANSP-issues
	AUSTRO CONTROL, General Comment:
	Observation:
	AUSTRO CONTROL is highly concerned about the general direction of this NPA, to put the burden of legal responsibility for EATM-system's liability only on the ANSP's shoulders.
	Drenesel
	Proposal: Even though it is clear responsibility of the ANSP to deliver safe services – including software - there should be a legal responsibility also for suppliers of EATMN systems and components, to develop their components according the aeronautical standards.
response	Noted
	This proposal follows the same principles as the ones laid down in Regulation (EU) 2017/373, where the responsibility lies with the ANSP for the provision of safe services. Consequently, no change is introduced by this set of AMC & GM on this particular aspect. It is considered that the ANSPs should have the appropriate interface with the developers of the EATM-systems in order to ensure the provision of safe services when using them.
comment	88 comment by: CANSO
	<u>Remark:</u> Rigour is used in EC 482/2008 as general sense, but in the present document it could also be understood in a stringent way where several rigour classes should be identified, depending of the SWAL, for the same process. The term rigour should be clarified in this document in the way that it means the same as used in EC 482/2008.
response	Partially accepted
	A review of the rule text has been performed. Some of the AMC & GM have been updated in order to avoid the potential misunderstanding identified by the commentator.
comment	106 comment by: ENAV
	There is high probability that the felt "potential safety weakness as regards the software assurance aspects" is a result of the complexity of the Common Requirements in this particular context. Adding more AMC, which do rather serve as new IR requirements than as means for implementation of existing ones, is not the right way to solve the complexity.
	These AMC represent a hurdle too high for the creation of any AltMoC.



	Instead, the provisions on safety management for ATM/ANS providers including changes to their functional systems should be revisited in applying the principles for Better Regulation, finding the right balance between IR and AMC and ensuring a level playing field.
response	Noted
	The comment is duly noted.
	The aim of the proposed set of AMC is not to trigger a development/management of AltMoC, but rather to provide AMC for the software assurance when introducing changes to the functional system. The need for this additional material regarding software assurance was expressed by several stakeholders, especially authorities during the Comitology process that resulted in Regulation (EU) 2017/373.
comment	107 comment by: ENAV
	Rigour is used in EC 482/2008 as general sense, but in the present document it could also be understood in a stringent way where several rigour classes should be identified, depending of the SWAL, for the same process. The term rigour should be clarified in this document in the way that it means the same as used in EC 482/2008.
response	Partially accepted
	A review of the rule text has been performed. Some of the AMC & GM has been updated in order to avoid the potential misunderstanding identified by the commentator.
comment	126 comment by: ENAV
	ENAV is highly concerned about the general direction of this NPA, to put the burden of legal responsibility for EATM-system's liability only on the ANSP's shoulders.
	Proposal: Even though it is clear responsibility of the ANSP to deliver safe services – including software - there should be a legal responsibility also for suppliers of EATMN systems and components, to develop their components according the aeronautical standards.
response	Noted
	This proposal follows the same principles as the ones laid down in Regulation (EU) 2017/373, where the responsibility lies with the ANSP for the provision of safe services. Consequently, no change is introduced by this set of AMC & GM on this particular aspect. It is considered that the ANSPs should have the appropriate interface with the developers of the EATM-systems in order to ensure the provision of safe services when using them.



comment	129 comment by: Avinor Air Navigation Services (Avinor Flysikring AS)
	Comment: We think there is too little focus on exactly how to provide software assurance for COTS or already developed software, which leads everyone to develop a new strategy for this every time.
	Justification: Our opinion is that the ANSPs tend to buy and use more of COTS or already developed software, instead of going through an entire development process (which is also more costly).
response	Accepted
	An amendment to the text was introduced to include the definition for commercial off-the-shelf (COTS). At this moment, the proposed approach follows Regulation (EC) No 482/2008, where this is subject to agreement between the ANSP and the competent authority.
comment	135 comment by: LFV
	Since NPA 2017-10 covers all ATM/ANS services, while current requirements for software assurance only covers ATS, ATFM, ASM and CNS services, a transition period is needed for these services, similar to those in EU 482/2008 article 7.
response	Not accepted
	It should be noted that Regulation (EC) No 482/2008 entered into force in 2010 and, hence, after several years of application, it is understood that the concept of software legacy does not require a particular treatment. Consequently, any new software or modifications to existing software should follow the software assurance processes.
comment	138 comment by: CANSO
	CANSO is concerned about the general direction of this NPA, to put the burden of
	legal responsibility for EATM-system's liability only on the ANSP's shoulders.
response	legal responsibility for EATM-system's liability only on the ANSP's shoulders. Proposal: Even though it is clear responsibility of the ANSP to deliver safe services – including software - there should be a legal responsibility also for suppliers of EATMN systems and components, to develop their components according the software development



interface with the developers of the EATM-systems in order to ensure the provision of safe services when using them.

comment	142 comment by: Federal Office of Civil Aviation (FOCA), Switzerland
	The Federal Office of Civil Aviation (FOCA) would like to thank the Agency for the opportunity to comment on the NPA 2017-10 Software assurance level requirements. Please by advise that FOCA fully supports the content of this NPA.
response	Noted
	EASA appreciates the comment.
comment	173 comment by: DSNA
	Rigour is used in EC 482/2008 as general sense, but in the present document it could also be understood in a stringent way where several rigour classes should be identified, depending of the SWAL, for the same process. The term rigour should be clarified in this document in the way that it means the same as used in EC 482/2008.
response	Partially accepted
	A review of the rule text has been performed. Some of the AMC & GM have been updated in order to avoid the potential misunderstanding identified by the commentator.
comment	183 comment by: AESA/DSANA
	What is considered a functional system in ATM and ANS? Does this NPA apply to all SW or only to operational SW? This NPA includes more service providers in the SW assurance processes than EC 482/2008. For example, ASD providers were not taken into account in EC 482/2008. Some doubts can arise such as: Are Flight Procedures Design SW solution considered as a functional system?
response	Noted
	The AMC & GM presented in this NPA corresponds to the software part of the ANSP functional system, which is subject to safety or safety support assessments.
	On the other hand, the applicability of Subpart C of Part-ATM/ANS.OR (safety support assessment requirements) and the associated AMC & GM to the Flight Procedure Design (FPD) provider is regulated in Article 6 of the subject Regulation.

comment 209

comment by: European Transport Workers Federation - ETF



	definitions in EU Reg. 482/2008	Those definitions are not proposed for transposition here, can you confirm those have all been transposed in EU Reg. 2017/373 and if not explain why some are not transposed.
response	Accepted	
	definitions from	omment, the text has been updated to ensure that either all the Regulation (EC) No 482/2008 are included in Regulation (EU) fically mentioned in this set of AMC & GM.
comment	212	comment by: <i>DSAC - FR NSA</i>
	concept as a nece	upports this NPA which explicitely develops software assurance essary argument for safety (suppport) cases. This NPA will highly oversight and the management of software aspects.
	understanding and propagated from a Moreover the app apply without Therefore, French of development including equipme	r of this NPA, first discussions about 2017/373 have shown few d considerations to system engineering concepts that have been software to the overall functional system in the scope of changes. Dication of SWAL or any concept of assurance level is difficult to an overal system development assurance level. NSA would also highly support the development of a complete set assurance levels addressing first system development aspects ent, people and procedures and then addressing all components of tem (people, procedure, swal, hwal).
response	Noted	
	EASA appreciates	the comment.
comment	213	comment by: DSAC - FR NSA
	However, to the q categories Most of complex e General Purpose few assurance cou of electronic har sufficient consider HWAL Some other ATM navigation system	1, French NSA is in favour of any kind of assurance level concept. uestion of developing a HWAL AMC/GM, it should be considered 2 of hardware devices. electronic devices involved in ATM systems are COTS and consist of Processors, Graphical Processor Units or microcontrollers. No or uld be obtained from manufacturers. However regarding this kind rdware, software assurance considerations could be deemed ring that software verifications would cover hw functionalities. No would be required. systems requiring specific functions and performances (radars, is (ILS, DME,), radios) may require dedicated hardware devices ely have to meet some safety performances. For these specific



	hardware devices which are not verified through a software assurance process, it should be considered to develop a hardware assurance concept at least allowing to establish their functional requirements (including functions needed for safety considerations) and to demonstrate their achievement.
response	Noted
	Acknowledging the stakeholders' feedback from the NPA 2017-10 consultation, EASA will consider a separate rulemaking activity dedicated on the hardware assurance level requirements related to the assessment of changes to functional systems, where the comment will be taken into account.
comment	218 comment by: NATS
	The structure of the guidance material leads to significant duplication of text that applies equally to service providers and ANSP sections, which could be presented more concisely.
	Impact: Duplication of text could lead to subtle unintended variations in compliance against similar requirements
	Suggested Resolution: Consider presenting guidance as applicable to both service providers and ANSPs in one section, and identifying differences at that level (rather than duplicating as currently)
response	Noted
	EASA acknowledges the existing duplications of provisions, but this approach was preferred to keep the segregated set of requirements separately, depending on the type of service provider.
	A recast of the order of the requirements at IR level and the associated AMC & GM could be considered at a later stage via a separate rulemaking activity.
comment	219 comment by: NATS
	Neither the NPA nor (EU)2017/373 appear to retain a definition of 'software', to set out what falls into scope. (EC) No 482/2008 states: 'software' means computer programmes and corresponding configuration data, including non-developmental software, but excluding electronic items, namely application specific integrated circuits, programmable gate arrays or solid-state logic controllers;
	Impact: Assurance activity may/may not be required, dependent on scope. Suggestion: Include a definition of software, either as stated for (EC) No 482/2008 or amended as appropriate to reflect the scope of (EU) No 2017/373.
response	Accepted
	The text has been updated in order to include the definition for 'software' in the set of AMC & GM, in line with Regulation (EC) No 482/2008.



comment	220 comment by: NATS
	Neither the NPA nor (EU)2017/373 identifies a harmonised severity classification scheme for use when setting assurance levels. Is this covered by the more general references to the (unspecified) "severity classification scheme"? Impact: The use of an unspecified 'severity' classification scheme potentially leads to different assurance requirements from different ANSPs, for the same software product being used in the same way. Suggestion: Provide guidance/requirements for the severity classification scheme to facilitate common software assurance requirements.
response	Noted
	The comment is duly noted.
	It should be highlighted that the proposed set of AMC & GM corresponds to the safety objectives laid down in Regulation (EU) 2017/373.
	On the other hand, the same product can be used in different ways by different ANSPs and could lead to hazardous effects of different severities. This is an element to be considered by each of the ANSPs when performing the assurance level allocation.
comment	221 comment by: NATS
	The term SWAL is used extensively in the NPA but no formal definition of it is provided. (EC) No 482/2008 mandated "a minimum of four software assurance levels shall be identified, with software assurance level 1 indicating the most critical level". Has this requirement been dropped intentionally? Impact: The lack of a definition for software assurance levels potentially leads to inconsistency of approach by ANSPs complying with the guidance material and therefore requiring different assurance evidence from system suppliers for the same product. Suggestion: Either: Add definition of SWAL to Annex I of (EU) 2017/373 or provide guidance/requirements regarding software assurance levels to facilitate common software assurance requirements.
response	Accepted
	Considering the comment, the text has been amended (please refer to ATM/ANS.OR.C.005(a)(2)).
comment	222 comment by: NATS
	(EC) No 482/2008 had a clear requirement (Article 3, 1.) for an organisation to define and implement a software safety assurance system. A stated objective of this NPA (2.2) is to maintain the level of safety in the definition and implementation of the



software assurance systems, yet there is no requirement, or even mention, in either (EU) 2017/373 or this NPA of a software (safety) assurance system. Issue: The migration from (EC) No 482/2008 to (EU) 2017/373 + NPA has lost the requirement for implementation of a software (safety) assurance system. Suggestion: Include a requirement equivalent to (EC) No 482/2008 Article 3, 1 and other associated requirements. response Partially accepted The commented element is duly considered. It is addressed by the combination of the new AMC & GM (for software aspects) with the existing AMC & GM, where all the software information is planned to be used as part of the safety (support) case(s) demonstration. It is noted that AMC3 ATS.OR.205(a)(2) requests that 'the ATS provider should ensure the existence of documented software assurance process necessary to produce evidence and arguments that demonstrate that the software behaves as intended (software requirements), which level is consistent with the criticality of the required application'. The main change in the concept is that the software safety assurance system is intended to provide inputs to the safety (support) assessments. comment 223 comment by: NATS In the transposition from (EC) No 482/2008 to the NPA, the requirements relating to "software safety requirements" (Article 3, 2.) have been broadened to "software requirements" (AMC6 ATM/ANS.OR.C.005(a)(2). NATS supports this change and believes it should improve the rigour applied to the software as a whole. No change required; this is a positive observation in support of the changes made from (EC) No 482/2008 response Noted EASA appreciates the comment. 224 comment comment by: NATS The concept of hardware assurance level would be of potential benefit for bespoke hardware developed to support ATM applications. Such hardware procured at the direct request of an ANSP is rare, with most hardware procured being COTS hardware. Assurance of such equipment is well understood and therefore introducing a HWAL concept would provide little benefit at increased cost and is covered as part of the safety argument. Impact: Increased difficulty and cost of assurance for minimal assurance benefit over current practice. There is no requirement for the introduction of hardware assurance level. response Noted



Acknowledging the stakeholders' feedback from the NPA 2017-10 consultation, EASA will consider a separate rulemaking activity dedicated on the hardware assurance level requirements related to the assessment of changes to functional systems, where the comment will be taken into account.

comment	225 comment by: NATS
	The suggested need for guidance for the assurance of complex hardware would be of limited use, albeit this type of hardware is more likely to be developed for ATM use. Impact: Increased difficulty and cost of assurance for minimal assurance benefit over current practice. Suggestion: There is no requirement for guidance regarding complex hardware.
response	Noted
	Acknowledging the stakeholders' feedback from the NPA 2017-10 consultation, EASA will consider a separate rulemaking activity dedicated on the hardware assurance level requirements related to the assessment of changes to functional systems, where the comment will be taken into account.
comment	270 comment by: German NSA (BAF)
	Whereas Regulation (EC) No 482/2008 is applicable to providers of ATS and CNS services as well as entities providing ATFM and ASM for general air traffic this NPA proposes to expand software safety assurance through the back-door to encompass all providers of ATM/ANS including those currently not subject to 482 requirements. The extra effort for those service providers newly affected as of 2020 has not been evaluated at all. In particular, it is not clear why this expansion is necessary.
response	Noted
	It should be noted that Regulation (EU) 2017/373 will be applicable from 2 January 2020. Considering also the feedback from this consultation, it was concluded that this extension to other service providers not addressed in Regulation (EC) No 482/2010 to use these means to demonstrate compliance would not affect significantly these other providers. On the other hand, the applicants may decide to show compliance with the requirements using other means and may propose an alternative means of compliance (AltMoC), based, or not, on those issued by EASA. These AltMoC must only be used when it is demonstrated that the safety objective set out in the Implementing Rules is met.
	Additionally, the presented AMC & GM includes high-level principles for the software assurance process that should be achievable for any organisation where the software failure might have an impact on the service specification.



comment	271 comment by: German NSA (BAF)
	Since none of the industry standards has been officially accepted as an AMC to Regulation (EC) No 482/2008 and since the NPA doesn't propose to do so either, the burden of negotiating / accepting approaches proposed by ATM/ANS providers to overcome the known deficiencies, gaps and weaknesses in each of the existing industry standards still lies with the CAs. It would have been helpful to propose standards which <u>fully</u> comply with the requirements set out in Regulation (EC) No 482/2008 and this NPA, respectively along with this NPA, to trigger harmonisation across Europe in that respect.
response	Noted
	The comment is duly considered. Currently, the software safety assurance systems of the ANSPs are compliant with Regulation (EC) No 482/2008 and under the oversight of the competent authorities. They are based on different software assurance standards (e.g. ED153, ED109A),
	already identified in the AMC & GM. Rather than defining a particular software assurance standard to be applied by all the EU ANSPs, the conclusion reached was that it would be better to keep today's flexibility that allows ANSPs to select the best suitable option and to ensure compliance with the provisions.
commont.	272 commont by Cormon NSA (BAS)
comment	272 comment by: German NSA (BAF) Related to complex electronical hardware items BAF supports measures to develop AMC/GM in respect of hardware assurance.
response	Noted
	Acknowledging the stakeholders' feedback from the NPA 2017-10 consultation, EASA will consider a separate rulemaking activity dedicated on the hardware assurance level requirements related to the assessment of changes to functional systems, where the comment will be taken into account.
comment	275 comment by: CANSO
	The structure of the guidance material leads to significant duplication of text that applies equally to service providers and ANSP sections, which could be presented more concisely.
	Impact: Duplication of text could lead to subtle unintended variations in compliance against similar requirements.
	Suggestion: Consider presenting guidance as applicable to both service providers and ANSPs in one section, and identifying differences at that level (rather than duplicating as currently)



response	Noted
	EASA acknowledges the existing duplications, but this approach was preferred to keep the segregated set of requirements separately, depending on the type of service provider.
	A recast of the order of the requirements at IR level and the associated AMC & GM could be considered at a later stage via a separate rulemaking activity.
comment	276 comment by: CANSO
	The term SWAL is used extensively in the NPA but no formal definition of it is provided. (EC) No 482/2008 mandated "a minimum of four software assurance levels shall be identified, with software assurance level 1 indicating the most critical level". Has this requirement been dropped intentionally?
	Impact: The lack of a definition for software assurance levels potentially leads to inconsistency of approach by ANSPs complying with the guidance material and therefore requiring different assurance evidence from system suppliers for the same product.
	Suggestion: Either: Add definition of SWAL to Annex I of (EU) 2017/373 or provide guidance/requirements regarding software assurance levels to facilitate common software assurance requirements.
response	Accepted
	Considering the comment, the text has been amended (please refer to ATM/ANS.OR.C.005(a)(2)).
comment	277 comment by: CANSO
	(EC) No 482/2008 had a clear requirement (Article 3, 1.) for an organisation to define and implement a software safety assurance system. A stated objective of this NPA (2.2) is to maintain the level of safety in the definition and implementation of the software assurance systems, yet there is no requirement, or even mention, in either (EU) 2017/373 or this NPA of a software (safety) assurance system.
	Impact: The migration from (EC) No 482/2008 to (EU) 2017/373 + NPA has lost the requirement for implementation of a software (safety) assurance system.
	Suggestion: Include a requirement equivalent to (EC) No 482/2008 Article 3, 1 and other associated requirements.
response	Partially accepted
	The commented element is duly considered.



It is addressed by the combination of the new AMC & GM (for software aspects) with the existing AMC & GM, where all the software information is planned to be used as part of the safety (support) case(s) demonstration. It is noted that the AMC3 ATS.OR.205(a)(2) requests that 'the ATS provider should ensure the existence of documented software assurance process necessary to produce evidence and arguments that demonstrate that the software behaves as intended (software requirements), which level is consistent with the criticality of the required application'. The main change in the concept is that the software safety assurance system is intended to provide inputs to the safety (support) assessments.

comment	282 comment by: Copenhagen Airport
	The most critical part of the NPA is based on the fact that ANSP providers apart from ATS no longer is supposed to produce a full safety case, thus the software assurance process
	no longer is related to the full scope of what a malfunction related to software potential can cause in terms of safety occurrences since the process is cut into two. The ATS and CNS are related to two different safety management systems, thus the full picture is left for the NSA to combine!
	Mostly all the engineering in regards to ATM/ANS functional system/services are defined as the specified functionality and the required safety specifications to it. These functional and safety specifications are defined and put in the specifications in the contract given to the manufacture when ordering software. These specifications are based upon experience and result of a safety study in regards what a fault in a particular part of software can cause, thus the development, test and robustness verifications to the functionality should increase accordingly. A complicated verification and validation process provide by two the different observers ANSPs are foreseen - and will cause both the Providers and NSA a troublesome future.
	The safety study should be developed by the combined effort from the involved providers (ATS,CNS) – neither the ATS provider nor the CNS provider is by themselves capable of fully to demonstrate the SWAL levels has been met, since the manufactures development process in regards to the assigned SWALL levels are not a simple figure but a combination of many arguments that combined forms the statement – "the system (software) is safe to put into operation"- and again relating to two different risc class specifications schemes.
response	Noted
	It should be highlighted that the already adopted IR as well as the already issued associated AMC & GM rely on the role of the ATS provider in order to set up the software requirements (and the associated assurance level) to be met by the system/equipment used by the ATS and non-ATS activities. Taking the example of the CNS provider mentioned in the comment, it is up to the ATS provider to establish those requirements for the CNS systems, which might be different from the use of

the same systems by another ATS provider, depending on the particular installation aspects. The comment will be duly considered for further rulemaking developments. comment 287 comment by: ASD/Thales Air Systems A section with definitions of terms is missing: What is: - software criticality - a safety support assessement - safety support requirements - previously developed software Not accepted response It should be highlighted that the NPA proposal relates to changes at the level of AMC/GM, while the proposal in the comment relates to an amendment at IR level, which is outside the scope of this consultation. On the other hand, it was acknowledged that the term 'software criticality' was already used in Regulation (EC) No 482/2008 with no particular definition and no major concern was reported by stakeholders when showing compliance. The other referenced terms are considered either already described in the set of AMC & GM or of a general nature, so it is found that there is no need of a particular definition in the frame of this proposal. comment 350 comment by: UK CAA Attachments #1 #2 Noted response All the comments were duly noted, evaluated and addressed. Please refer to the specific comments in the CRD. Furthermore, EASA appreciated the work performed by the commentator as it was recognised by EASA as a benefit to the subject rulemaking activity, which facilitated the review of the proposed set of AMC & GM. comment 351 comment by: Yves Rodenas

ATC requirements as defined in ED73 are complex requirements with multiple options based on the aircraft characteristics and the development team targeted design.



Experience shows that it is not always evident for the development team and/or the certification authority to select the requirements associated with a specific transponder option.

This is a source of inefficiency during the development and certification process that may increase costs, development time and is a non-value added activity (each project development/certification team repeating the same process).

It would be beneficial to include an addendum to the requirements standard, linking each transponder option with its associated set of requirements. This could be done once for all development/certification teams. It would save valuable validation time on the requirements and would prevent possible implementation error (what requirements to implement based on the multiple options).

AIRplus Maintenance GmbH

response Noted

It is perceived that the comment refers to another document subject to consultation.

comment	354
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comment by: DWD

General comment

The proposed new AMC/GM in order to include SWAL in Reg (EU) No 2017/373 introduces SWAL for MET SPs where previously the regulations did not specify this requirement. Thus, MET SPs cannot "continue with their existing SWAL systems as part of the safety (support) assessments" as written in Section 2.4 of NPA 2017-10. In order to allow MET SPs to fulfill this obligation in a meaningful manner, the AMC/GM should more clearly specify that SWAL is needed for safety critical software that is part of EATMN-software (in the sense of Reg (EU) 482/2008) or for software of an ANSP that provides direct input into EATMN-software.

Best regards, Dorothea Banse

response Noted

The comment is duly considered.

It should be highlighted that in the current regulatory framework, the software aspects are covered in detail through Regulation (EC) No 482/2008, which applies to any changes to the software of the systems for air traffic services (ATS), airspace management (ASM), air traffic flow management (ATFM), i.e. air traffic management (ATM) and communication, navigation, or surveillance (CNS). Additionally, the software aspects for aeronautical information services (AIS) provision are included in Regulation (EU) No 73/2010. On the other hand, it is acknowledged that the MET providers will be affected as regards the software assurance AMC & GM.

EASA considers that some of the service providers other than the ones that are subject to Regulation (EC) No 482/2008 today have a contribution to software (e.g. MET providers, FPD) and in order EASA to take an informed decision, a specific



meeting with other stakeholders was organised to address this issue (among others). The discussion clearly concluded that some features of the MET systems are affected by the current regulatory requirements, which also supports the approach taken for the proposed set of AMC & GM; that is, to apply for all service providers of ATM/ANS, including AIS and MET providers, towards software assurance level standardisation.

Procedural information p. 1

comment	266 comment by: ASD/Thales Air Systems
	Please add Manufacturers as Affected stakeholders since they provide software and have to comply with the sw assurance level requirements.
response	Accepted

2. In summary — why and what | 2.1. Why we need to change the rules — issue/rat

р. 4-5

comment	2 comment by: DFS Deutsche Flugsicherung GmbH
	We agree that hardware can be as complex as software, but just complexity is not the issue. The question is what can happen in case of a failure. In this matter software seems to be more critical as a malfunction can lead to wrong conclusions of the air traffic controller whereas hardware problems will most likely cause an outage, which is in most cases less critical.
	Secondly, the introduction of HWALs (together with a "Hardware Assurance System") can have a benefit, if it is possible to certify hardware aspects, which is very difficult.
	In general, the assessment and assurance of hardware changes is included in ATS.OR.205 (a) since <u>all</u> notified changes are subject to that rule. (And according to ATM/ANS.OR.A.045 all changes of the functional system are to be notified). Therefore, the assurance of electronic hardware items is covered by 2017/373. Knowledgeable support for establishing assurance processes could be given by developing appropriate ED-standard.
	There are many other areas, e.g. "procedures", where no specific assurance requirements exist in addition to 2017/373 and the relevant assurance is covered by the general safety assessment processes from ATS.OR.205.
	Therefore, additional regulation for hardware assurance is not necessary!
response	Noted
	The comment is noted and duly considered in the assessment of the stakeholders' views as regards the hardware assurance level (HWAL).

comment 27

comment by: ENAIRE



Reliability, Availability and Maintainability (RAM) analysis assess the HW features. HW firmware is a SW type that is covered for SWAL (ED-153 is clear in this aspect). Electronic hardware items are study as a part of the RAM analysis. The HW delevop should include specification and test at the level that HWAL demmand when a "HWAL standard" is defined.

response Noted

The comment is noted and duly considered in the assessment of the stakeholders' views as regards the hardware assurance level (HWAL).

comment 57

comment by: CANSO

The so called "potential safety weakness as regards the safety assurance aspects when dealing with the safety support" assessment of changes to a functional system in ATM/ANS and other ATM network functions" might result from the complexity of understanding the Common Requirements, especially when software is involved. Most people misunderstand what is software.

Adding AMC's will not solve the complexity. A better definition of what is a software and its place within an equipment being part of a system would help in the application of the regulation

Proposal:

In Annex I (below), you will find a simple proposed approach to understand what is a software and how the regulation should be understood for a correct application. **Annex I: Considerations on Software:**

What is a Software?

We will consider here the technical approach, the safety approach and how they can match.

1. Technical approach

Software is an *intangible* part of the equipment.

Software can't execute without an underlying hardware. The hardware is the *tangible* part of the equipment.

Software is not really measurable, quantifiable but its contribution to the behaviour of the equipment is.

Software is a *Versatile* way to change the behaviour of the equipment.

Versatility is :

- A strength.

- A huge weakness.

Engineering defines working methods to cope with the versatility in order to achieve: - Goals to be fulfilled by the software.

- Reduce as much as possible unwanted behaviour.

Be careful that the technical approach often neglects functional approach

2. Safety approach

Software is an equipment constituent contributing in the realization of functions within a context.

Due to its nature, software reproduces exactly the same behaviour in the same circumstances.



	Software is causal: When it fails to fulfil a function for a specific reason, it is always in the same way. Software is a versatile way to change the behaviour of an equipment. To avoid this to become a weakness, any change must be done in a controlled way How to have the assurance of a controlled production of software ? > Via a quality process with measurable assurance level 3. Understanding Regulation EC-482/2008 in a real world context: matching the technical and the safety approaches We will use here EU-1035/2011 and EC-482/2008 for a better understanding of the problematic. Both are now repealed as they are part of EU-2017/373 . With this in mind, we have the following consideration:
	- EC-482/2008 is an extension of EC1035/2011 (System approach).
	Software Safety Assurance System is a part of System Safety Assurance.Whatever the change, an ANSP is required to implement a risk assessment and
	mitigation process (EC 1035/2011). - EC 482/2008 describes what is required for software specific aspects of the changes.
	It has to be seen as some kind of plugin to the safety assurance system.
	- By change, we understand corrections, modifications and projects
response	Noted
	Considering that the proposed text would fall more within a training context, the AMC & GM are not amended.
comment	108 comment by: ENAV
	The so called "potential safety weakness as regards the safety assurance aspects when dealing with the safety support" assessment of changes to a functional system in ATM/ANS and other ATM network functions" might result from the complexity of understanding the Common Requirements, especially when software is involved. Most people misunderstand what is software. Adding AMC's will not solve the complexity. A better definition of what is a software and its place within an equipment being part of a system would help in the application of the regulation
	Proposal: In Annex I (below), you will find a simple proposed approach to understand what is a software and how the regulation should be understood for a correct application. <u>Annex I: Considerations on Software:</u> What is a Software?
	We will consider here the technical approach, the safety approach and how they can match.
	1. Technical approach
	Software is an <i>intangible</i> part of the equipment. Software can't execute without an underlying hardware. The hardware is the <i>tangible</i> part of the equipment.



	Software is not really measurable, quantifiable but its contribution to the behaviour of the equipment is. Software is a <i>Versatile</i> way to change the behaviour of the equipment. <i>Versatility</i> is : - A strength. - A huge weakness.
	Engineering defines working methods to cope with the versatility in order to achieve: - Goals to be fulfilled by the software. - Reduce as much as possible unwanted behaviour. Be careful that the technical approach often neglects functional approach
	 2. Safety approach Software is an equipment constituent contributing in the realization of functions within a context. Due to its nature, software reproduces exactly the same behaviour in the same circumstances. Software is causal: When it fails to fulfil a function for a specific reason, it is always in the same way. Software is a versatile way to change the behaviour of an equipment. To avoid this to become a weakness, any change must be done in a controlled way
	How to have the assurance of a controlled production of software ? > Via a quality process with measurable assurance level
	 3. Understanding Regulation EC-482/2008 in a real world context: matching the technical and the safety approaches We will use here EU-1035/2011 and EC-482/2008 for a better understanding of the problematic. Both are now repealed as they are part of EU-2017/373. With this in mind, we have the following consideration: EC-482/2008 is an extension of EC1035/2011 (System approach). Software Safety Assurance System is a part of System Safety Assurance. Whatever the change, an ANSP is required to implement a risk assessment and mitigation process (EC 1035/2011). EC 482/2008 describes what is required for software specific aspects of the changes. It has to be seen as some kind of plugin to the safety assurance system. By change, we understand corrections, modifications and projects
response	<i>Noted</i> Considering that the clarifications would fall more within a training context, the AMC & GM are not amended.
comment	136 comment by: LFV
Connicili	An introduction of HWAL will most probably increase the cost for HW and decrease the competition in HW manufacturing. Since the process of HW development and verification is mature, EASA should evaluate if the benefit of an introduction of HWAL justifies the cost.



response	Noted
	Acknowledging the stakeholders' feedback from the NPA 2017-10 consultation, EASA will consider a separate rulemaking activity dedicated on the hardware assurance level requirements related to the assessment of changes to functional systems, where the comment will be taken into account.
comment	153 comment by: DSNA "In addition, through the present NPA on SWAL AMC/GM would like to gain stakeholders' views as regards the hardware assurance level (HWAL) to ensure that EASA is taking an informed decision on the next steps."
	The NPA is mentioning HWAL. It is premature to invoke HWAL where the ATM community is being doing quite a hard job to educate to SSAS. So, we are not in favour of addressing HWAL in AMC/GM.
response	Noted
	Acknowledging the stakeholders' feedback from the NPA 2017-10 consultation, EASA will consider a separate rulemaking activity dedicated on the hardware assurance level requirements related to the assessment of changes to functional systems, where the comment will be taken into account.
comment	184 comment by: AESA/DSANA
	Hardware assurance (HWAL), if regulated, should be integrated with SW assurance (SWAL) and procedures assurance (PAL) as long as only the combination of the three perform each ATM/ANS function and all complement each other. The hardware assurance regulation shall have the same level of detail than SW assurance as long as me electronic hardware items include nowadays its own software.
	In response to "() to indicate their views on the possibility of an equivalent set of AMC/GM in respect of hardware assurance being developed by EASA and consulted via a separate NPA."
response	Noted
	Acknowledging the stakeholders' feedback from the NPA 2017-10 consultation, EASA will consider a separate rulemaking activity dedicated on the hardware assurance level requirements related to the assessment of changes to functional systems, where the comment will be taken into account.
comment	267 comment by: ASD/Thales Air Systems Regarding hardware assurance, a PIA with cost-benefit analysis seemes necessary to
	evaluate the expected added value. Indeed, the question is: what is the proportion



	of electronic hardware items in the equipment covered by regulation (EU) 2017/373? In software-intensive systems, hardware is usually COTS and is covered by the current safety assurance practices and the main industrial standards. This question needs dedicated discussion (workshop, group,) with appropriate stakeholders, and industry is one of them.
response	Noted
	Acknowledging the stakeholders' feedback from the NPA 2017-10 consultation, EASA will consider a separate rulemaking activity dedicated on the hardware assurance level requirements related to the assessment of changes to functional systems, where the comment will be taken into account.
comment	278 comment by: CANSO
	"In addition, through the present NPA on SWAL AMC/GM would like to gain stakeholders' views as regards the hardware assurance level (HWAL) to ensure that EASA is taking an informed decision on the next steps."
	The NPA is mentioning HWAL. It could be premature to invoke HWAL where the ATM community is being doing quite a hard job to educate to SSAS. However, CANSO is open for discussion about how to address HWAL in order to improve its maturity.
response	Noted
	Acknowledging the stakeholders' feedback from the NPA 2017-10 consultation, EASA will consider a separate rulemaking activity dedicated on the hardware assurance level requirements related to the assessment of changes to functional systems, where the comment will be taken into account.
comment	352 comment by: DWD
	"2.1 Why we need to change the rules — issue/rationale
	"Regulation (EU) 2017/373 lays down common requirements for providers of ATM/ANS and other ATM network functions and their oversight and repeals amongst others Regulation (EC) No 482/2008 that establishes a software safety assurance system to be implemented by ATM/ANS providers."
	Comment: Regulation (EC) No 482/2008 establishes a software assurance system to be implemented by ATS, ATFM, ASM and CNS providers. It does not establish such a system for MET SPs, which are also ANSP. Hence, the wording is misleading and should be corrected.
response	Accepted
	Considering the comment, the text has been amended to promote clarity.

2. In summary — why and what | 2.2. What we want to achieve — object

р. 6



р. 6

comment	79 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)
	This might not be the right place for this comment, but this is as good as it gets. In some countries, such as Sweden thera are alot of small service providers that benefit from exemptions to some requirements with current regulation. These are typically small regional airports that carry the own ANS certificates för ATS, MET and/or CN, the ATS service provided are predominantly AFIS but can be ATC and infrastructurevise they provide only basic equippage and with few, very few movements. nad yet provides an important service to the community.
	We argue that it could be worth concidering criteras to exempt some ANSPs from these requirements, as thay today are exempted from some requirements in 1035/2011 as there are limited benefits to impose these requirements on such ANSPs.
response	Noted
	EASA has duly assessed the comment.
	No amendment is considered necessary to address the comment as it is mainly focusing on the applicability of safety vs safety support assessment principles and activities.

2. In summary — why and what | 2.3. How we want to achieve it — overview of the propo

comment	353	comment by: <i>DWD</i>
	"2.3	. How we want to achieve it — overview of the proposals
in ATM/ANS (i.e. Regulations (EU) Nos 1034/2011 and 1035/201 'functional system' as a combination of systems, procedures and hun organised to perform a function within the context of ATM/ANS." Comment: The definition in Regulations (EU) Nos 1034/2011 and specifies functional systems only for ATM:		ment: The definition in Regulations (EU) Nos 1034/2011 and 1035/2011
		'functional system' means a combination of systems, procedures and human resources organised to perform a function within the context of ATM;
		new Commission Implementing Regulation (EU) No. 2017/373 introduces tional systems for ANS
response	Note	d



2. Individual comments and responses

comment	176 comment by: The Boeing Compan
	Page: 6 Paragraph: 2.3.1
	The proposed text states: "Two new GM are proposed, which stem from Article 3(3) of Regulation (EC) N 482/2008. The service provider is required to produce an assurance argument whether or not it is to be reviewed by the competent authority. In this context, GN ATM/ANS.OR.A.045(a) clarifies with regard to the notification that depending on the complexity of the change to the functional system and the criticality of the software the depth of the evaluation may vary."
	<u>Requested change</u> : We request that EASA specify which software is beir referenced; the software used in house for production, or the software used products delivered to the customer.
	Justification: Clarification.
response	Noted
	The referenced software corresponds to the part of the functional system that used by the ANSP for the service provision. Then, it would fall under the secon option identified by the commentator.
comment	185 comment by: AESA/DSAN
	It should be clearly stated in the NPA what documentation shall be provided by each type of service provide and the relationship between them
	- ATS providers produce Risk Assessment - Non- ATS providers produce Assurance Arguments able to support the Ris Assessments, as long as non-ATS providers may not be aware of the safety aspect of the ATS provider using their services.
	- ATS providers produce Risk Assessment - Non- ATS providers produce Assurance Arguments able to support the Ris Assessments, as long as non-ATS providers may not be aware of the safety aspec
response	 ATS providers produce Risk Assessment Non- ATS providers produce Assurance Arguments able to support the Risk Assessments, as long as non-ATS providers may not be aware of the safety aspect of the ATS provider using their services. Regulation is needed to support the NSAs to demand the correct documentation
response	 ATS providers produce Risk Assessment Non- ATS providers produce Assurance Arguments able to support the Risk Assessments, as long as non-ATS providers may not be aware of the safety aspect of the ATS provider using their services. Regulation is needed to support the NSAs to demand the correct documentation from each service provider type.



	What is it to be understood by criticality? Is the service provider the only responsible for its determination or should it be agreed with the NSA? A definition for " criticality of the software " is needed.This is an issue which could be controversial and now seems a key factor to decide the depth od revision.
response	Not accepted
	The term 'software criticality' was already used in Regulation (EC) No 482/2008 with no particular definition and no major concern was reported by stakeholders when showing compliance. Therefore, no amendments to the text are introduced in this context.
comment	187 comment by: AESA/DSANA
	In section 2.3.1 it is suggested to review the proposed GM2 ATM/ANS.OR.A.045(a), and to include a new AMC, in order to clearly establish, as it is said in the rationale of 2.3.1, that "the service provider is required to produce an assurance argument whether or not it is to be reviewed by the competent authority". This statement is not really found in the referred new GM.
	It should be explicitly stated in this NPA that the service providers should produce a SW assurance argument in order to demonstrate that the level of safety after a SW-related functional change will continue to be safe.
response	Noted
	The comment is duly considered.
	It should be noted that the software is part of the functional system and the software assurance argument should be considered as a contributor to the functional system safety argument. It is noted that for non-ATS providers, the argument will be a safety support argument, focusing on the service requirements.

2.3.2. Proposed amendments to Subpart C 'Specific organisational requirements for service providers other than air traffic services providers' of Annex III 'AMC/GM to Part-ATM/ANS.OR – Common requirement

p. 7

comment	109 comment by: ENAV
	We propose to insert a new section "Coordination between ATS Service Provider and SW industry" in order to define the interactions between the Service Provider and the SW industry.
	For example, can the SW industry propose a less restrictive SWAL and how can the SW industry justify it?
response	Noted



The software assurance aspects are established at service provider level, as it is today regulated with Regulation (EC) No 482/2008.

In most of the cases, the ANSPs do not develop the software of their systems, thus, the coordination with the industry already exists.

In the example mentioned, the SW industry can propose a less restrictive SWAL that could lead to two possible situations:

1) it is not acceptable for the intended use; or

2) the ANSP modifies the conditions of usage of the affected equipment (adding mitigation techniques) in order to be able to make use of this lower SWAL equipment.

However, the coordination activities are necessary for the SWAL allocation, but also for the functionalities inside the equipment.

Consequently, the comment does not result in amendment to the proposed AMC & GM.

2.3.3. Proposed amendments to Subpart A 'Additional organisation requirements for providers of air traffic services) of Annex IV 'AMC/GM to Part-ATS — Specific requirements for providers p. 7 of air traffic ser

comment	47 comment by: CANSO
	We propose to insert a new section "Coordination between ATS Service Provider and SW industry" in order to define the interactions between the Service Provider and the SW industry.
	For example, can the SW industry propose a less restrictive SWAL and how can the SW industry justify it?
response	Noted
	The software assurance aspects are established at service provider level, as it is today regulated with Regulation (EC) No 482/2008.
	In most of the cases, the ANSPs do not develop the software of their systems, thus, the coordination with the industry already exists.
	In the example mentioned, the SW industry can propose a less restrictive SWAL that could lead to two possible situations:
	1) it is not acceptable for the intended use; or
	2) the ANSP modifies the conditions of usage of the affected equipment (adding mitigation techniques) in order to be able to make use of this lower SWAL equipment.



However, the coordination activities are necessary for the SWAL allocation, but also for the functionalities inside the equipment.

Consequently, the comment does not result in amendment to the proposed AMC & GM.

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р. 7-8

comment	132 comment by: LFV
	The NPA states that "service providers can continue with their existing SWAL systems and hence, there are no drawbacks identified For this reason, no RIA has been developed for this task." But an important change with NPA 2017-10 is that it covers all ATM/ANS services, while current requirements for software assurance only covers ATS, ATFM, ASM and CNS services. For the "new" services covered by software assurance requirements, NPA 2017-10 might cause a considerable change, both for the service providers and for the system suppliers, why a RIA should be performed.
response	Noted
	EASA agrees that in the current regulatory framework, the software aspects are covered in detail through Regulation (EC) No 482/2008, which applies to any changes to the software of the systems for air traffic services (ATS), airspace management (ASM), air traffic flow management (ATFM), and communication, navigation, or surveillance (CNS).
	On the other hand, it should be noted that the software aspects for aeronautical information services (AIS) provision are included today in Regulation (EU) No 73/2010.
	Consequently, the applicability of the proposed AMC & GM on software assurance would be novelty only for MET providers and DAT providers — the latter ones partially.
	In this context, it should be considered also that AMC serve as a means by which the requirements contained in the IRs can be met. However, applicants may decide to show compliance with the requirements using other means and may propose an alternative means of compliance, based, or not, on those issued by the Agency. These alternative means of compliance (AltMoC) must only be used when it is demonstrated that the safety objective set out in the implementing rules, i.e. Regulation (EU) 2017/373 applicable also for MET providers, is met.
	In conclusion, EASA performed a regulatory impact assessment (RIA) for a number of key regulatory developments proposed in NPA 2014-13 'Requirements for safety assessment of changes to ATM/ANS functional systems' and it addressed the impact



p. 9

of changes affecting software (applicable also for MET providers) and Regulation (EC) No 482/2008.

Therefore, no RIA was developed with NPA 2017-10.

3.1. Draft AMC/GM

comment	236 comment by: UK CAA
	Attachment <u>#3</u>
	Page No: 9 to 19
	Paragraph No: 3.1. Draft acceptable means of compliance and guidance material
	Comment: We believe the proposed text duplicates AMC/GM already published in Regulation (EU) 2017/373. We are of the opinion that this has the potential to lead to inconsistent implementation of the related elements of Regulation (EU) 2017/373 amongst Member States. We strongly urge that the AMC/GM is not published. Instead, we strongly recommend that the approaches foreseen on CRD 2014-13 Issue 2 (see below), should be actively pursued as soon as possible.
	Response to various comments in 'section 2. Explanatory Note – 2.4. Overview of the proposed amendments – 2.4.2. Proposed amendments to Article 8 'Transitional provision', Article 9 'Repeal' and Article 10 'Entry into force' in the Cover Regulation' (Pgs 97 – 125): "The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures)"
	• Response to comments 186 & 257 in 'section 4. Regulatory Impact Assessment (RIA) — 4.7. Changes affecting software and Regulation (EC) No 482/2008':
	"It is also acknowledged that the assurance of people, procedures and hardware is not fully covered. This will be tackled in the 2nd NPA and by future additions to the AMC/GM"
	Justification: One of the objectives of the Regulation (EU) 2017/373 rulemaking group was to remove the need for Regulation (EC) 482/2008 (see Regulation (EU) 2017/373 - recital 19). It was held that Regulation (EC) 482/2008 gave undue importance (and inappropriate legislative status) to the assurance of software over that of People, Procedures and Hardware, which are responsible for the vast majority of safety occurrences in the CNS/ATM domain.
	The 482/2008 content required to instantiate an assurance system that adequately covered People, Procedures and Hardware as well as software has already been included in Regulation (EU) 2017/373 and its supporting AMC and the GM (see Appendix II of NPA 2014-13).



NPA 2017-10 is considered contrary to these objectives. It introduces clauses specifically related to software that imply differences between the assurance of software and the assurance of People, Procedures and Equipment (hardware & software). These differences do not exist and we believe implying that they do is harmful to harmonisation. Consequently the proposals in NPA 2017-10 are unnecessary as they duplicate the IR, AMC and GM already provided with Regulation (EU) 2017/373.

It was recognised that guidance on assurance was insufficiently addressed by NPA 2014-13, however this did not result in a need for more specific software assurance guidance. Instead, guidance appropriate for People, Procedures and Equipment (hardware & software) was required to ensure harmonisation of the approach. See CRD 2014-13 Issue 2 responses to comments 186 and 257, and the explanatory note to Opinion No 03/2014 (*"Based on the consultation, it has been concluded that Regulation (EC) No 482/2008 can be repealed, but certain provisions should be moved to AMC. When the Agency completes the AMC/GM, these aspects will be addressed"*). This does not imply an additional NPA, rather it refers to changes to be made to the draft AMC/GM material prior to the decision (i.e. ED Decision 2017/001/R), which result from addressing comments in the CRD. Consequently these changes have already been addressed.

Additional material duplicating extant AMC/GM confuses the harmonised approach to regulating people, procedures and equipment. It implies differences that do not in fact exist, and encourages divergent local developments (see attached table). Such divergence will result in differences in interpretation and potentially cause disputes between competent authorities and service providers.

Proposed Text: Delete duplicated amendments proposed in section 3.1. Instead it is strongly recommended that EASA should consider the need to establish a rulemaking task to progress the assurance of People, Procedures and Equipment (hardware & software) in a more coherent and harmonised manner as proposed for the 2nd NPA, as described in CRD 2014–13 Issue 2.

response Noted

This rulemaking activity was based on a specific request from several competent authorities during the Comitology process of Regulation (EU) 2017/373. It was identified that in the existing set AMC & GM, there are no AMC & GM on the functional system aspects, especially in the software domain.

EASA concurs with the commentator's view on the need to address the other components of the functional system (hardware, procedures and people), which issues will be addressed through a different rulemaking task, in the future.

comment by: UK CAA

comment 294

Page No: 9 to 19

Paragraph No: 3.1. Draft acceptable means of compliance and guidance material



Comment: We are of the view that placement of Assurance Levels and SWALs at IR/AMC levels is inappropriate. In addition, that both are inadequately and inappropriately defined in the NPA is cause for concern to the UK CAA.

Justification:

Assurance Levels are very complex to define and use. When used correctly they are an expression of the confidence held in an element of a specification. Consequently, an element of a specification would have one or more Assurance Levels associated with it to express the confidence held in the various attributes of the element (e.g. reliability, accuracy, timing, robustness, etc).

As International Electrotechnical Commission (IEC) standard 61508: Functional Safety - 2010 is the only assurance standard that addresses all of the attributes of a specification, the use of any other assurance standards will require multiple types of Assurance Levels to facilitate the cross referencing to different standards (and note that, whilst IEC 61508 addresses all attributes, it does not address how they are related to risk as this is not considered technically possible). Due to the diversity of solutions available this is not a topic for legal material nor does the proposed material in the NPA address the problem adequately.

The requirements for SWALs from Regulation (EC) 482/2008 were deliberately omitted from Regulation (EU) 2017/373 as they were inadequately and inappropriately defined (see justification in Section 6.2. – Appendix II of NPA 2014-13). However, it was accepted that some assurance level material that relates assurance levels to confidence (an undefined concept that this NPA tries to use without defining but needs to address) for People, Procedures and Equipment (hardware & software) and not just software might be introduced as GM in the future and it is this that is proposed to be done in 'NPA 2'.

Furthermore, the argument for the removal of SWALs was challenged but not upheld in CRD 2014-13 Issue 2 and no subsequent evidence has been subsequently provided showing this argument to be flawed. See CRD 2014-13 Issue 2 responses to comments 186 and 257.

Moreover:

- the proposed material does not address the inadequacies described above
- such material should only be considered for GM.
- the meaning of SWALs is unfortunately, and inappropriately, ambiguous. It is unclear whether they are meant to be an expression of confidence in achieving a claim or effort expended in providing evidence.
- SWALs are not associated with any fixed objective or quantitative scale, their relationship to confidence is undefined, consequently they neither benefit harmonisation nor standardisation.

Proposed Text: Delete proposed amendments relating to SWALs and assurance levels proposed in section 3.1 as follows:

Reference to SWALs in the following should be removed:

- AMC5 ATM/ANS.OR.C.005(a)(2)
- GM1 to AMC6 ATM/ANS.OR.C.005(a)(2)



GM2 to AMC6 ATM/ANS.OR.C.005(a)(2)
 GM3 to AMC6 ATM/ANS.OR.C.005(a)(2)
 GM1 to AMC4 ATS.OR.205(a)(2)

- GM2 to AMC4 ATS.OR.205(a)(2)
- · GM3 to AMC4 ATS.OR.205(a)(2)

Reference to assurance levels in the following should be removed:

- AMC5 ATM/ANS.OR.C.005(a)(2)
- GM1 to AMC6 ATM/ANS.OR.C.005(a)(2)
- AMC3 ATS.OR.205(a)(2)

response Not accepted

EASA agrees that there is no universal definition of assurance level, but the available industrial software standards make the link between the assurance levels and the activities (objectives) to be performed in order to gain the claimed confidence. When comparing different available software standards, there is a high degree of correlation between the different sets of assurance levels.

The software assurance level is an expression of confidence, including all the phases of the software development and verification activities. This is not quantitative, as quantitative aspects are not fully aligned with the software domain. On the other hand, the assurance level is widely used by the software development industry and ANSPs to cope with the possible contribution of the software to the different system failure conditions.

comment 295

comment by: UK CAA

Page No: 9 - 19

Paragraph No: 3.1. Draft acceptable means of compliance and guidance material

Comment: The existing AMC and GM to Regulation (EU) 2017/373 provides a harmonised approach to the assurance of People, Procedures and Equipment (hardware & software). We believe NPA 2017-10 inappropriately identifies the assurance of software as a special case and in doing so conflicts with AMC/GM already published in support of Regulation (EU) 2017/373. Additionally, we are of the view that NPA 2017-10 is ambiguous, inconsistent and incorrect and causes the UK CAA significant concern.

Justification:

A) NPA 2017-10 does not appear to conform to the concepts established in Regulation (EU) 2017/373, namely:

- 1. Procedures are approved prior to change and are intended to cover many changes, consequently they may be approved as part of the MS approval.
- 2. Assurance cases are provided for each change and contain arguments about that change only.



- 3. Assurance cases argue the product properties not the goodness of the procedures (it is a false argument that claims the product is safe/trustworthy because approved procedures have been followed (process evidence may be used as backing but is not prime).
- 4. Service providers other than ATS providers have no view of safety and so cannot use or create safety requirements, safety criteria or assurance levels related to safety. Regulation (EU) 2017/373 states that only ATS providers can actively intervene in an unsafe situation, only they can establish safety requirements and criteria. Other service providers cannot directly intervene in an unsafe situation and hence merely have requirements. This is reflected in the structure of Regulation (EU) 2017/373, namely Annex III and Annex IV,

Consequently, we suggest that the following NPA2017-10 proposals are invalid and/or impracticable:

GM2 ATM/ANS.OR.A.045(a)

It is impracticable for the CA to agree the depth of safety assurance for every change. We are notified of over 1500 changes per year in UK

GM1 ATM/ANS.OR.A.050

The assessment of the application of assurance processes (whether for software or any other part of the functional system) is performed as part of the assessment of the assurance cases and is governed by ATM/ANS.OR.C.005. Moreover the assurance case would be invalid if it did not contain all the necessary evidence or the evidence was inconsistent.

If it were felt necessary to highlight this co-operation it would have to include all regulatory interaction governed by the IR.

AMC6 ATM/ANS.OR.C.005(a)(2)

We believe **t**his is in the wrong section. Processes are dealt with in ATM/ANS.OR.B.010.

This section appears to go against the fundamental philosophy of Regulation (EU) 2017/373, which sets objective criteria for judging the behaviour of the change to the system, as opposed to this AMC, which tries to judge the behaviour of the system from the process followed.

AMC6 ATM/ANS.OR.C.005(a)(2), (a)

It is not possible for ANSPs to construct a logical argument as to why their procedures will, in all circumstances, achieve the 5 objectives listed. It adds no value if a valid assurance case has been provided. In addition, this section appears to go against the fundamental philosophy of Regulation (EU) 2017/373, which is to set objective criteria for judging the behaviour of the change to the system, as opposed to this AMC, which tries to judge the behaviour of the system from the process followed.

AMC6 ATM/ANS.OR.C.005(a)(2), (a)(2)(ii)

We believe this is incorrect. There is no view of safety in Annex III text.

AMC6 ATM/ANS.OR.C.005(a)(2), (a)(3)

We believe this is incorrect. There is no view of safety in Annex III text.

AMC6 ATM/ANS.OR.C.005(a)(2), (c)



The evidence and arguments described in (c) cannot contribute to the argument in (a), which is about the software assurance processes.

AMC6 ATM/ANS.OR.C.005(a)(2), (f)

We believe this is incorrect: There is no view of safety in Annex III text.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (b)

This implies a relationship between ATSP and other ANSPs that is not required by the rule text. The rule text does not require the ATSP to provide the ANSP with a SWAL. In fact it deliberately isolates the two parties.

AMC4 ATS.OR.205(a)(2)

This section appears to go against the fundamental philosophy of Regulation (EU) 2017/373, which sets objective criteria for judging the behaviour of the change to the system, as opposed to this AMC, which tries to judge the behaviour of the system from the process followed.

AMC4 ATS.OR.205(a)(2), (a)

It is not possible for ANSPs to construct a logical argument as to why their procedures will, in all circumstances, achieve the 5 objectives listed. This is why the safety cases have to be reviewed in addition to the processes that create them.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (a)

We believe this is incorrect. Criticality in Annex III is not related to safety criticality because safety is outside of the scope of Annex III.

GM2 to AMC6 ATM/ANS.OR.C.005(a)(2), (a)

There can be no foreseen criticality of the software as this will depend upon the air traffic service that uses it. Different services of different criticality may use the same software. Rules in Annex III can only require the confidence in the software's behaviour to be specified.

GM2 to AMC6 ATM/ANS.OR.C.005(a)(2), (b)

We believe this is incorrect: the severity of the effect for the user cannot be known by the supplier, to any degree of certainty because by definition they do not have sight of safety.

AMC4 ATS.OR.205(a)(2), (b)

The evidence and arguments described in (c) cannot contribute to the argument in (a), which is about the software assurance processes.

B) Elements of NPA 2017-10 are considered ambiguous. It uses many undefined terms and concepts. Additionally there are several ambiguous grammatical constructs. Numerous elements can be interpreted in several different ways; consequently, we are of the opinion that the proposals as presented have the potential to result in disparate approaches between ANSPs and Competent Authorities within and across states. Such ambiguities appear as follows:

AMC5 ATM/ANS.OR.C.005(a)(2), (b)

As SWALs and Rigour are undefined, any judgements made about the behaviour in order to provide such feedback will be subjective and not only vary within an


organisation but vary from ANSP to ANSP. Consequently requiring such feedback is meaningless. It would only work if the CA harmonised all ANSP's schemes, an unrealistic expectation.

GM2 ATM/ANS.OR.A.045(a)

This statement is considered ambiguous. The criteria for measuring the complexity of the change are not defined.

AMC6 ATM/ANS.OR.C.005(a)(2), (d)

The processes can identify a need that may or may not be satisfied. If unsatisfied the user system will have to be redesigned. It is considered ambiguous because it is not clear whether it relates to the processes or the software itself. Furthermore it is incorrect because if it means software itself, it's inconsistent with (a) and if it means processes, it's impossible.

GM2 to AMC6 ATM/ANS.OR.C.005(a)(2)

This is considered ambiguous because there are no criteria for (a), (b), (c) or (d) and hence it has no value as GM. Moreover there are no requirements for a SWAL allocation scheme. This undermines harmonisation as each ANSP across Europe will have a different scheme.

• **GM3 to AMC6 ATM/ANS.OR.C.005(a)(2)** This is considered an ambiguous statement. Safety Critical software is an undefined term that has been abandoned since 1990; it is considered impossible to define. It is suggested that it would be unproductive to try to define it as all previous attempts by the safety engineering community have failed to do so.

AMC3 ATS.OR.205(a)(2), (b)

As the definition of SWALs and Rigour is left to individual service providers, any judgements made about the behaviour in order to provide such feedback will be subjective and not only vary within an organisation but vary from ATSP to ATSP. Consequently requiring such feedback brings no value to the process. It would only work if the CA harmonised all ATSP's schemes, an unrealistic expectation on the CAs, due to the resource required.

GM1 to AMC4 ATS.OR.205(a)(2), (a) & (b)

Use of the term 'criticality of the software' is meaningless as software criticality is undefined

GM1 to AMC4 ATS.OR.205(a)(2), (c)(1)

This is considered an ambiguous statement, software criticality is an undefined term

• GM2 to AMC4 ATS.OR.205(a)(2)

This is considered ambiguous because there are no criteria for (a), (b), (c) or (d) and hence it has no value as GM. Moreover there are no requirements for a SWAL allocation scheme. This undermines harmonisation as each ANSP will have a different scheme

• GM3 to AMC4 ATS.OR.205(a)(2), (a) This is considered an ambiguous statement. Safety Critical software is an undefined term



C) NPA 2017-10 is considered inconsistent in the following respects:

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (c)

This clause implies that multiple SWALs have already been introduced. They have not.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (d)

This guidance is inconsistent with itself. It states that 'if processes do not exist use processes'. Moreover, it is generally accepted that there is no evidence that arguments and evidence cannot be provided for these types of software. Confidence does not depend on SWAL so there is no conflict between the requirement for confidence (ATM/ANS.OR.205(a)(2)) and the type of software.

D) NPA 2017-10 is considered incomplete and incorrect. It does not correctly explain the relationship between assurance standards and their use with safety cases and safety support cases. Furthermore the NPA is incomplete as it does not make it clear that the safety assurance standards listed need to be instantiated for the change and the change safety case that uses them. Nor does it make clear that the assurance standards listed do not address all of the attributes that are required to be addressed by Regulation (EU) 2017/373. Incompleteness and/or error has been identified as follows:

AMC5 ATM/ANS.OR.C.005(a)(2), (b)

Incorrect reference: there is no requirement for SWALS, they are introduced only in GM.

AMC6 ATM/ANS.OR.C.005(a)(2), (a)(2)(i)

The content is incorrect – tautology. Not specific to software. However, it is covered by: AMC2 ATM/ANS.OR.C.005(a)(2), (d) where it is correct.

AMC6 ATM/ANS.OR.C.005(a)(2), (f)

Incorrect, this clause is not a requirement as it uses the word 'should' and provides no criteria for 'particularities' or what is to be done for these particularities. This is more appropriate as GM rather than AMC. The rule itself is adequate as it covers this and is not specific to software.

AMC6 ATM/ANS.OR.C.005(a)(2), (f)

Incorrect, It is not a requirement as it uses the word 'should' and provides no criteria for 'sufficient'. This is more appropriate as GM rather than AMC. The rule itself is adequate as it covers this and is not specific to software.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (a)

Incorrect reference – should be ATM/ANS.OR.C.005(a)(2).

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (a)

Undefined concept (relating confidence to rigour). In addition, 'Software criticality' is undefined.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (a)

The relationship between rigour and confidence is undefined and in a safety support case rigour does not imply correctness. A SWAL allocation scheme can only provide



a link between criticality and assurance processes. The appropriateness of the rigour of process followed and the robustness of the assurance data generated can only be judged for its adequacy with reference to the safety support case that uses it.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (b)

It is not clear that in "many changes" the safety support case is written from the perspective of a non-ATS provider being a subcontractor of the ATS provider and, no guidance is provided for the case where the safety support case has been generated without knowledge of the level of confidence required of the specification. Guidance for both cases is already provided in GM Section 3.3. Multi Actor View. The GM in NPA 2017-10 therefore is considered incomplete and incorrect, and it contradicts the guidance already provided. Furthermore, while the confidence in the claim for a property of a service that is assured in a safety support case should be the same as the confidence required of that property in the safety case, there may be no relationship between the SWAL schemes used for the assurance of safety and the assurance of trustworthiness.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (c)

We believe this is unworkable as the text allows each ANSP to declare their own SWALS and processes. If SWALS are to be used they have to be harmonised, at the European level, to be useable, as intended by NPA 2017-10, by industry. There is no evidence that rigour relates to correctness and neither is there any evidence that these criteria affect rigour. Rigour is undefined and the need for this is unexplained and is considered unjustified. It is questioned where these three classes have come from – as there appears to be no justification.

GM2 to AMC6 ATM/ANS.OR.C.005(a)(2), (a)

There is no direct relationship between the rigour required and criticality. This is a false relationship. Rigour should be related to the difficulty in arguing the satisfaction of a requirement to a given level of confidence and not to its criticality. Furthermore, in this instance, a requirement may relate to criticality but this will be unknown to a service provider other than an ATS provider. Whilst SWALs are related to software practices whose aim is to increase confidence, the relationship between rigour and confidence is undefined and may or may not be relevant to the assurance being made.

GM3 to AMC6 ATM/ANS.OR.C.005(a)(2)

We believe these standards do not satisfy the rule text well and suggest that IEC 61508 Functional Safety 2010 would be far better. It covers the same scope as the regulation and addresses People, Procedures and Equipment (hardware & software). Also as a multi sector standard it is more likely to be used by the ATM/CNS supply chain better.

AMC3 ATS.OR.205(a)(2), (b)

This is not a correct statement. There is no requirement for assurance levels in (EU) 2017/373

AMC4 ATS.OR.205(a)(2), (c)

We believe this cannot work in practice as the text allows each ANSP to declare their own SWALS and processes. If SWALS are to be used they have to be harmonised, at least at the state level, to be useable by industry. There is no evidence that rigour



relates to correctness and neither is there any evidence that these criteria affect rigour. Rigour is undefined and the need for this is unexplained in NPA 2017-10 and is therefore considered unjustified. The origin of these three classes is unclear, nor are the clauses justified in NPA 2017-10.

AMC4 ATS.OR.205(a)(2), (e)

It is not possible to define a process that guarantees to provide sufficient confidence for all safety cases. This is why assurance standards have to be instantiated for particular changes. This needs to be argued in the safety case.

GM1 to AMC4 ATS.OR.205(a)(2), (a)

Incorrect reference – should be ATS.OR.205(a)(2)

GM1 to AMC4 ATS.OR.205(a)(2), (b)

SWALs are related to software practices whose aim is to increase confidence. The relation between rigour and criticality whilst required by NPA 2017-10 is undefined and may or may not help in providing sufficient confidence for the argument being made.

GM1 to AMC4 ATS.OR.205(a)(2), (c)(1)

There is no direct relationship between the rigour required and criticality. This is a false relationship. Rigour should be related to the difficulty in arguing the satisfaction of a requirement to a given level of confidence and not to its criticality. Furthermore, the criticality will already have been expressed in setting the requirement as a level of confidence. Whilst SWALs are related to software practices whose aim is to increase confidence, the relation between rigour and confidence is undefined and may or may not be relevant to the assurance being made.

GM1 to AMC4 ATS.OR.205(a)(2), (c)(2)

We believe this is unworkable in practice as the text allows each ANSP to declare their own SWALS and processes. If SWALS are to be used they have to be harmonised, at least at the state level, to be useable by industry. There is no evidence that rigour relates to correctness and neither is there any evidence that these criteria affect rigour. Rigour is undefined; the need for this is unexplained in NPA 2017–10 and is therefore considered unjustified. It is questioned where these three classes have come from – there appears to be no justification.

GM1 to AMC4 ATS.OR.205(a)(2), (d)

There is no evidence that arguments and evidence cannot be provided for these types of software. Confidence does not depend on SWAL so there is no conflict between the requirement for confidence (ATM/ANS.OR.205(a)(2)) and the type of software.

GM2 to AMC4 ATS.OR.205(a)(2)

Incorrect. There is no requirement for SWALs in Regulation (EU) 2017/373.

GM2 to AMC4 ATS.OR.205(a)(2), (a) & (b)

Neither rigour nor software criticality are defined and neither is the purpose of relating one to the other. There is no direct relationship between the rigour required and criticality. This is a false relationship. Rigour should be related to the difficulty in arguing the satisfaction of a requirement to a given level of confidence and not to its



criticality. Furthermore, the criticality will already have been expressed in setting the requirement as a level of confidence. Whilst SWALs are related to software practices whose aim is to increase confidence, the relationship between rigour and confidence is undefined and may or may not be relevant to the assurance being made.

GM2 to AMC4 ATS.OR.205(a)(2), (d)

This is considered incorrect. Software criticalities for ATSPs are harm based while those for non ATSPs are trustworthiness based. They are not comparable so there can be no notion of consistency. Additionally the rigour and confidence required of the safety case is not dictated by the rigour and confidence provided by the safety support cases.

GM3 to AMC4 ATS.OR.205(a)(2)

We believe these standards do not satisfy the rule text well and suggest IEC 61508 Functional Safety 2010 would be far better. It covers the same scope as the regulation and addresses People, Procedures and Equipment (hardware & software). Also as a multi sector standard it is more likely to address the ATM/CNS supply chain better.

Proposed Text: It is strongly recommended that the following proposed texts are withdrawn:

- AMC5 ATM/ANS.OR.C.005(a)(2)
- AMC6 ATM/ANS.OR.C.005(a)(2)
- GM1 to AMC6 ATM/ANS.OR.C.005(a)(2)
- GM2 to AMC6 ATM/ANS.OR.C.005(a)(2)
- GM3 to AMC6 ATM/ANS.OR.C.005(a)(2)
- AMC3 ATS.OR.205(a)(2)
- AMC4 ATS.OR.205(a)(2)
- GM1 to AMC4 ATS.OR.205(a)(2)
- GM3 to AMC4 ATS.OR.205(a)(2)
- GM4 to AMC4 ATS.OR.205(a)(2)

We believe there are too many errors, ambiguities and inconsistencies in section 3.1 to allow for individual correction. Additionally the section does not comply with the intent of Regulation (EU) 2017/373 with respect to changes to functional systems. Section 3.1 requires further development work, to which end EASA is encouraged not to proceed with the elements identified above. Further rulemaking activity to develop text addressing assurance of People, Procedures and Equipment (HW & SW) in a coherent and harmonised manner is proposed as the most appropriate course of action.

response *Partially accepted*

Following the order of the comments, below please see the responses to them:

GM2 ATM/ANS.OR.A.045(a): The text was presented as guidance material, and such coordination should exist between the ANSP and the competent authority in a more general way for the changes to the functional system. Nevertheless, the text has been amended to remove GM2.



GM1 ATM/ANS.OR.A.050: The main purpose of the guidance material is to highlight the possible need of performing audits for the software assurance aspects. It is to be noted that Regulation (EU) 2017/373 already considers the use of audits for the continuous oversight activities, but it was considered necessary to make a more specific guidance for the software related audits.

AMC6 ATM/ANS.OR.C.005(a)(2): The reference could be changed to the OR.B.010 requirement, but the mentioned procedures would need to be approved by the competent authority. Furthermore, the proposal is following the philosophy of Regulation (EU) 2017/373 as it is requested that not only the processes are followed but also the behaviour of the system (as done with the change management procedures). Finally, it has been decided to keep it separate due to the link to the functional system.

AMC6 ATM/ANS.OR.C.005(a)(2), (a): The five principles are considered fundamental elements of any software assurance process, for any SWAL, covering the requirements, implementation and verification, complemented by the traceability.

AMC6 ATM/ANS.OR.C.005(a)(2), (a)(2)(ii): The text has been amended to refer to safety support requirements instead of safety requirements.

AMC6 ATM/ANS.OR.C.005(a)(2), (a)(3): The text has been amended to refer to safety support requirements instead of safety requirements

AMC6 ATM/ANS.OR.C.005(a)(2), (c): The text has been amended to make the link with the software assurance processes.

AMC6 ATM/ANS.OR.C.005(a)(2), (f): The text has been amended to address the identified inconsistency.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (b). It is found necessary to mention that this guidance material intends to address the use of software assurance levels (SWALs), so the statement about this relationship between ATSP and other ANSPs is considered valid.

AMC4 ATS.OR.205(a)(2): The reference could be changed to the ATM/ANS.OR.B.010 requirement, but the procedures mentioned would need to be approved by the competent authority. The provision is following the philosophy of Regulation (EU) 2017/373, as it is requested that not only the processes are followed but also the behaviour of the system (as done with the change management procedures). Finally, it has been decided to keep it separate due to the link to the functional system.

AMC4 ATS.OR.205(a)(2), (a): The five principles are considered fundamental elements of the any software assurance process, for any SWAL, covering the requirements, implementation and verification, complemented by the traceability.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (a): The term 'criticality' was used to differentiate between the different potential contributions of the software component for the intended services. In the context of this guidance material, it is understood that the term 'criticality' is correctly used as it refers to safety criticality.



GM2 to AMC6 ATM/ANS.OR.C.005(a)(2), (a): This guidance material states that the SWAL allocation relates the rigour of the software assurance to the foreseen criticality of the software. The text has been updated in order to make this link clearer.

GM2 to AMC6 ATM/ANS.OR.C.005(a)(2), (b): The comment is not well understood as this item is the result of the safety support assessment. It refers to the most severe effect that software malfunctions or failures may cause.

AMC4 ATS.OR.205(a)(2), (b): Considering the comment, the text has been amended to make the link with the software assurance processes.

AMC5 ATM/ANS.OR.C.005(a)(2), (b): The comment is duly noted.

GM2 ATM/ANS.OR.A.045(a): The commented guidance material has been removed.

AMC6 ATM/ANS.OR.C.005(a)(2), (d): It should be taken into account that this AMC aims to address the need for the processes to determine the rigour for evidence and arguments. In other words, this is requirement for the process definition.

GM2 to AMC6 ATM/ANS.OR.C.005(a)(2): No information about SWAL allocation scheme is included following the same principles as in Regulation (EU) 2017/373, where no severity classification scheme or risk classification scheme is defined.

GM3 to AMC6 ATM/ANS.OR.C.005(a)(2): Considering the comment, the text has been amended to avoid the potential misunderstanding.

AMC3 ATS.OR.205(a)(2), (b): The comment is duly noted.

GM1 to AMC4 ATS.OR.205(a)(2), (a) & (b): The comment is duly noted.

GM1 to AMC4 ATS.OR.205(a)(2), (c)(1): The comment is duly noted.

GM2 to AMC4 ATS.OR.205(a)(2): No information about SWAL allocation scheme is included, following the same principles as in Regulation (EU) 2017/373, where no severity classification scheme or risk classification scheme is defined.

GM3 to AMC4 ATS.OR.205(a)(2), (a): Considering the comment, the text has been amended to avoid the potential misunderstanding.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (c): it should be noted that the use of multiple SWALs is introduced by this point.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (d): The inconsistency mentioned is not acknowledged.

AMC5 ATM/ANS.OR.C.005(a)(2), (b): It is to be noted that the paragraph states 'when applicable'.

AMC6 ATM/ANS.OR.C.005(a)(2), (a)(2)(i): It is to be noted that this AMC & GM might be applied to different level of software requirements. This is considered to be an important element to be addressed.



AMC6 ATM/ANS.OR.C.005(a)(2), (f): It is to be considered more appropriate to keep at the same level as the previous points, because they belong to the definition of the software assurance processes for this specific type of software components.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (a): It is to be noted that this is guidance material for AMC6.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (a): The comment is duly noted.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (a): Amendments have been introduced in the text to solve the aspect identified as the term 'rigour' has been reworded.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (b): The comment is not well understood, if it refers to the term 'many changes' or the fact that a non-ATS provider may have a safety support case without knowledge of the level of confidence required by the specification (ATS provider). Under the second scenario, it is not considered to be a realistic scenario and, even for non-ATS providers, providing service to several ATS providers, it will be necessary to have a consolidation process to define the more demanding specification confidence level.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2), (c): The comment is duly noted. However, it should be noted that the same situation occurs at European level with the risk classification schemes in Regulation (EU) 2017/373.

GM2 to AMC6 ATM/ANS.OR.C.005(a)(2), (a): The direct relationship would be between the rigour and the confidence with which a particular requirement is met by the software in operation, which at the end can be related with the criticality.

GM3 to AMC6 ATM/ANS.OR.C.005(a)(2): The proposed standard has been added in the list.

AMC3 ATS.OR.205(a)(2), (b): The comment is duly noted. The presence of 'when applicable' in the commented text should be noted.

AMC4 ATS.OR.205(a)(2), (c): No information about SWAL allocation scheme is included following the same principles as in Regulation (EU) 2017/373, where no severity classification scheme or risk classification scheme are defined.

AMC4 ATS.OR.205(a)(2), (e): The assurance standards include several methods that can be used for all these types of COTS software. In fact, this is the current situation, where the same software standards describe techniques that are used for several types of COTS software. The dependence for each safety case is not shared by EASA.

GM1 to AMC4 ATS.OR.205(a)(2), (a): It is to be noted that this is guidance material for the associated AMC.

GM1 to AMC4 ATS.OR.205(a)(2), (b): The comment is duly considered.

GM1 to AMC4 ATS.OR.205(a)(2), (c)(1): The comment is duly considered.



GM1 to AMC4 ATS.OR.205(a)(2), (c)(2): The comment is duly noted and understood. Nevertheless, it is to be noted that the same situation occurs at European level with the risk classification schemes in Regulation (EU) 2017/373.

GM1 to AMC4 ATS.OR.205(a)(2), (d): The comment is duly considered.

GM2 to AMC4 ATS.OR.205(a)(2): The comment is duly considered.

GM2 to AMC4 ATS.OR.205(a)(2), (a) & (b): The comment is duly considered.

GM2 to AMC4 ATS.OR.205(a)(2), (d): The comment is duly considered.

GM3 to AMC4 ATS.OR.205(a)(2): The proposed standard has been added in the list.

GM2 ATM/ANS.OR.A.045(a) Changes to a functional system

p. 9

comment	3 comment by: DFS Deutsche Flugsicherung GmbH
	This GM implies a new procedure, which is neither subject to Regulations (EU) 2017/373 nor (EC) 482/2008. This is not proportionate and inconsistent as no similar GM is provided to the AR rules. Change review activities are already sufficiently addressed through existing AMC/GM.
	We therefore suggest to delete this GM. If particular interest of the NSA shall be drawn on software, we suggest to add the first paragraph of the GM into the current GM1 (not subject to this NPA) point a):
	GM1 ATM/ANS.OR.A.045(a) Changes to a functional system
	NOTIFICATION (a) A change should be notified as soon as the data defined in AMC1 ATM/ANS.OR.A.045(a) is available. The decision to review a change by the competent authority will be based, in most circumstances, on the notification data. Exceptions to this are cases where the competent authority is not familiar with the type of change or the complexity of the change requires a more thorough consideration. Depending on the complexity of the change to the functional system and the criticality of the software, the depth of the evaluation may vary.
	(b) Early and accurate notification facilitates
response	Accepted
	Considering the comment, the text has been amended accordingly.
comment	9 comment by: D Winship
connent	s continent by. b withinp

For 2nd sentence the current wording could be interpreted as giving joint responsibility between SP & CA for the definition of a software oversight strategy.

In addition there is an implication in this text that the CA will be defining a software oversight strategy for each individual change – this is not practicable when most CAs receive hundreds of change notifications per year. In practice the CA is likely to employ a standard change oversight process with the level of review conducted commensurate with the complexity/criticality/level of risk.



response	Suggest revision to; "The service provider should coordinate as soon as practicable with the competent authority taking into consideration that the CA's review timelines will be partially dependent on the complexity and criticality of the change." <i>Partially accepted</i> Taking into account this comment as well as other comments, the sentence about software oversight strategy has been removed from the set of AMC & GM.
comment	30 comment by: ENAIRE We do not agree to define a software oversight strategy as part of the change review with the NSA. The ANSP shall define a software strategy and the NSA shall validate for all changes. This is not proportionate and inconsistent as no similar GM is provided to the AR rules. Change review activities are already sufficiently addressed through existing AMC/GM. We therefore suggest to delete this GM.
response	Partially accepted Taking into account this comment as well as other comments, the sentence about software oversight strategy has been removed from the set of AMC & GM.
comment	 41 comment by: CANSO This GM implies a new procedure, which is neither subject to Regulations (EU) 2017/373 nor (EC) 482/2008. This is not proportionate and inconsistent as no similar GM is provided to the AR rules. Change review activities are already sufficiently addressed through existing AMC/GM. We therefore suggest to delete this GM. If particular interest of the NSA shall be drawn on software, we suggest to add the first paragraph of the GM into the current GM1 (not subject to this NPA) point a): GM1 ATM/ANS.OR.A.045(a) Changes to a functional system NOTIFICATION (a) A change should be notified as soon as the data defined in AMC1 ATM/ANS.OR.A.045(a) is available. The decision to review a change by the competent authority will be based, in most circumstances, on the notification data. Exceptions to this are cases where the competent authority is not familiar with the type of change or the complexity of the change requires a more thorough consideration. Depending on the complexity of the change to the functional system and the criticality of the software, the depth of the evaluation may vary.

(b) Early and accurate notification facilitates....



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response	Accepted
	Considering the comment, the text has been amended accordingly.
comment	76 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)
	What is the rational for changing the overall procedure for oversight of change and encurage ANSPs to request early feedback from the CA/NSA to verify the level of details in the software assurance strategy for an individual change, rather than including the software criticality as one aspect to be assessed during the oversight of change.
	The obvious drawback of this proposal is that the CA/NSA does not have all the facts on the table and therefore might mislead the service provider. We know that from experience that it is not beneficial from the ANSPs nor from the NSA perspective to handle a specific subset of the change interdependently. The Software assurance Processes has to be agreed by the ANSP and the CA/NSA before any feedback can be given to the ANSP
response	Partially accepted
	Taking into account this comment as well as other comments, the sentence about software oversight strategy has been removed from the set of AMC & GM.
comment	110 comment by: ENAV
	This GM implies a new procedure, which is neither subject to Regulations (EU) 2017/373 nor (EC) 482/2008. This is not proportionate and inconsistent as no similar GM is provided to the AR rules. Change review activities are already sufficiently addressed through existing AMC/GM. We therefore suggest to delete this GM. If particular interest of the NSA shall be drawn on software, we suggest to add the first paragraph of the GM into the current
	GM1 (not subject to this NPA) point a):
	GM1 ATM/ANS.OR.A.045(a) Changes to a functional system NOTIFICATION (a) A change should be notified as soon as the data defined in AMC1 ATM/ANS.OR.A.045(a) is available. The decision to review a change by the competent authority will be based, in most circumstances, on the notification data. Exceptions to this are cases where the competent authority is not familiar with the type of change or the complexity of the change requires a more thorough consideration. Depending on the complexity of the change to the functional system and the criticality of the software, the depth of the evaluation may vary. (b) Early and accurate notification facilitates

response	Accepted
	Considering the comment, the text has been amended accordingly.
omment	177 comment by: <i>The Boeing Company</i>
	Page: 9 Paragraph: GM2 ATM/ANS.OR.A.045(a)
	The proposed text states: "NOTIFICATION — SOFTWARE CRITICALITY"
	<u>Requested Change</u> : We request that EASA specify which software is being referenced; the software used in house for production, or the software used in products delivered to the customer.
	Justification: Clarification.
response	Noted
	The software mentioned is that part of the functional system, which is used by the ANSP for the service provision. Then, it will fall under the second option identified by the commenter.
omment	188 comment by: AESA/DSANA
	Change "as soon as possible" to the following text: "prior to the implementation of the software assurance processes".
	A regulation should not define requirements that cannot be assessed.
response	Partially accepted
	Taking into account this comment as well as other comments, the sentence about software oversight strategy has been removed from the set of AMC & GM.
omment	189 comment by: AESA/DSANA
	The depth of the evaluation should depend on the criticality of the SW according to the service provided and not on the complexity of the change.
	According to GM2 ATM/ANS.OR.A.045(a), each change could, in principle, have different oversight strategies, even if the criticality of the service they are providing is the same.
esponse	Noted
	The complexity of the change would have a clear contribution to the depth of the evaluation of a particular change.

comment 190

comment by: AESA/DSANA



	What is it to be understood by complexity? Is the service provider the only responsible for its determination or should it be agreed with the NSA?
	This is an issue which could be controversial and now seems a key factor to decide the depth of the revision.
response	Noted
	The comment is not well understood. The complexity of the change or activities would not require a particular definition.
comment	191 comment by: AESA/DSANA
	It is not clear which SW - related information should be included by the Service Provider in the Notification of the change, if any.
	Some key SW-related aspects should be identified and included in the list of data to notify to the Competent Authority in order to help them to decide whether to review or not (AMC1 ATM/ANS.OR.A.045(a); GM1 ATM/ANS.OR.A.045(a)).
response	Partially accepted
	Taking into account this comment as well as other comments, the sentence about software oversight strategy has been removed from the set of AMC & GM.
comment	192 comment by: AESA/DSANA
	An important concept is included without guidelines to interpretation or application: "criticality of the software". A definition should be included.
	The concept "criticality of the software" is used to determine the depth of the evaluation. The level of confidence to "ensure the existence of documented software assurance processes necessary to produce evidence and arguments that demonstrate that the software behaves as intended (software requirements)", and the rigour to which the assurances are established to achieve compliance with the objectives of the software assurance processes are, among other things, also depending on the "criticality of the software". Due to the importance of the concept, it is considered necessary to establish some guidance material on how to determinate the criticality of the software. Some examples, or a scale of criticality would be also useful for the sake of harmonisation.
response	Not accepted
	The term software criticality was already used in Regulation (EC) No 482/2008 with no particular definition and no major concern was reported by stakeholders when showing compliance. Therefore, no amendments to the text are introduced in this context.
commont	214 comment by: DSAC - FR NSA
comment	217 Comment by. DSAC - PR NSA



French NSA fully supports the idea of early coordination between CA and SP for software aspects. However, this GM is refering to the "Notification" process and may be misinterprated as in some cases it is more than likely that the criticality and the SWAL of involved software will be unknown at the moment of the notification. Suggestion would be to mention explicitly that SWAL is not due in the initial notification form but should be communicated as soon as known.

	notification form but should be communicated as soon as known.
response	Noted
	Based on this comment and considering other comments, it has been decided to remove GM2 ATM/ANS.OR.A.045(a) on Notification – Software Criticality. The provisions presented in the AMC & GM for 'ATM/ANS.AR.C.035(a) Decision to review a notified change to the functional system' cover this aspect.
comment	268 comment by: ASD/Thales Air Systems
	The concept of "software criticality" may be interprated in various manner since the term criticality is not defined. It may be useful to link it to the concept of SWAL (allocation) who is the translation of this criticality in terms of evaluation of the direct or indirect crontribution of the software to a feared event having with a given severity.
response	Noted
	Based on this comment and considering other comments, it has been decided to remove GM2 ATM/ANS.OR.A.045(a) on Notification – Software Criticality. The provisions presented in the AMC & GM for 'ATM/ANS.AR.C.035(a) Decision to review a notified change to the functional system' cover this aspect.
comment	297 comment by: UK CAA
	Equivalent coverage in EC 2017/373 text:
	GM1 ATM/ANS.OR.A.045(a) (b), (c), (d) (e) & (f)
	General GM – 3.2
	Comments:
	Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE.Covered in GM1 and General GM – 3.2 to a much greater depth.
response	Accepted



GM1 ATM/ANS.OR.A.050 Facilitation and cooperation	p. 9

comment	4 comment by: DFS Deutsche Flugsicherung GmbH
	Access right of the competent authority is crucial to a contract between an ANSP and sub-contracted organisations. Probably a lot of contracts need to be updated accordingly. A simple explanation within GM may not be the right place to address such facilitation and its empowerment. Furthermore, if it's essential to provide information how a CA should review a change by which software is affected, this should be subject to Part AR.
response	Noted
	As correctly mentioned by the commentator, the access right of the competent authority is crucial. This is why it is required under Article 5 of Regulation (EU) 2017/373 and further regulated in ATM/ANS.OR.B.015 'Contracted activities' that stipulates that contracts with software suppliers shall already consider the possibility to offer the access to the compliance demonstration data to the competent authority. The purpose of this GM to illustrate the actions to be taken by the ATM/ANS providers in this context.
comment	10 comment by: D Winship
	Consider revision to Paragraph (a) - readability issues. Specifically "In this context,access to the development environment and to the configuration management system to the competent authority that needs to verify:
	Also editorial below: "the fact that all the evidence <i>{missing is}</i> derived from a known version of software."
response	Partially accepted
	Considering the comments, the text has been amended.
comment	11 comment by: D Winship
	Para b(1) appears to add little value and isn't specifically relevant to software assurance processes – the principle that the CA has the right to conduct audits as appropriate is well established in the legislation and doesn't need to be restated specifically within the software assurance AMC/GM.
response	Noted
	EASA shares the commentator's view that on-site audits and inspections are already covered by other parts of the legislation. Nevertheless, the potential software audits/inspections might be necessary in the frame of the review of a particular



change, for which specific considerations should be paid by the ATM/ANS providers when planning the introduction of a particular type of changes (e.g. new systems).

comment	12 comment by: D Winship
	Para b(2) "rights to audit into the contractual provisions" – intent unclear – the CA may wish to comment or obtain more detailed evidence from the service provider on assurance material provided by a supplier but generally it isn't specifically "contractual provisions" that would be audited – it is just as likely that technical information would be requested as opposed to "contractual provisions". Again this section adds little to what is a 'normal' oversight task not specific to the oversight of software.
response	Partially accepted
	The purpose of this GM is to stress the fact that ATM/ANS providers should clarify with the suppliers the requirement from the competent authority about the need of providing such visibility even from the supplier activities, as far as this is related to the regulatory compliance demonstration or the safety/safety support argument demonstration. Considering the comment, the text has been amended.
comment	31 comment by: ENAIRE
	Access to the configuration management system to the component authority should be enough. For this reason, it is suggested to change the paragraph as follows: "The assessment of an effective application of the documented software assurance processes may necessitate a technical evaluation of the evidence and arguments produced for the software assurance by the competent authority when reviewing a notified change. In this context, the service provider should ensure access to the development environment and to the configuration management system to the competent authority that needs to verify".
response	Accepted
commont	42 commont by CANCO
comment	 42 comment by: CANSO Access right of the competent authority is crucial to a contract between an ANSP and sub-contracted organisations. Probably a lot of contracts need to be updated accordingly. A simple explanation within GM may not be the right place to address such facilitation and its empowerment. Furthermore, if it's essential to provide information how a CA should review a change by which software is affected, this should be subject to Part AR.
response	Noted
	As correctly mentioned by the commentator, the access right of the competent authority is crucial. This is why it is required under Article 5 of Regulation (EU) 2017/373 and further regulated in ATM/ANS.OR.B.015 'Contracted activities' that



stipulates that contracts with software suppliers shall already consider the possibility to offer the access to the compliance demonstration data to the competent authority. The purpose of this GM to illustrate the actions to be taken by the ATM/ANS providers in this context.

comment	50 comment by: CANSO
	Access to the configuration management system to the component authority should be enough. We suggest to change GM1(a) as follows:
	"(a) The assessment of an effective application of the documented software assurance processes may necessitate a technical evaluation of the evidence and arguments produced for the software assurance by the competent authority when reviewing a notified change. In this context, the service provider should ensure access to the development environment and to the configuration management system to the competent authority that needs to verify".
response	Accepted
comment	83 comment by: Copenhagen Airport
	a) Providing access to the development environment and configuration management at contracted organizations to the competent authority may prove to be without value or even produce false evidence. The competences of the authorities will be significantly challenged as software development is a highly complicated process. The service provider is in a far better position to do quality audits at contracted organizations. The suggestion is therefore to let the authority assess the service provider and his quality management system as well as the safety arguments provided.
	b.2) Refer to a)
response	Noted EASA shares the commentator's view that as part of the compliance monitoring, the ATM/ANS providers will evaluate in detail the necessary aspects from the contracted organisation to support the regulatory compliance. Nevertheless, the competent authority should have the possibility to decide either to rely on the quality audit results obtained by the ATM/ANS provider or to perform independent evaluation of the software assurance compliance records. Based on this second scenario, it is considered necessary to keep the proposed GM.
comment	85 comment by: EASA Focal Point for AustroControl ANSP-issues
	CN41 ATNA/ANIC OR A 050 Facilitation and accuration

GM1 ATM/ANS.OR.A.050 Facilitation and cooperation

(a) The assessment of an effective application of the documented software assurance processes may necessitate a technical evaluation of the evidence and arguments produced for the software assurance by the competent authority when reviewing a notified change. In this context, the service provider should ensure access to the



development environment and to the configuration management system to the competent authority that needs to verify:

(1) the consistency of all the evidence; and

(2) the fact that all the evidence derived from a known version of the software (i.e. all evidence and arguments are actually available and can be traced without ambiguity to the executable version).

AUSTROCONTROL Comment:

It should be clear stated, that access for Competent Authorities to developing environment u. configuration management can only be ensured for ANSP inhouse development and never for an external supplier.

response Noted

The comment is duly noted.

However, it should be highlighted that the commented GM is in line with the currently applicable Regulation (please refer to Articles 6 and 7 of Regulation (EU) No 1035/2011) and Article 5 of Regulation (EU) 2017/373. Therefore, contracts with software suppliers shall already consider the possibility to offer access to the compliance demonstration data to the competent authority.

comment	86 comment by: EASA Focal Point for AustroControl ANSP-issues
	GM1 ATM/ANS.OR.A.050 Facilitation and cooperation
	(b) The service provider should: (1) anticipate the possibility for on-site audits or inspections by the competent
	authority; and
	(2) when evidence and arguments are developed by contracted organisations, include the corresponding rights to audit into the contractual provisions.
	AUSTRO CONTROL Comment: Point (2) could be read or understood in the way that the ANSP should also include the corresponding right to audit of contracted organisations for CA. This requires clarification and probably goes beyond the scope of a GM.
response	Noted
	The comment is duly noted.
	However, it should be highlighted that the commented GM is in line with the currently applicable Regulation (please refer to Articles 6 and 7 of Regulation (EU) No 1035/2011) and Article 5 of Regulation (EU) 2017/373. Therefore, contracts with software suppliers shall already consider the possibility to offer the access to the compliance demonstration data to the competent authority, including the possibility to perform on-site audits, as it would be the case for the software assurance processes.



comment	111 comment by: ENAV
	Access right of the competent authority is crucial to a contract between an ANSP and sub-contracted organisations. Probably a lot of contracts need to be updated accordingly. A simple explanation within GM may not be the right place to address such facilitation and its empowerment. Furthermore, if it's essential to provide information how a CA should review a change by which software is affected, this should be subject to Part AR.
response	Noted
	The comment is duly noted.
	However, it should be highlighted that the commented GM is in line with the currently applicable Regulation (please refer to Articles 6 and 7 of Regulation (EU) No 1035/2011) and Article 5 of Regulation (EU) 2017/373. Therefore, contracts with software suppliers shall already consider the possibility to offer the access to the compliance demonstration data to the competent authority. Furthermore, it is to be noted that the current AMC & GM for review of changes to functional system do not establish the means to be followed by the competent authority for the review of changes.
comment	112 comment by: ENAV
	Access to the configuration management system to the component authority should be enough. We suggest to change GM1(a) as follows:
	"(a) The assessment of an effective application of the documented software assurance processes may necessitate a technical evaluation of the evidence and arguments produced for the software assurance by the competent authority when reviewing a notified change. In this context, the service provider should ensure access to the development environment and to the configuration management system to the competent authority that needs to verify".
response	Accepted
comment	127 comment by: ENAV
	 GM1 ATM/ANS.OR.A.050 Facilitation and cooperation (a) The assessment of an effective application of the documented software assurance processes may necessitate a technical evaluation of the evidence and arguments produced for the software assurance by the competent authority when reviewing a notified change. In this context, the service provider should ensure access to the development environment and to the configuration management system to the competent authority that needs to verify: (1) the consistency of all the evidence; and (2) the fact that all the evidence derived from a known version of the software (i.e. all evidence and arguments are actually available and can be traced without ambiguity to the executable version).



	Comment: It should be clear stated, that access for Competent Authorities to developing environment u. configuration management can only be ensured for ANSP inhouse development and never for an external supplier.
response	Noted
	The comment is duly noted.
	However, it should be highlighted that the commented GM is in line with the currently applicable Regulation (please refer to Articles 6 and 7 of Regulation (EU) No 1035/2011) and Article 5 of Regulation (EU) 2017/373. Therefore, contracts with software suppliers shall already consider the possibility to offer the access to the compliance demonstration data to the competent authority.
commont.	120 commont by FNAV
comment	128 comment by: ENAV GM1 ATM/ANS.OR.A.050 Facilitation and cooperation
	 (b) The service provider should: (1) anticipate the possibility for on-site audits or inspections by the competent authority; and (2) when evidence and arguments are developed by contracted organisations, include the corresponding rights to audit into the contractual provisions. Comment:
	Point (2) could be read or understood in the way that the ANSP should also include the corresponding right to audit of contracted organisations for CA. This requires clarification and probably goes beyond the scope of a GM.
response	Noted
	The comment is duly noted.
	However, it should be highlighted that the commented GM is in line with the currently applicable Regulation (please refer to Articles 6 and 7 of Regulation (EU) No 1035/2011) and Article 5 of Regulation (EU) 2017/373. Therefore, contracts with software suppliers shall already consider the possibility to offer the access to the compliance demonstration data to the competent authority. Furthermore, the current AMC & GM for review of changes to functional system do not establish the means to be followed by the competent authority for the review of changes, including the possibility to perform on-site audits, as it would be the case for the software assurance processes.
comment	133 comment by: LFV
	It may be difficult to contractually ensure the right for the competent authority to

It may be difficult to contractually ensure the right for the competent authority to access a supplier's development environment and to audit system suppliers. Please consider whether GM1 ATM/ANS.OR.A.050 is feasible.



response	Noted
	The comment is duly noted.
	However, it should be highlighted that the commented GM is in line with the currently applicable Regulation (please refer to Articles 6 and 7 of Regulation (EU) No 1035/2011) and Article 5 of Regulation (EU) 2017/373. Therefore, contracts with software suppliers shall already consider the possibility to offer the access to the compliance demonstration data to the competent authority. Furthermore, the current AMC & GM for review of changes to functional system do not establish the means to be followed by the competent authority for the review of changes, including the possibility to perform on-site audits, as it would be the case for the software assurance processes.
comment	139 comment by: CANSO
	GM1 ATM/ANS.OR.A.050 Facilitation and cooperation (a) The assessment of an effective application of the documented software assurance processes may necessitate a technical evaluation of the evidence and arguments produced for the software assurance by the competent authority when reviewing a notified change. In this context, the service provider should ensure access to the development environment and to the configuration management system to the competent authority that needs to verify: (1) the consistency of all the evidence; and (2) the fact that all the evidence derived from a known version of the software (i.e. all evidence and arguments are actually available and can be traced without ambiguity to the executable version).
	CANSO Comment: It should be clear stated, that access for Competent Authorities to developing environment u. configuration management can only be ensured for ANSP inhouse development and never for an external supplier.
response	Noted
	The comment is duly noted.
	However, it should be highlighted that the commented GM is in line with the currently applicable Regulation (please refer to Articles 6 and 7 of Regulation (EU) No 1035/2011) and Article 5 of Regulation (EU) 2017/373. Therefore, contracts with software suppliers shall already consider the possibility to offer the access to the compliance demonstration data to the competent authority. Furthermore, the current AMC & GM for review of changes to functional system do not establish the means to be followed by the competent authority for the review of changes, including the possibility to perform on-site audits, as it would be the case for the software assurance processes.

comment 140

comment by: CANSO



GM1 ATM/ANS.OR.A.050 Facilitation and cooperation (b) The service provider should: (1) anticipate the possibility for on-site audits or inspections by the competent authority; and (2) when evidence and arguments are developed by contracted organisations, include the corresponding rights to audit into the contractual provisions. **CANSO Comment:** Point (2) could be read or understood in the way that the ANSP should also include the corresponding right to audit of contracted organisations for CA. This requires clarification and probably goes beyond the scope of a GM. Noted response The comment is duly noted. However, it should be highlighted that the commented GM is in line with the currently applicable Regulation (please refer to Articles 6 and 7 of Regulation (EU) No 1035/2011) and Article 5 of Regulation (EU) 2017/373. Therefore, contracts with software suppliers shall already consider the possibility to offer the access to the compliance demonstration data to the competent authority. Furthermore, the current AMC & GM for review of changes to functional system do not establish the means to be followed by the competent authority for the review of changes, including the possibility to perform on-site audits, as it would be the case for the software assurance processes. 178 comment comment by: *The Boeing Company* Page: 9 Paragraph: GM1 ATM/ANS.OR.A.050 (b) (2) The proposed text states: "(2) when evidence and arguments are developed by contracted organizations, include the corresponding rights to audit into the contractual provisions." **Requested Change:** We request that EASA specify which contractual provisions, in particular. Justification: Contractual provisions may be confidential. In some cases, it may even be impossible to reveal that there is a contract and who the contract partner is. Noted response It should be highlighted that the commented GM is in line with the currently

applicable Regulation (please refer to Articles 6 and 7 of Regulation (EU) No 1035/2011) and Article 5 of Regulation (EU) 2017/373. Therefore, contracts with software suppliers shall already consider the possibility to offer the access to the compliance demonstration data to the competent authority.



comment	194 comment by: AESA/DSANA		
connicite	Consider to include GM2 ATM/ANS.OR.A.050(a) in NPA 2017/373 AR.		
	GM2 ATM/ANS.OR.A.050(a)involves, in fact, requirements for the NSA.		
response	Noted		
The commented GM is limited to the service providers. The involver competent authority is covered by the existing AMC & GM where the as level of involvement are addressed, covering the software as one of the the change management.			
comment	210 comment by: European Transport Workers Federation - ETF		
	ETF welcomes this approach and encourages EASA to closely monitor that system manufacturers enable ANSPs to go down this path.		
response	Noted		
comment	273 comment by: German NSA (BAF)		
	"The service provider should coordinate as soon as possible with the competent authority in order to define a software oversight strategy as part of the change review activities." Proposal:		
	Replace "should" be by "shall".		
response	Not accepted		
	The use of 'shall' is reserved for the implementing rules, which stipulate an obligation for the person or organisation that is subject to the rule. An AMC or GM, having a non-binding nature, cannot use any language that expresses an obligation (neither 'shall' nor 'must'); thus, the use of 'should'.		
comment	284 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)		
	This implies that the CA/NSA has to have competency in assesment of software development to be able review the proposed software assurance processes from the ANSP		
response	Noted		
	Considering the requirements laid down in Regulation (EU) 2017/373 on competent authority training aspects, the answer is affirmative.		
comment	298 comment by: UK CAA		

* * * * * An agency of the European Union Equivalent coverage in EC 2017/373 text:

ATM/ANS.OR.A.045 (c) ATM/ANS.OR.B.010 (a) ATM/ANS.OR.C.005 (a)(2) & (b)(2)

Comments:

Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE.

This section is out of context. Content and application of assurance cases is covered in AMC/GM associated with ATM/ANS.OR.C.005(a). The approval of processes is covered in ATM/ANS.OR.B.10 and its associated AMC/GM

If the evidence required by (b)(2) is necessary but not included in the assurance case then the assurance case would not be valid and could not be approved – see ATM/ANS.OR.C.005(a)(2) and its associated AMC/GM

Co-operation between the service provider and the CA during change is covered, in detail, in section 3 of the General GM.

If it were felt necessary to highlight this co-operation it would have to include all regulatory interaction governed by the IR.

response Noted

EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.

AMC5 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system

p. 10

comment	13 comment by: D Winship
	The service provider should "ensure the existence of documented software assurance processes"
	Even though 482/2008 is repealed, by requiring "software assurance processes" rather than a system assurance process the AMC effectively still enforces an obligation on the ANSP to have a stand-alone software assurance system as very few ANSPs/CAs have the time and resources required to develop suitable AltMoCs. This requires careful consideration given that a more 'systems oriented' assurance approach is suggested in the introduction.
response	Noted
	The reference to the software assurance processes follows the same approach as in Regulation (EC) No 482/2008. The approach followed is to address the software elements and to ask about the HW assurance aspects. It is noted that the scope of a system assurance process is not covering the software aspects at the level requested by Regulation (EC) No 482/2008. However, the reference to the development of suitable AltMoC is not understood as, according to the currently applicable



Regulation (EC) No 482/2008, all the ANSPs should have in place a software safety assurance system.

oo na na o na t	14 commont by D Winchin
comment	14 comment by: D Winship
	"For that purposes, the effects from a software malfunction or failure reported according to the relevant requirements on reporting and assessment of service occurrences should be assessedin comparison with the effects identified for the system"
	This text could be open to several interpretations and requires enhancement to improve clarity. Specific concerns include use of "reported according to the relevant requirements on reporting and assessment of service occurrences " – as written this could be interpreted as stating only those failures/malfunctions reported under the Occurrence Reporting Regulation are considered/assessed which would not in practice be advisable – for most systems the majority of software-related errors/failures would not be likely to result in the generation of an "occurrence report" falling within the scope of the OR regulation (e.g. those detected during testing or those having no actual impact on the service).
response	Partially accepted
	Considering the comment, the text has been amended to avoid misunderstandings.
comment	15 comment by: D Winship
	For section (b) The intent of the requirement to assess the effect of a software 'occurrence' in comparison with the "effects identified for the system concerned as per the service specification" is also unclear. The intent/meaning of this sentence could be open to widely varying interpretations. In 482/2008 the effects were referenced to the severity classification scheme in the common requirements. If this is no longer relevant then consideration should be given to rewording as "effects in a service specification" doesn't appear to be meaningful – specifications normally contain system requirements, behaviours, interface definitions etc. rather than "effects".
response	Accepted
	Considering the comment, the text has been amended by adding the demonstration of the service specification.
comment	62 comment by: CANSO
	As stated in explanatory note on NPA 2014-13 "While today CNS providers are seen to try to comply with these requirements, they cannot always do so. This is because CNS providers, as other non-ATS providers, do not have a dynamic view of the use of the service and, therefore, cannot intervene in order to alter a developing situation. Furthermore, the non-ATS provider may not know how the service it offers is being used by the ATS provider, either in normal circumstances or in circumstances where immediate intervention is necessary in order to maintain safety".



Therefore, service providers other than ATS providers cannot assess the software "criticality of the required application" as described at the end of item (a).

Service providers other than ATS providers can only assess the PERFORMANCE of the service provided.

In the same spirit of previous comment, considering that service providers other than ATS providers are not the user of the software, it is not possible for them to realize a feedback of software experience,

=> These items shall be deleted on this AMC or modified to address PERFORMANCE instead of safety.

response Accepted

Considering the comment, amendments have been made to the text.

However, it is necessary to clarify two aspects:

- Service providers other than ATS providers can assess the satisfaction of the service requirements (not only the performance, understood as performance requirements).

- Service providers other than ATS are users of the software (at least, they should monitor the service and the system status) and, hence, they have information to provide feedback on software experience.

comment	64 comment by: CANSO
	Remark: In item (a), in case of modifications to existing software, the existence of documented software assurance processes could not be systematically available, especially if the development was performed several years before. Additionally, the state of art at the moment for the previous development could be significantly different as the current standards. In these cases, the service history could be claimed without any existence of documentation. => The following sentence is proposed for amendment: (a) When a change to a functional system includes the introduction of new software or modifications to existing software, the service provider should ensure the existence of documented software assurance processes necessary to produce evidence and arguments that demonstrate that the software behaves as intended (software requirements), with a level of confidence consistent with the criticality of the required application. In case of incomplete or absence to this expected documentation, the service experience, if exists, could be considered as a relevant complementary way.
response	Not accepted
	It is necessary to point out that, as described in AMC6 ATM/ANC.OR.C.005(a)(2), (f), it is always possible to have specific software assurance processes for managing previously developed software and to use the technique that is mentioned in the comment. Based on the existence of this provision, it is not considered necessary to include the additional clarification proposed by the commentator.

comment 82



ATM/ANS.OR.C.205(a)(2) - Pages 10 to 14

(Same comment as for ATS.OR.205(a)(2)).

The EUROCONTROL Agency finds that there is no AMC/GM explaining how the criticality of the software (SWAL) is linked to the criticality of the application. This might lead, for the same functional system, to a situation with different SWAL allocations by different ANSPs, although for the same required application. It would be therefore beneficial at European level to rely on a standardised mechanism for SWAL allocation, depending on the criticality of the application.

response Noted

The comment is duly considered.

It is agreed that there is a difference between the criticality of the software and the criticality of the particular application by an ANSP. The same software can be used in different contexts by several ANSPs. Nevertheless, the objective of the AMC & GM is to address the software assurance aspects associated with the software, once the criticality of the application has been addressed by the ANSP.

On the other hand, EASA concurs with the idea of having a common European SWAL allocation matrix, as currently presented in some of the software standards. However, Regulation (EU) 2017/373 and the existing AMC & GM do not go in that direction regarding the severity classification scheme and risk classification scheme, where there is no harmonised severity classification scheme (as there is today under Regulation (EU) No 1035/2011). Then, this limits the possibility of establishing a common European SWAL allocation matrix.

comment	113 comment by: ENAV
	In item (a), in case of modifications to existing software, the existence of documented
	software assurance processes could not be systematically available, especially if the development was performed several years before.
	Additionally, the state of art at the moment for the previous development could be significantly different as the current standards.
	In these cases, the service history could be claimed without any existence of documentation.
	=> The following sentence is proposed for amendment:
	(a) When a change to a functional system includes the introduction of new software or modifications to existing software, the service provider should ensure the existence
	of documented software assurance processes necessary to produce evidence and arguments that demonstrate that the software behaves as intended (software
	requirements), with a level of confidence consistent with the criticality of the required application. In case of incomplete or absence to this expected documentation, the service experience, if exists, could be considered as a relevant complementary way

response Not accepted



It is necessary to point out that, as described in AMC6 ATM/ANC.OR.C.005(a)(2), (f), it is always possible to have specific software assurance processes for managing previously developed software and to use the technique that is mentioned in the comment. Based on the existence of this provision, it is not considered necessary to include the additional clarification proposed by the commentator.

comment	143comment by: DSNA
	In some specific cases, some Risk Mitigation Means are foreseen in order to be a response for some hazards. These Risk Mitigation Means could be considered as an acceptable alternative way instead of software safety support assessment. => The following sentence is proposed for amendment and should be added : "An acceptable alternative way for software safety support assessment could be the demonstration of existence of adequate Risk Mitigation Means."
response	Not accepted The term 'software safety support assessment' is not used in the proposed set of AMC & GM.

comment	154 comment by: DSNA		
	Regarding CE482/2008 matrix on §6 of this NPA, item (b) of this AMC is linked to the article 4(5), so the use of the feedback of software experience is a transverse and ongoing process which is not related to a specific change and specific software. More globally, this AMC is related to safety assessment by ATS proviver and is already covered by "ATS.OR.200 Safety management system" (a Software safety Assurance System is part of a Safety Management System). Therefore, item (b) shall be deleted		
response	Not accepted		
	The use of software experience is a transverse process but provides results at the		
	time of implementing a specific change. This could be the case for the introduction		
	of a new COTS version. Then, EASA considers that item (b) is still relevant.		
comment	155 comment by: DSNA		
	As stated in explanatory note on NPA 2014-13 "While today CNS providers are seen		
	to try to comply with these requirements, they cannot always do so. This is because		
	CNS providers, as other non-ATS providers, do not have a dynamic view of the use of the service and, therefore, cannot intervene in order to alter a developing situation.		
	Furthermore, the non-ATS provider may not know how the service it offers is being		
	used by the ATS provider, either in normal circumstances or in circumstances where		
	immediate intervention is necessary in order to maintain safety".		
	Therefore, service providers other than ATS providers can not assess the software <i>"criticality of the required application"</i> as described at the end of item (a).		
	Service providers other than ATS providers can only assess the PERFORMANCE of the		
	service provided.		



In the same spirit of previous comment, considering that service providers other than			
ATS providers are not the user of the software, it is not possible for them to realize a			
feedback	of	software	experience,
=> These items shall be deleted on this AMC or modified to address PERFORMANCE			
instead of safety			

response Accepted

Considering the comment, amendments have been made to the text.

However, it is necessary to clarify two aspects:

- Service providers other than ATS providers can assess the satisfaction of the service requirements (not only the performances, understood as performance requirements)

- Service providers other than ATS are users of the software (at least, should monitor the service and the system status) and, hence, with information to provide feedback of software experience.

comment	t 156 comment by: DSNA		
	In item (a), in case of modifications to existing software, the existence of documented software assurance processes could not be systematically available, especially if the development was performed several years before. Additionally, the state of art at the moment for the previous development could be significantly different as the current standards. In these cases, the service history could be claimed without any existence of documentation.		
	=> The following sentence is proposed for amendment: (a) When a change to a functional system includes the introduction of new software or modifications to existing software, the service provider should ensure the existence of documented software assurance processes necessary to produce evidence and arguments that demonstrate that the software behaves as intended (software requirements), with a level of confidence consistent with the criticality of the required application. In case of incomplete or absence to this expected documentation, the service experience, if exists, could be considered as a relevant alternative way.		
response	e Not accepted		
	It is necessary to point out that, as described in AMC6 ATM/ANC.OR.C.005(a)(2), (f), it is always possible to have specific software assurance processes for managing previously developed software and to use the technique that is mentioned in the comment. Based on the existence of this provision, it is not considered necessary to include the additional clarification proposed by the commentator.		
	470		
comment	179 comment by: DSNA		
	In some specific cases, for instance, meteorological services, the assessment of the software providing the service support is out of the managerial control scope from the ANSP. Therefore, software assessment of support services can't be assessed by		



the

ANSP.

=> The following sentence is proposed for amendment and should be added : "In case the support is out of the definition and/or managerial control scope, the safety support assessment will be specifically not foreseen."

response Not accepted

In the current regulatory framework, the software aspects are covered in detail through Regulation (EC) No 482/2008, which applies to any changes to the software of the systems for air traffic services (ATS), airspace management (ASM), and air traffic flow management (ATFM), i.e. air traffic management (ATM) and communication, navigation, or surveillance (CNS). Additionally, the software aspects for aeronautical information services (AIS) provision are included in Regulation (EU) No 73/2010. On the other hand, it is acknowledged that the MET providers will be affected as regards the software assurance AMC & GM.

EASA considers that some of the service providers other than the ones that are subject to Regulation (EC) No 482/2008 today have a contribution to software (e.g. MET providers, FPD) and it was concluded that some features of the MET systems are affected by the current regulatory requirements, which also supports the approach taken for the proposed set of AMC & GM; that is, to apply for all service providers of ATM/ANS, including AIS and MET providers, towards software assurance level standardisation.

comment	195	comment by: AESA/DSANA		
	A definition for "Software Assurance Level (SWAL)" should be included.			
		ng of the AMC/GM a definition for what should ce Level (SWAL)" should be included. The ED153		
response	Accepted			
	Considering the comment, the text ha	as been amended to address the proposal.		
comment	196	comment by: AESA/DSANA		
	The need of a "documented software assurance process" should be more evident and unambiguous. It is considered that requirements about defining and establishing SW safety assessment and assurance procedures should be stated as an AMC of ATM/ANS.OR.B.010 (a) "Change management procedures". Additionally, in that framework of pre-established a approved SW procedures, criteria about how to define a software oversight strategy and guidelines to include it in the notification should be developed by the service providers in their documented procedures.			
		understanding of the requirements, as an AMC e stated that "The service provider should have		

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	documented software assurance processes to assure the introduction of new software or the modification to existing software included in a change to a functional system." Also at this level could be moved the wording: "Those processes are necessary to produce evidence and arguments that demonstrate that the software behaves as intended (software requirements), with a level of confidence consistent with the criticality of the required application." These procedures should be under approval of the Competent Authority, like the rest of change management procedures. Hence, it is proposed to rely the software oversight strategies on proper defined procedures of both sides the NSA (notification and oversight procedures) and the ANSPs (documented procedures of software assurance).
response	Not accepted
	It was considered more relevant to maintain the link with the functional system and the associated changes rather to include it as part of the service provider's management system. It is noted that the software assurance processes might also be at the level of the system suppliers.
comment	211 comment by: European Transport Workers Federation - ETF
	ETF calls for transparency by ANSPs and system manufacturers to make this feedback
	effective. ETF believes it would be useful to include a regulatory requirement to establish a responsibility by system manufacturers on the system provided during the time of implementation and if a problem stemming from this occurs, the associated update to the system should be done by system manufacturers with no additional costs.
response	Noted
	The comment is duly noted that is outside the scope of the proposed set of AMC & GM. $% \left({\left {{{\rm{GM}}} \right _{\rm{T}}} \right)$
comment	232 comment by: NATS
connent	para (b) The wording as stated places the confirmation of the SWAL allocation and rigour of the SWAL processes on the Service Provider, "when applicable", when SWAL is an ATS provider concept. Impact: As currently stated this is likely to cause confusion, especially in cases where the service provider has no concept of SWAL. The service provider should be using software experience to confirms that (their) software assurance processes are effective and can provide data to confirm that the SWAL is appropriate (rather than

providing confirmation themselves). **Suggestion:** Suggest amending the wording to remove the implied need for the service provider to confirm the allocated SWAL and rigour of the allocated SWAL.

response Accepted

Considering the comment, the text has been amended.



comment	279 comment by: CANSO
	AMC5 ATM.OR.C.005(a)(2)(b),
	The wording as stated places the confirmation of the SWAL allocation and rigour of the SWAL processes on the Service Provider, "when applicable", when SWAL is an ATS provider concept.
	Impact: As currently stated this is likely to cause confusion, especially in cases where the service provider has no concept of SWAL. The service provider should be using software experience to confirms that (their) software assurance processes are effective and can provide data to confirm that the SWAL is appropriate (rather than providing confirmation themselves).
	Suggestion: Suggest amending the wording to remove the implied need for the service provider to confirm the allocated SWAL and rigour of the allocated SWAL.
response	Accepted
	Considering the comment, the text has been amended.
comment	288 comment by: ASD/Thales Air Systems
	It is not clear why the concept of safety <u>support</u> assessement is introduced specifically in SUBPART C (and is not mentionned in SUBPART A which contains the same requirements). At least, this concept should be clearly defined.
response	Noted
	The comment is noted.
	It should be pointed out that the set of AMC & GM follows the order of the requirements as laid down in Regulation (EU) 2017/373, which is not subject to this consultation.
comment	291 comment by: ASD/Thales Air Systems
	AMC5 (b): " and, when applicable , the allocated SWAL" criteria of applicability is not clear and needs to be clarified.
response	Partially accepted
	Considering the comment, the text has been amended to clarify the message that it refers more to the usage than the applicability.
comment	299 comment by: UK CAA
	Comments:
	Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE.



Most of these points (see below) are covered by AMC/GM related to ATM/ANS.OR.B.005, B.010 & C.005 Noted response The comment is duly noted. However, EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities. 300 comment comment by: UK CAA AMC5 ATM/ANS.OR.C.005(a)(2), point (a) Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.B.010 (a) ATM/ANS.OR.C.005 (a)(2) **Comments:** SW is part of a functional system. Before changing any part of a functional system the service provider must ensure that the procedures to be used are approved by the CA. This is covered in ATM/ANS.OR.B.010. response Not accepted It was considered more relevant to maintain the link with the functional system and the associated changes rather to include it as part of the service provider's management system. It is noted that the software assurance processes might also be at the level of the system suppliers. comment 301 comment by: UK CAA AMC5 ATM/ANS.OR.C.005(a)(2) point (b) Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.B.005 (a)(4), (c) & (d) ATM/ANS.OR.B.010 (b) & (c) **Comments:** The management system rules cover the reporting, analysis and correction of failures of the functional system and adequate performance of procedures. They cover the complete functional system and change management procedures and therefore, by definition, cover software. Noted response It should be pointed out that the level of granularity would not be enough in order to confirm the effectiveness of the software assurance process. Based on this specific



need, it is considered necessary to provide additional guidance compared with the general one at functional system level.

AMC6 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the p. 10-11 functional system

comment	16 comment by: D Winship
	para (a) (1) (i) Software requirements "correct, complete and compliant with the upper level requirements" Use of "compliantupper level" requirements implies a multi-layered requirements set which may, or may not be, the case. The different levels of system/software requirements should be consistent, coherent and 'aligned with', rather than 'compliant with', each other (as compliance is normally verified <i>for</i> each requirement as opposed to <i>between</i> different levels of requirements).
	Replacing this text with "aligned with the system requirements" would appear to be more appropriate.
response	Not accepted
	It is considered preferable to keep the current wording in order to allow this multi- layered software architecture, as it is the case in most of the current implementations.
comment	18 comment by: D Winship
	section a(5) "following verification methodsagreed with the CA" – It is essential to recognise that the CA focus is on the adequacy of the verification results/assurance – it is neither practical, achievable or desirable for the CA to

It is essential to recognise that the CA focus is on the adequacy of the verification results/assurance – it is neither practical, achievable or desirable for the CA to engage in approving "verification methods" for individual changes. In addition, the text as written doesn't take into account the reality that, in most projects, much of the software is not unique or custom designed specifically for a single service provider – some of the verification work on core functionality may have been completed long before the service provider and CA became involved (i.e. re-used software from other projects). Some of the results of this earlier verification activity could be permissible as evidence (e.g. 'core' algorithm testing) even though the CA hasn't been engaged in agreeing the "verification method".

This text should be reconsidered – the original text from 482 (with NSA replaced by CA) appears more appropriate.

"The EATMN software shall be adequately verified by analysis and/or testing and/or equivalent means, as agreed with the..."

response Accepted



The commented provision has been amended following the suggestion to align with Regulation (EC) No 482/2008.

comment	32 comment by: ENAIRE
	Regarding "software resource usage on the target hardware" there is the following potential interpretation: Hardware resource usage on the target hardware could be excluded. I.e. The number of CPU cores required by the software or the I/o interface types available to the software.
	Problem arising: Hardware resource may not be verified as complete and correct. Especially when dealing with COTS or unintended software as these may cause the software to function unexpectedly when different hardware configurations are used.
	Suggested improvement: Either of the following would solve the problem:
	 Remove the Word software to leave to following "accuracy, resource usage on the target hardware"
	or
	 Add hardware leaving the following " accuracy, software and hardware resource usage on the target hardware"
response	Accepted
	The commented provision has been amended following the first suggestion of the commentator.
comment	33 comment by: ENAIRE
	Regarding the sentence "if a requirement cannot be traced", there is the following potential interpretation: Software requirements may be tagged as safety or integrity requirements because its parent requirement (the upper level requirement it traces to) is tagged as safety or integrity related. Therefore a software requirement that does not trace to a requirement above may never be identified as software safety or integrity requirement.
	Problem arising: Any software fix implemented in order to solve a problem reported from testing at a higher level, should require the retest of all affected requirements (i.e. all requirements that trace to the requirement associated with the problem) should be verified as not being affected. Any requirement without traceability will never benefit from this relationship and potential fault may be overlooked.
	Suggested improvement: Add de following: Nevertheless all requirements determined as potentially affecting safety, if not implemented correctly or completely, should be traced to a corresponding upper level requirement.



response	Not accepted
	It should be pointed out that the concept of derived (non-traced) requirements is not only applicable to safety integrity requirements. Even in Regulation (EC) No 482/2008, it is necessary to ensure that the software implementation does not have a safety impact. Based on that, any non-traced requirement should be justified and assessed as non-impacting either the satisfaction of the safety requirements or safety support requirements, as appropriate.
comment	34 comment by: ENAIRE
	Regarding AMC6 ATM/ANS.OR.C.005(a)(2) - (a)(5) "The verification of the software is correct an complete, following verification methods", there is the following potential interpretation: This can mean that the objective is to determine if the verification process is correct and not that the Software being verified is complete and correct.
	Problem arising: The result of applying the objective as read means that the verification process could be correct and complete but the software being verified may not.
	Suggested improvement: Change to the following: "The verification that the software is correct and complete,"
response	Not accepted
	It should be pointed out that the correctness and completeness refer to the software verification.
	The text as it stands states 'the software verification is correct and complete'
comment	35 comment by: ENAIRE
	AMC6 ATM/ANS.OR.C.005(a)(2) - (f)(6) "monitoring": Potential interpretation: This could be read that a software could be put into operation, monitored, and then an argument be established.
	Problem arising: Monitoring can only happen during operation. Therefore using monitoring in order to argue that a product meets a desired rigour could mean that the software could be used during a period without an established argument.
	Suggested improvement: Suggest removing monitoring as existing service level experience should cover the same. If monitoring is used for proving that the rigour argument is correct then this is covered by "AMC5 ATM/ANS.OR.C.005 (a)(2) – (b)".
response	Not accepted
	It should be highlighted that they are complementary mitigation ways, one based on the assurance level and the other highlighting some safety or safety support


requirements derived from the need of monitoring a particular COTS. Therefore, it is preferable to keep the wording as initially proposed.

52 comment by: CANSO
(1)(ii) specify the functional behaviour, in nominal and downgraded modes, timing performances, capacity, accuracy, <u>software resource usage on the target hardware</u> , robustness to abnormal operating conditions and overload tolerance, as appropriate, of the software.
Potential interpretation of (1) (ii): Hardware resource usage on the target hardware could be excluded. I.e. The number of CPU cores required by the software or the I/o interface types available to the software.
Issue: Hardware resource may not be verified as complete and correct. Especially when dealing with COTS or unintended software as these may cause the software to function unexpectedly when different hardware configurations are used.
Suggested improvement: Either of the following would solve the problem: Remove the Word software to leave to following "accuracy, resource usage on the target hardware" Or Add hardware leaving the following "accuracy", software and hardware
Accepted
The text has been amended considering the first proposal.
55 comment by: <i>CANSO</i>
(f) (6) Potential interpretation: This could be read that a software could be put into operation, monitored, and then an argument be established.
Issue: Monitoring can only be done during operation. Therefore using monitoring in order to argue that a product meets the desired rigour could mean that the software could be used during a period without an established argument.
Suggested improvement: We suggest to remove '(6) monitoring' as existing service level experience should cover the same. If monitoring is used for proving that the rigour argument is correct then this is covered by "AMC5 ATM/ANS.OR.C.005 (a)(2) – (b)".



response	Not accepted
	It should be highlighted that they are complementary mitigation ways, one based on the assurance level and the other highlighting some safety or safety support requirements derived from the need of monitoring a particular COTS. Therefore, it is preferable to keep the wording as initially proposed.
comment	60 comment by: CANSO
	Pages 10-14 In some specific cases, for instance, meteorological services, the assessment of the software providing the service support is out of the managerial control scope from the ANSP. Therefore, software assessment of support services can't be assessed by the ANSP. => The following sentence is proposed for amendment and should be added in each concerned AMC (see below): In case the support is out of the definition and/or managerial control scope, the safety support assessment will be specifically not foreseen.
response	Not accepted
	It should be highlighted that in the current regulatory framework, the software aspects are covered in detail through Regulation (EC) No 482/2008, which applies to any changes to the software of the systems for air traffic services (ATS), airspace management (ASM), air traffic flow management (ATFM), i.e. air traffic management (ATM) and communication, navigation, or surveillance (CNS). Additionally, the software aspects for aeronautical information services (AIS) provision are included in Regulation (EU) No 73/2010. On the other hand, it is acknowledged that the MET providers will be affected as regards the software assurance AMC & GM.
	EASA considers that some of the service providers other than the ones that are subject to Regulation (EC) No 482/2008 today have a contribution to software (e.g. MET providers, FPD) and in order EASA to take an informed decision, a specific meeting with other stakeholders was organised to address this issue (among others). The discussion clearly concluded that some features of the MET systems are affected by the current regulatory requirements, which also supports the approach taken for the proposed set of AMC & GM; that is, to apply for all service providers of ATM/ANS, including AIS and MET providers, towards software assurance level standardisation.
comment	67 comment by: CANSO
	Remark: Item (b) is missing.
response	Accepted
	The text has been amended accordingly.



comment	68 comment by: CANSO
	Remark: Items (f)(1), (f)(2),(f)(3) are missing.
response	Accepted
	The text has been amended accordingly.
comment	114 comment by: ENAV
	Remark: Sentence of item (2)(i) seems to be ambiguous and clarification is expected. => The following sentence is proposed for amendment: (i) Each software requirement introduced at each level in the design lifecycle should be traced to the same level of design lifecycle at which its satisfaction is demonstrated.
response	Partially accepted
	Considering the comment the text has been amended to promote clarity.
	However, it should be noted that the proposed solution was different from the original text and the intent of the rule.
comment	115 comment by: ENAV
	Remark: Item (b) is missing. Items (f)(1), (f)(2),(f)(3) are missing.
response	Accepted
	The text has been amended accordingly.
comment	116 comment by: ENAV
	§3.1 Annexe III, subpart C AMC5 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system
	- As stated in explanatory note on NPA 2014-13 "While today CNS providers are seen to try to comply with these requirements, they cannot always do so. This is because CNS providers, as other non-ATS providers, do not have a dynamic view of the use of the service and, therefore, cannot intervene in order to alter a developing situation. Furthermore, the non-ATS provider may not know how the service it offers is being used by the ATS provider, either in normal circumstances or in circumstances where immediate intervention is necessary in order to maintain safety". Therefore, service providers other than ATS providers can not assess the software "criticality of the required application" as described at the end of item (a). Service providers other than ATS providers can only assess the PERFORMANCE of the service providers other than ATS providers can only assess the PERFORMANCE of the



	In the same spirit of previous comment, considering that service providers other than ATS providers are not the user of the software, it is not possible for them to realize a feedback of software experience, => These items shall be deleted on this AMC or modified to address PERFORMANCE instead of safety
response	Accepted
	Considering the comment, amendments have been made to the text.
	However, it is necessary to clarify two aspects:
	- Service providers other than ATS providers can assess the satisfaction of the service requirements (not only the performance, understood as performance requirements).
	- Service providers other than ATS are users of the software (at least, they should monitor the service and the system status) and, hence, they have information to provide feedback on software experience.
comment	117 comment by: ENAV
	<u>Remark:</u> Sentence of item (2)(i) seems to be ambiguous and clarification is expected. => The following sentence is proposed for amendment: (i) Each software requirement introduced at each level in the design lifecycle should be traced to the same level of design lifecycle at which its satisfaction is demonstrated.
response	Partially accepted
	Considering the comment, the text has been amended to promote clarity.
	However, it should be noted that the proposed solution was different from the original text and the intent of the rule.
comment	134 comment by: <i>LFV</i>
	Bullet number b) is missing.
response	Accepted
	The text has been amended accordingly.
comment	141 comment by: CANSO
	Remark: Sentence of item (2)(i) seems to be ambiguous and clarification is expected. => The following sentence is proposed for amendment: (i) Each software requirement introduced at each level in the design lifecycle should be traced to the same level of design lifecycle at which its satisfaction is demonstrated.



response	Partially accepted
	Considering the comment, the text has been amended to promote clarity.
	However, it should be noted that the proposed solution was different from the original text and the intent of the rule.
comment	144 comment by: DSNA
	In some specific cases, some Risk Mitigation Means are foreseen in order to be a response for some hazards. These Risk Mitigation Means could be considered as an acceptable alternative way instead of software safety support assessment. => The following sentence is proposed for amendment and should be added : "An acceptable alternative way for software safety support assessment could be the demonstration of existence of adequate Risk Mitigation Means."
response	<i>Not accepted</i> The term 'software safety support assessment' is not used in the proposed set of AMC & GM.
comment	161 comment by: DSNA
	In some specific cases, for instance, meteorological services, the assessment of the software providing the service support is out of the managerial control scope from the ANSP. Therefore, software assessment of support services can't be assessed by the ANSP.
	The following sentence is proposed for amendment:
	In case the support is out of the definition and/or managerial control scope, the safety support assessment will be specifically not foreseen.
response	Not accepted
	It should be highlighted that in the current regulatory framework, the software aspects are covered in detail through Regulation (EC) No 482/2008, which applies to any changes to the software of the systems for air traffic services (ATS), airspace management (ASM), air traffic flow management (ATFM), i.e. air traffic management (ATM) and communication, navigation, or surveillance (CNS). Additionally, the software aspects for aeronautical information services (AIS) provision are included in Regulation (EU) No 73/2010. On the other hand, it is acknowledged that the MET providers will be affected as regards the software assurance AMC & GM.
	EASA considers that some of the service providers other than the ones that are subject to Regulation (EC) No 482/2008 today have a contribution to software (e.g. MET providers, FPD) and in order EASA to take an informed decision, a specific meeting with other stakeholders was organised to address this issue (among others). The discussion clearly concluded that some features of the MET systems are affected by the current regulatory requirements, which also supports the approach taken for

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the proposed set of AMC & GM; that is, to apply for all service providers of ATM/ANS, including AIS and MET providers, towards software assurance level standardisation. In addition, the AMC could not elevate an objective laid down in the rule. comment 162 comment by: DSNA Justification of "derived" requirements (e.g no traced to upper level) is state of the art and in line with ED109A. Assessing that it does not affect the satisfaction of the safety requierements goes beyond the existing industrial standards In point (2) (ii). Please change : "If a requirement cannot be traced to any upper level requirement, its need should be justified and assessed that it does not affect the satisfaction of the safety requirements allocated to the component" Into "If a requirement cannot be traced to any upper level requirement, its need should justified" be (remove text after "justified") response Not accepted It is considered relevant to address the main criteria to be used for the justification (and acceptance) of the requirement. Removing this information could open the door to other criteria which might not be consistent with the intended purpose. comment 163 comment by: DSNA As stated in item (a)(1)(ii), one may understand that the demonstration is covering all the software. Actually, the demonstration should only cover the scope of the change. => following The sentence is proposed for amendment: (a)(1)(ii) specify in the scope of the change, the functional behaviour, in nominal and downgraded modes, timing performances, capacity, accuracy, software resource usage on the target hardware, robustness to abnormal operating conditions and overload tolerance, as appropriate, of the **new software or modified** software **part**.

response Not accepted

It must be highlighted that the requirement refers to features requested in the software assurance process. They can be applied for a particular change but the processes should be change-independent.

comment	164 comment by: DSNA
	Sentence of item (2)(i) seems to be ambiguous and clarification is expected.
	=> The following sentence is proposed for amendment:
	"(i) Each software requirement introduced at each level in the design lifecycle should be traced to the same level of design lifecycle at which its satisfaction is
	demonstrated."
	Development

response | Partially accepted



Considering the comment, the text has been amended to promote clarity.

However, it should be noted that the proposed solution was different from the original text and the intent of the rule.

comment	165 comment by: DSNA
	Item (b) is missing.
response	Accepted
comment	166 comment by: DSNA
	Items (f)(1), (f)(2),(f)(3) are missing.
response	Accepted
comment	180 comment by: DSNA
	In some specific cases, for instance, meteorological services, the assessment of the software providing the service support is out of the managerial control scope from the ANSP. Therefore, software assessment of support services can't be assessed by the ANSP. => The following sentence is proposed for amendment and should be added :
	"In case the support is out of the definition and/or managerial control scope, the safety support assessment will be specifically not foreseen."
response	Not accepted
	It should be highlighted that in the current regulatory framework, the software aspects are covered in detail through Regulation (EC) No 482/2008, which applies to any changes to the software of the systems for air traffic services (ATS), airspace management (ASM), air traffic flow management (ATFM), i.e. air traffic management (ATM) and communication, navigation, or surveillance (CNS). Additionally, the software aspects for aeronautical information services (AIS) provision are included in Regulation (EU) No 73/2010. On the other hand, it is acknowledged that the MET providers will be affected as regards the software assurance AMC & GM.
	EASA considers that some of the service providers other than the ones that are subject to Regulation (EC) No 482/2008 today have a contribution to software (e.g. MET providers, FPD) and in order EASA to take an informed decision, a specific meeting with other stakeholders was organised to address this issue (among others). The discussion clearly concluded that some features of the MET systems are affected by the current regulatory requirements, which also supports the approach taken for the proposed set of AMC & GM; that is, to apply for all service providers of ATM/ANS, including AIS and MET providers, towards software assurance level standardisation.

comment 193

comment by: AESA/DSANA



	SW legacy, referred to as used software in EC 482/2008 and as previously developed software in this NPA needs to be defined. What is the reason for changing "used SW" for "previously developed SW" which seems to be more general? NSAs are not notified of SW development unless the software is expected to be in operational service. What has to be done with previously existing SW at which this NPA would apply and at which the former Regulation (EC) No 482/2008 did not?
	Time indications on what to consider SW legacy s are lost when repealing Regulation (EC) No 482/2008 as long as they were gathered in its article 7 : Article 7 Entry into force This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union. It shall apply from 1 January 2009 to the new software of EATMN systems referred to in Article 1(2), first subparagraph. It shall apply from 1 July 2010 to any changes to the software of EATMN systems referred to in Article 1(2), first subparagraph, in operation by that date.
response	Noted
	It should be noted that Regulation (EC) No 482/2008 entered into force in 2010 and, hence, after several years of application, it is understood that the concept of software legacy does not require a particular treatment. Consequently, any new software or modifications to existing software should follow the software assurance processes.
comment	197 comment by: AESA/DSANA
comment	197 comment by: AESA/DSANA Renumbering is required.
comment	
comment	Renumbering is required.
	Renumbering is required. Errata in number scheme. There is no (b) in the main scheme.
	Renumbering is required. Errata in number scheme. There is no (b) in the main scheme.
response	Renumbering is required. Errata in number scheme. There is no (b) in the main scheme. Accepted
response	Renumbering is required. Errata in number scheme. There is no (b) in the main scheme. Accepted 198 comment by: AESA/DSANA
response	Renumbering is required. Errata in number scheme. There is no (b) in the main scheme. Accepted 198 Comment by: AESA/DSANA A definition of "Configuration data" should be included. For the sake of a better understanding of the AMC/GM, a definition of what should it be understood by "Configuration Data" should be introduced. The ED153 definition
response comment	Renumbering is required. Errata in number scheme. There is no (b) in the main scheme. Accepted 198 comment by: AESA/DSANA A definition of "Configuration data" should be included. For the sake of a better understanding of the AMC/GM, a definition of what should it be understood by "Configuration Data" should be introduced. The ED153 definition is proposed.
response comment response	Renumbering is required. Errata in number scheme. There is no (b) in the main scheme. Accepted 198 comment by: AESA/DSANA A definition of "Configuration data" should be included. For the sake of a better understanding of the AMC/GM, a definition of what should it be understood by "Configuration Data" should be introduced. The ED153 definition is proposed. Accepted Considering the comment, the text has been amended.
response comment	Renumbering is required. Errata in number scheme. There is no (b) in the main scheme. Accepted 198 comment by: AESA/DSANA A definition of "Configuration data" should be included. For the sake of a better understanding of the AMC/GM, a definition of what should it be understood by "Configuration Data" should be introduced. The ED153 definition is proposed. Accepted



For the sake of a better understanding of the AMC/GM, a definition of what should it be understood by "Commercial Off The Shelf (COTS)" should be introduced. The ED153 definition is proposed. response Accepted Considering the comment, the text has been amended. comment 204 comment by: AESA/DSANA Guidelines to clarify which is the purpose of a set of SWALs and to establish that the service provider should define its own set of SWALs, should be included. No requirement is included for service providers to define its own set of SWALs in its own procedures. In the same way that a "severity (classification) scheme" is addressed in "GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system", even if non SWAL classification is adopted, at least the indication that each service provider should define its own set of SWALs and also the explanation of what is expected from а set of SWALs should be made. It is considered that the Software Assurance Processes and the Software Assurance Levels of an organization should be defined in its procedures before the organization starts providing its service. An AMC related to "ATM/ANS.OR.B.010 Change management procedures" should be established in order to clarify this issue. Not accepted response It was considered more relevant to maintain the link with the functional system and the associated changes rather to include it as part of the service provider's management system. It is noted that the software assurance processes might also be at the level of the system suppliers. 205 comment comment by: European Transport Workers Federation - ETF ETF notes that a bullet (b) is missing. response Accepted Considering the comment, the text has been amended. comment 207 comment by: European Transport Workers Federation - ETF p10 : non-ATS services AMC6 (a)(2)(ii) Is the difference intended ? Each software requirement [...] should From a regulatory perspective, it does **be traced** to an upper level requirement not seem to create any difference in the provision or at least we do not [...] understand it.



	p15 : ATS services : AMC4 (a)(2)(ii) Ea software requirement [] is traced to an upper level requirement []	ch
response	Accepted	
	The text has been amended to addres	s the inconsistency.
comment	208 comment	by: European Transport Workers Federation - ETF
	p11 : non-ATS services : AMC6 (f) [] If no sufficient assurance can be provided [] p16 : ATS services : AMC4 (e) [] If no sufficient assurance may be provided []	Is the difference intended ? From a regulatory perspective, it does not seem to create any difference in the provision or at least we do not understand it.
response	Accepted	
	The text has been amended to addres	s the inconsistency.
comment	215	comment by: <i>DSAC - FR NSA</i>
	In paragraph (a)(3), the demonstration that the software implementation contains no functions which adversely affect safety may be difficult to achieve especially for COTS. This paragraph may be rephrased as "the functions contained in the software implementation do not adversely affect safety".	
response	Not accepted	
	highlighted in point (f) of the AMC. Th	ss can be defined by the service provider as e reference to the software implementation is se of the COTS, where activated functions need at on safety or service specifications.



Para (a) (2) (ii) The first sentence establishes a requirement. The second pr requirement for when the first requirement cannot be met. The commas in sentence make unclear what the qualifier "at which its satisfaction is demor	
applies to. The last sentence introduces a "component" without defining v component is.	nstrated"
Impact: Ambiguity as to what the first statement means and whether it must be met. Ambiguity in the second sentence as to what the requirement assessed against. Suggested wording: "Each software requirement allocated to a component EITHER be traced to an upper level requirement OR its need should be just the requirement assessed to ensure that it does not affect the satisfaction safety requirements allocated to the component.	must be nt should ified and
response Accepted	
Considering the comment, the text has been amended.	
comment 235 comment	by: NATS
para (a) (3) The requirement is too restrictive. For instance a training mode is the software may adversely affect safety if enabled during operation, but th risk if this mode is effectively disabled. It is also not clear what the "s implementation" is: does it mean the source code or the executable? This because compile-time switches can be used to disable functions that were is the source code.	iere is no software matters
Impact: Service providers will be forced to develop multiple versions products with overlapping functionality, increasing costs without improving Suggested resolution: Replace with "Any functions of the software th adversely affect safety are disabled".	g safety.
response Not accepted	
It is considered that the current wording is appropriate for the case mentic offers the possibility to include disabled elements in the software implement provided that the disabling mechanism is appropriate.	
comment 237 comment	by: NATS
para (f) The sub-paragraphs are numbered $4-6$ not $1-3$. This could cause constants Suggest renumber the sub paragraphs	onfusion.
response Accepted	
Considering the comment, the text has been amended.	
comment 238 comment	by: ΝΔΤ ς

comment 238

comment by: NATS



	para (c) (1) "a known executable version of the software" seems too imprecise; the "known" version should be the one that is to be deployed into operation. Suggest: rewording to "the executable version of the software which is to be deployed into operation" Similar changes should be made to (2) and (3) of clause (c)
response	Not accepted
	It should be considered that the verification activities can be based on several (known) versions of the software, without mandatorily being the last one. An assessment of the versions evolutions might allow to take credit of the verification in previous versions of particular requirements, subject to a non-regression policy.
comment	240 comment by: NATS
	 par (a) (1) (ii) Although a straight copy of the EC 482/2008 requirement the concept of "software resource usage on target hardware" is not required. It could be argued that to meet the other software requirements as stated (such as performance and overload tolerance) "software resource usage" must be met. Impact: Difficult to specify and meet especially for software deployed within a virtualised environment. Suggest the removal of the statement "software resource usage on target hardware" from the list.
response	Partially accepted
	The text has been amended considering also other comments and the word 'software' has been removed.
comment	241 comment by: NATS
	para (a) (2) (ii) The text as stated refers to non interference with the safety requirements allocated to the component. Whilst this is technically correct a service provider may not recognise a 'safety requirement' on their service provision Impact: Lack of clarity across service provision boundary with respect to performance/integrity requirements that support safety requirements. Suggestion: Removal of the term "safety" from the statement to become "does not affect the satisfaction of the requirements allocated to the component".
response	Accepted
	Considering the comment, the text has been amended.
	242
comment	242 comment by: NATS
	para (a) (3) The service provider may not have any knowledge of how their service is to be used, and may not be in the position to know how their software implementation could "affect safety". Issue: Impact assessment may not occur or may be inappropriate from a safety perspective.



	Suggested resolution: More generically this is a non-interference statement, and therefore should state "which adversely affect other software functions"
response	Accepted
	It is noted that the proposal made by the commentator does not refer to the potential effect on safety or service specification but on the non-interference. The associated paragraph is intended to avoid particular functions in the software that might have an impact on safety. This would require the implementation of reliable disabling mechanisms for those functions that should remain in the software although not active operationally.
comment	243 comment by: NATS
	para (a) (4) Although a straight copy of the EC 482/2008 requirement the concept of "software resource usage on target hardware" is not required. It could be argued that to meet the other software requirements as stated (such as performance and overload tolerance) "software resource usage" must be met. Impact: Difficult to specify and meet especially for software deployed within a virtualised environment. Resolution: Suggest the removal of the statement "software resource usage on target hardware" from the list.
response	Accepted
	Considering the comment, the text has been amended.
comment	244 comment by: NATS
	para (a) (5) Its unclear as to the scope of the agreement with respect to verification with the CA i.e. is the intention a strategy or a requirement by requirement verification method or selection from an agreed set of verification methods? Impact: Potential inconsistency of application. Effort required from CA associated with agreeing software verification approach. Resolution: Clarification with regards to the intention of the statement.
response	Accepted
	This potential misunderstanding has been acknowledged, leading to the possible understanding that the verification methods shall be subject to approval by the competent authority. The intention of the paragraph was to focus the approval of the competent authority on the equivalent means. Rewording of this paragraph has been introduced.
comment	245 comment by: NATS
	 (c) List item (b) is either missing or item (c) should be modified (along with following list items) to be item (b) etc. Issue: Integrity of requirement Suggest modifying as appropriate



response	Accepted
	Considering the comment, the text has been amended.
comment	246 comment by: NATS
	 para (c) As written there is no means to use arguments or evidence from previous versions of software if suitably justified. Impact: Unnecessary re-generation of assurance evidence, with associated cost. Suggested resolution: Modify (3) to read "that have been used in the production of that version, or can be justified as applicable to that version.'
response	Accepted
	Considering the comment, the text has been amended.
comment	247 comment by: NATS
comment	 para (f) It is not necessarily true that "generic assurance processes cannot be applied" to COTS, NDS or PDS. It is however unlikely Impact: the inference that generic assurance approach is not applicable to these types of software. suggested resolution: Modify "generic assurance processes cannot be applied" to "generic assurance processes may not be applicable"
response	Not accepted
	It was considered more relevant to keep the current wording to highlight the impossibility to apply the generic assurance process. There would be some COTS or NDS where the generic assurance process is possible and can be provided by the COTS supplier.
comment	248 comment by: NATS
	Para (f) Modify last sentence for readability. Issue: Needs clarity Suggestion: Modify to read "If sufficient assurance cannot be provided, complementary"
response	Accepted
	Considering the comment, the text has been amended.
comment	249 comment by: NATS
	para (f) In themselves neither "existing service level experience" nor "monitoring" are a "mitigation means aiming at decreasing the impact of specific failure modes of this type of software", whereas software/system architectural considerations are. Impact: Confusion between failure mode mitigation and means of addressing assurance shortfalls. General clarity.



	Suggestion: Reword preceding text to read "If sufficient assurance cannot be provided, complementary mitigation should be applied. This may include but is not limited to:"
response	Not accepted
	It is to be noted that the three cases presented would belong to the mitigation of specific failure modes pre- and post-implementation. Therefore, the current wording is maintained.
comment	281 comment by: CANSO
	AMC6 ATM/ANS.OR.C.005(a)(2) para (a) (2) (ii) The first sentence establishes a requirement. The second provides a requirement for when the first requirement cannot be met. The commas in the first sentence make unclear what the qualifier "at which its satisfaction is demonstrated" applies to. The last sentence introduces a "component" without defining what this component is. Impact: Ambiguity as to what the first statement means and whether it must actually
	be met. Ambiguity in the second sentence as to what the requirement must be assessed against.
	Suggestion: Suggested wording: "Each software requirement allocated to a component should EITHER be traced to an upper level requirement OR its need should be justified and the requirement assessed to ensure that it does not affect the satisfaction of the safety requirements allocated to the component.
response	Accepted
	Considering the comment, the text has been amended.
comment	285 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)
	Open-source (eg. Linux) should to be mentioned,
	The software assurance process should address (wher security in the context that the

The software assurance process should address Cyber security in the context that the ANSP has to verify that the software is resilient and checked against harmful software.

response Partially accepted

As regards 'open source' software, it is considered preferable not to mention it explicitly due to the particular considerations in the possible usage of open source. The example presented by the commentator could be subject of confusion as the ANSPs are using Linux implementations supplied by software suppliers, belonging to the COTS domain.

As regards 'cyber security' aspects, the point has been taken and discussed in specific sessions with stakeholders. It has been concluded that this should not be addressed in the frame of this set of AMC & GM. A transversal regulatory activity to all the



domains is under development and the cyber security aspects will be better covered in that way. 286 comment comment by: ASD/Thales Air Systems In the item (a)(1)(ii), it is mentionned "specify the functional behaviour in ... downgraded modes ..." and later "... robustness to abnormal operating conditions ...". What is the difference between the 2 points? It seems that these 2 points are redundant o at least linked since requirements on "downgraded modes" cover "robustness to abnormal operating conditions". May be the last part of the sentence could be used as an example of downgraded mode. response Noted The comment is duly noted. Downgraded modes might correspond to a situation in which the software provides lower performances but works under normal operating conditions. Then, both concepts are separate and would need to be maintained in this way. comment 289 comment by: ASD/Thales Air Systems In AMC6, item (b) is missing. response Accepted The text has been amended. 296 comment comment by: UK CAA Page No: 10/11 Paragraph No: AMC6 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system 'ASSURANCE - SOFTWARE ASSURANCE PROCESSES' **Comment:** The draft text jumps from paragraph (a)(5) to paragraph (c). It is questioned whether paragraph (b) is missing or the subsequent paragraphs are erroneously numbered. Justification: Missing text or erroneous paragraph numbering. **Proposed Text:** Renumber paragraphs after paragraph (a)(5) Accepted response comment 302 comment by: UK CAA

AMC6 ATM/ANS.OR.C.005(a)(2)



	Equivalent coverage in EC 2017/373 text: —
	Comments: Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE. Most of these points (see below) are covered by AMC/GM related to ATM/ANS.OR.C.005 This section is out of context. Processes are dealt with in ATM/ANS.OR.B.010 and its associated AMC/GM. This section of the IR and its associated AMC/GM deals with the criteria for safety support assurance cases and not the processes that created a safety support case.
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	303 comment by: UK CAA
	AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(1)(i) See also:# AMC4 ATS.OR.205(a)(2), point (a)(1)(i)
	Equivalent coverage in EC 2017/373 text: <u>AMC2 ATM/ANS.OR.C.005(a)(2)</u> (b), (c), (d)
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	304 comment by: UK CAA
	AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(1)(ii)
	Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.C.005(a)(1)(v) GM3 ATM/ANS.OR.C.005(a)(2) (a)
response	Noted
	The comment is duly noted.



EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.

comment	305 comment by: UK CAA
	AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(2)(i)
	Equivalent coverage in EC 2017/373 text: AMC2 ATM/ANS.OR.C.005(a)(2) (d)
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the
	particularities and specificities of the software-related activities.
comment	306 comment by: UK CAA
comment	AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(2)(ii)
	Equivalent coverage in EC 2017/373 text: AMC2 ATM/ANS.OR.C.005(a)(2) (d)
response	Noted
·	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	307 comment by: UK CAA
	AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(3)
	Equivalent coverage in EC 2017/373 text: N/A
	Comments: Incorrect: There is no view of safety in Annex III text
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.

comment 308

comment by: UK CAA



	AMC6 ATM/ANS.OR.C.005(a)(2) point (a)(4)
	Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.C.005 (a)(1)(ii) <u>AMC1 ATM/ANS.OR.C.005(b)(1) (</u> h)
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	309 comment by: UK CAA
	AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(5)
	Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.C.005 (a)(2), (b)(1) AMC1 ATM/ANS.OR.C.005(b)(1)
	Comments: The procedures for verification are covered in ATM/ANS.OR.B.010 and its associated AMC/GM and will have been agreed with the CA prior to their use.
response	Accepted
	Considering the comment, the text has been amended.
comment	310 comment by: UK CAA
	AMC6 ATM/ANS.OR.C.005(a)(2) point (c)
	Equivalent coverage in EC 2017/373 text: AMC2 ATM/ANS.OR.C.005(a)(2) (f)
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	311 comment by: UK CAA
	AMC6 ATM/ANS.OR.C.005(a)(2) point (d) See also: GM1 to AMC6 ATM/ANS.OR.C.005(a)(2) points (a) (b) & (c) GM2 to AMC6 ATM/ANS.OR.C.005(a)(2) points (a), (b), (c) & (d)



	Equivalent coverage in EC 2017/373 text: N/A
	Comments: The concept of rigour is not used in the IR, confidence is used. Assurance levels are used in Regulation (EC) No 482/2008 to determine 'the rigour to which the assurances are established'. This can only be understood as a means to provide the required level of confidence. Hence this clause is incorrect.
response	Accepted
	Considering the comment, the text has been amended.
omment	312 comment by: UK CAA
	AMC6 ATM/ANS.OR.C.005(a)(2), point (e)(1)
	Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.B.030 (a), (b) & (c). AMC2 ATM/ANS.OR.C.005(a)(2) (f)
ocnonce	Noted
eshouse	
eshouse	The comment is duly noted.
eshouze	
	The comment is duly noted. EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
	The comment is duly noted. EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	The comment is duly noted. EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities. 313 comment by: UK CAA
	The comment is duly noted. EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities. 313 comment by: UK CAA AMC6 ATM/ANS.OR.C.005(a)(2), point (e)(2) Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.B.005 (a)(4), (c) & (d)
omment	The comment is duly noted. EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities. 313 comment by: UK CAA AMC6 ATM/ANS.OR.C.005(a)(2), point (e)(2) Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.B.005 (a)(4), (c) & (d) ATM/ANS.OR.B.030 (a), (b) & (c) Comments: The management system rules cover the reporting, analysis and
	The comment is duly noted. EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities. 313 comment by: UK CAA AMC6 ATM/ANS.OR.C.005(a)(2), point (e)(2) Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.B.005 (a)(4), (c) & (d) ATM/ANS.OR.B.030 (a), (b) & (c) Comments: The management system rules cover the reporting, analysis and correction of failures of the functional system.

comment 314

comment by: UK CAA



	AMC6 ATM/ANS.OR.C.005(a)(2), point (e)(3) See also: AMC4 ATS.OR.205(a)(2), point (d)(3)
	Equivalent coverage in EC 2017/373 text: <u>ATM/ANS.OR.B.030 (a), (b) & (c)</u>
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	315 comment by: UK CAA
	AMC6 ATM/ANS.OR.C.005(a)(2), point (f)
	Equivalent coverage in EC 2017/373 text: N/A
	Comments:
	Incorrect. The requirement for assurance (ATS.OR.205(a)(2)) applies to all parts of the functional system and therefore includes software, no matter whether it is bespoke, COTS or previously developed.
	This is GM not AMC. The rule itself is adequate, it covers this and is not specific to software.
response	Not accepted
	It was considered relevant to address the particular situation of this type of software as far as generic assurance processes cannot be applied.

GM1 to AMC6 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system

p. 12

comment	20 comment by: D Winship
	para (c) "The use of multiple SWALsseveral criticalities of softwareby same set of software assurance processes". This text is potentially misleading as the software assurance system may be designed to invoke more comprehensive and rigorous processes for more critical code – in other words not employing the same set of processes.
response	Not accepted
	The processes are written in general terms. Typically, software suppliers have a unique set of software development processes that are able to cope with several



software assurance levels, depending on the activities carried out. Therefore, it was considered relevant to maintain the text as proposed.

comment	23 comment by: D Winship
	Para (c) "processes are intended to rely on several software assurance levels". Suggest replace 'intended to rely on' with 'employ'. Assurance processes don't ' rely' on SWALs, assurance evidence rigour is driven by the software's designated SWAL(s).
response	Accepted
	Considering the comment, the text has been amended.
comment	36 comment by: ENAIRE
	GM1 to AMC6 ATM/ANS.OR.C.005(a)(2) - (c)(1):
	Regarding the sentence "the rigour should increase as the software increases in criticality", there is the following potential interpretation: In general, software is not critical. The correct wording is mission critical software or safety critical software.
	Problem arising: A solution could be a mixture between SW and hardware where a hardware element could be a fall back element if the software fails. In this case, the criticality of the service provided by the system may not directly affect the software itself but the overall solution. i.e. introduce a third hardware fall-back element.
	Suggested improvement: Suggest rewording as "the rigour should increase as the criticality of the service supported by the software solution increases;"
response	Accepted
	Considering the comment, the text has been amended.
comment	200 comment by: AESA/DSANA
	A definition for "Software Component" should be included.
	For the sake of a better understanding of the AMC/GM, a definition of what should it be understood by "Software Component" should be introduced. The ED153 definition is proposed.
response	Accepted
	Considering the comment, the text has been amended.
comment	206 comment by: European Transport Workers Federation - ETF
	ETF is of the opinion that it is of tremendous importance that the software assurance level is to be determined by the ATS provider (under the appropriate



	oversight by the competent authority) and not by the system manufacturer if any.
response	Noted
	The comment is duly noted.
comment	216 comment by: DSAC - FR NSA
	Paragraph (d) is somehow contradictory and difficult to understand since it says that the SWAL concept can be useful, but not relevant for non-ATS providers. This paragraph only provides an introduction to paragraph (b), they thus could be merged.
response	Accepted
	Considering the comment, the text has been amended.
comment	217 comment by: DSAC - FR NSA
	Paragraph (d) doesn't provide added guidance to AMC6 ATM/ANS.OR.C.005(a)(2) - (f) regarding the "alternative means [] to demonstrate", therefore it could be removed.
response	Accepted
	Considering the comment, the text has been amended in Part-ATS as well as in Section 3 to Part-ATM/ANS.OR.
comment	226 comment by: DSAC - FR NSA
	Only ED-153 provides a methodology to allocate SWAL and it is not sufficiently detailed and "constraining" to assure that SWAL will be allocated on the same way by all users. A more detailed GM would help to harmonize SWAL allocation.
response	Noted
	The commented provision is linked to the way, in which the safety (support) assessment is performed by each of the ANSPs.
	The proposal will be considered in future rulemaking activities on the subject.
comment	250 comment by: NATS
	para (c) "The use of multiple SWALs would also allow the possibility of managing several criticalities of the different software components within the system by the same set of software assurance processes." Where this is the case, appropriate partitioning needs to be demonstrated Issue: Suggests it is OK to have components of different criticality in the same system without partitioning



	Suggestion: Reword to "The use of multiple SWALs would also allow the possibility of managing several criticalities of the different software components within the system (with appropriate partitioning) by the same set of software assurance processes."
response	Accepted
	Considering the comment, the text has been amended.
comment	251 comment by: NATS
	Para (d) It is not necessarily true that "generic assurance processes cannot be
	applied" to COTS, NDS or PDS. It is however unlikely. Issue: Remove the inference that generic assurance approach is not applicable to
	these types of software Suggestion: Modify "generic assurance processes cannot be applied" to "generic
	assurance processes may not be applicable"
response	Partially accepted
	The commented point was removed as it is redundant given the presence of point (f) of AMC6 ATM/ANS.OR.C.005(a)(2).
comment	252 comment by: NATS
	Para (b) "When tools are used during the software development lifecycle". It is difficult to imagine a software development lifecycle that does not include at least one tool (such as a compiler or development environment). In those terms "Tool Qualification" always exists for a software development lifecycle. Issue Clarify that tool qualification it not 'optional' as implied by the statement. Suggestion: Add ED-215 to the list of ED-109A related supplements
response	Accepted
	EASA agrees that tools are widely used for software development and verification. Nevertheless, it might be possible that the tools do not require qualification because the output is verified independently.
comment	290 comment by: ASD/Thales Air Systems
	GM1 to AMC6 item (a): the last sentence "non-ATS providers may not be aware of the safety aspects of ATS providers using their services" is not understood as from a classical top-down safety methodology approach, the ATS provider (using a service or equipment coming from a non-ATS provider) will allocate a safety objective (e.g. target SWAL level) to any service or equipment having an identified impact on a hazard (defined in its FHA). In the case where there is no identified impact, there will be no allocation of safety objective. The problem described in this last sentence can come from an ATS provider who does not do allocate safety objectives to its providers.



GM1 to AMC6 item (b): this item is explaining that what is written in item (a) above is not relevant in most of the cases ... this makes item (a) and (b) very confusing and with poor added value.

To improve both item (a) and (b), the definition of the minimal interface between ATS providers and non-ATS providers might be described with a guidance on what is expected in terms of inputs/outputs by both sides.

response Not accepted

The non-ATS provider would not have the full picture about how the service is going to be used by the ATS provider. Nevertheless, the interactions ATS/non-ATS might depend on the non-ATS services and the particular set-up. A similar situation might occur between safety case and safety support case(s) for a particular change. Then, it is found not realistic to be precise enough on a possible guidance for the inputs/outputs by both sides, with the high risk of being incomplete.

comment	316 comment by: UK CAA
	GM1 to AMC6 ATM/ANS.OR.C.005(a)(2)
	See also:
	AMC6 ATM/ANS.OR.C.005(a)(2) point (d)
	GM2 to AMC6 ATM/ANS.OR.C.005(a)(2) points (a), (b), (c) & (d)
	Equivalent coverage in EC 2017/373 text: N/A
	SWALS as defined in EC 482 cannot be applied to the software covered by Annex III.
	The ATM IR does not define assurance levels. It allows their use but points out that
	there can be many different types and that their use does not imply satisfaction of requirement
	Comments:
	Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE.
	Assurance levels can be used in other fields as well e.g. DALs, HWALs
	The relationship between confidence and SWALs is not defined and so introducing
	SWALs should not be done until there is some solid underpinning evidence for such
	a relationship
response	Noted
	The comment is duly noted.

GM2 to AMC6 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes p. 12-13 to the functional system

37 comment

comment by: ENAIRE

AMC6 ATM/ANS.OR.C.005(a)(2) – (a)



ED-153 does not allow requirements without traceabillity (explicit requirement with indepence of the SWAL level). This paragraph should be changed.

Software requirements may be tagged as safety or integrity requirements because its parent requirement (the upper level requirement it traces to) is tagged as safety or integrity related. Therefore a software requirement that does not trace to a requirement above may never be identified as software safety or integrity requirement.

Problem arising: Any software fix implemented in order to solve a problem reported from testing at a higher level, should require the retest of all affected requirements (i.e. all requirements that trace to the requirement associated with the problem) should be verified as not being affected. Any requirement without traceability will never benefit from this relationship and potential fault may be overlooked.

Suggested improvement: Add the following: "Nevertheless all requirements determined as potentially affecting safety, if not implemented correctly or completely, should be traced to a corresponding upper level requirement".

response Not accepted

It should be pointed out that derived (non-traced) requirements are possible for other standards different from ED-153. It is considered that both strategies are possible and provide equivalent assurance levels, when applied correctly.

comment	69 comment by: CANSO
	Remark: Item (c):Partitioning between several software components with distinct SWAL should be acceptable taken into account the integrity control between data exchanged. It could be an alternative way to reduce SWAL from some sub- components. Space and timing partitioning consideration should be demonstrated depending on the SWAL criticality. => The following sentence is proposed for amendment: (c) The software components that cannot be shown to be independent of one another should be allocated to the SWAL of the most critical of the dependent components. In case of integrity control of data exchanges between software components or in case of with space and timing partitioning argumentation, distinct SWAL could be considered.
response	Not accepted
	It is to be noted that the integrity control between data exchanged is only valid when there is design and implementation independence between the control component and the controlled component. Then, point (c) would not be applicable.
comment	145comment by: DSNA



	In some specific cases, some Risk Mitigation Means are foreseen in order to be a response for some hazards. These Risk Mitigation Means could be considered as an acceptable alternative way instead of software safety support assessment. => The following sentence is proposed for amendment and should be added : "An acceptable alternative way for software safety support assessment could be the demonstration of existence of adequate Risk Mitigation Means."
response	Not accepted
	The term 'software safety support assessment' is not used in the proposed set of AMC & GM.
comment	167 comment by: DSNA
	Item (c):Partitioning between several software components with distinct SWAL should be acceptable taken into account the integrity control between data exchanged. It could be an alternative way to reduce SWAL from some sub-components.
	Space and timing partitioning consideration should be demonstrated depending the SWAL criticality.
	=> The following sentence is proposed for amendment:
	"(c) The software components that cannot be shown to be independent of one another should be allocated to the SWAL of the most critical of the dependent components. In case of integrity control of data exchanges between software components or in case of with space and timing partitioning argumentation, distinct SWAL could be considered."
response	Not accepted
	It is to be noted that the integrity control between data exchanged is only valid when
	there is design and implementation independence between the control component and the controlled component. Then, point (c) would not be applicable.
comment	181 comment by: DSNA
comment	
	In some specific cases, for instance, meteorological services, the assessment of the software providing the service support is out of the managerial control scope from the ANSP. Therefore, software assessment of support services can't be assessed by the ANSP.
	=> The following sentence is proposed for amendment and should be added : "In case the support is out of the definition and/or managerial control scope, the safety support assessment will be specifically not foreseen."
response	Not accepted
	It should be highlighted that in the current regulatory framework, the software aspects are covered in detail through Regulation (EC) No 482/2008, which applies to any changes to the software of the systems for air traffic services (ATS), airspace management (ASM), air traffic flow management (ATFM), i.e. air traffic management (ATM) and communication, navigation, or surveillance (CNS). Additionally, the



software aspects for aeronautical information services (AIS) provision are included in Regulation (EU) No 73/2010. On the other hand, it is acknowledged that the MET providers will be affected as regards the software assurance AMC & GM.

EASA considers that some of the service providers other than the ones that are subject to Regulation (EC) No 482/2008 today have a contribution to software (e.g. MET providers, FPD) and in order EASA to take an informed decision, a specific meeting with other stakeholders was organised to address this issue (among others). The discussion clearly concluded that some features of the MET systems are affected by the current regulatory requirements, which also supports the approach taken for the proposed set of AMC & GM; that is, to apply for all service providers of ATM/ANS, including AIS and MET providers, towards software assurance level standardisation.

comment	253 comment by: NATS
	 Para (b) The requirement is that the allocated SWAL be commensurate with the most severe effect that software [] may cause. This fails to take into account the likelihood of the effect. In many cases effects of high severity are less likely, and this likelihood may be reduced by other mitigations in the system. Issue Software assurance effort will be diverted into reducing likelihoods of severe effects that are already very low, while lower severity effects with higher likelihoods are neglected Suggestion: Include the likelihood of an outcome in the evaluation of the severity.
response	Not accepted
	There is no general consensus about the need of considering the likelihood in the
	software assurance level allocation. Even in the software standards, several
	approaches are presented.
comment	317 comment by: UK CAA
comment	
	GM2 to AMC6 ATM/ANS.OR.C.005(a)(2) See also
	AMC6 ATM/ANS.OR.C.005(a)(2) point (d)
	GM1 to AMC6 ATM/ANS.OR.C.005(a)(2) points (a) (b) & (c)
	Equivalent coverage in EC 2017/373 text: N/A SWALS as defined in EC 482 cannot be applied to the software covered by Annex III. The ATM IR does not define assurance levels. It allows their use but points out that there can be many different types and that their use does not imply satisfaction of requirement
	Comments:
	Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE.



Assurance levels can be used in other fields as well e.g. DALs, HWALs The relationship between confidence and SWALs is not defined and so introducing SWALs should not be done until there is some solid underpinning evidence for such a relationship

response Noted

The comment is duly noted.

GM3 to AMC6 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes p. 13-14 p. 13-14

comment	24 comment by: D Winship
	 para (c) "The definition of the software assurance processes may be based on one of these industrial standards without" The intent of this statement requires consideration – there is no reason why the service provider can't utilise best practices from a number of the relevant standards. The sentence as currently written could be interpreted as stating they can only select one due to the use of "without combining provisions for different standards". Please clarify intent of this paragraph and consider revision.
response	Noted
	As already explained in the guidance material, it would not be considered as a good practice to combine objectives from different standards as they were developed separately under different considerations and there could be some internal compensation means (one objective is less demanding in a particular standard because another objective is more demanding). On the other hand, the use of the verb 'may' allows the service provider to use the best practices to complement one of the standards or to define the full set of software assurance processes.
comment	146 comment by: DSNA
	In some specific cases, some Risk Mitigation Means are foreseen in order to be a response for some hazards. These Risk Mitigation Means could be considered as an acceptable alternative way instead of software safety support assessment. => The following sentence is proposed for amendment and should be added : "An acceptable alternative way for software safety support assessment could be the demonstration of existence of adequate Risk Mitigation Means."
response	Not accepted
	The term 'software safety support assessment' is not used in the proposed set of AMC & GM.
comment	151 comment by: DSNA



In item (b), The DO-200B defines constraints on the development and the maintenance of aeronautical data. It is generally used in aeronautical embedded contexts and associated suppliers are familiar to. Moreover, in ATM/AIS context, these objectives could lead to a significant gap which will impact the development cost/planning. This document should be removed from this table. The ED-12C/DO-178C should be removed too due to the fact that the ED-109A/DO-278A already same assumptions for ATM context. covers Note also that DO-278B doesn't exist yet, and should be replaced by DO-278A. Finally, ED109 also should be considered as it is a standard currently used in industry right now (not all software development have switched from ed109 to ed109A).

response | Partially accepted

The comment is duly considered. Following the order of the referenced Standards, the following should be noted:

- DO200B should be retained as the DAT providers are part of the scope of the Regulation as non-ATS providers;

- ED12C/DO178C should be retained due to the fact that it is being used as reference by some service providers in Europe; and

- the text as regards DO278B has been amended.

comment	152 comment by: DSNA
	Even if the service provider may be able to validate pre-defined/standard additional software assurance processes, it may not be always able to _define_ them because it requires a high level of expertise on the subject which may not be its core business.
response	Noted
	In order to mitigate such effect, the guidance material includes the reference to these software standards that can be used as reference by the service provider to build the software assurance process. Nevertheless, it is to be pointed out that the software assurance is not a new domain for the ANSPs that were previously implementing Regulation (EC) No 482/2008.
comment	182 comment by: DSNA
	In some specific cases, for instance, meteorological services, the assessment of the software providing the service support is out of the managerial control scope from the ANSP. Therefore, software assessment of support services can't be assessed by the ANSP. => The following sentence is proposed for amendment and should be added : "In case the support is out of the definition and/or managerial control scope, the safety support assessment will be specifically not foreseen."

response Not accepted

***** **** It should be highlighted that in the current regulatory framework, the software aspects are covered in detail through Regulation (EC) No 482/2008, which applies to any changes to the software of the systems for air traffic services (ATS), airspace management (ASM), air traffic flow management (ATFM), i.e. air traffic management (ATM) and communication, navigation, or surveillance (CNS). Additionally, the software aspects for aeronautical information services (AIS) provision are included in Regulation (EU) No 73/2010. On the other hand, it is acknowledged that the MET providers will be affected as regards the software assurance AMC & GM.

EASA considers that some of the service providers other than the ones that are subject to Regulation (EC) No 482/2008 today have a contribution to software (e.g. MET providers, FPD) and in order EASA to take an informed decision, a specific meeting with other stakeholders was organised to address this issue (among others). The discussion clearly concluded that some features of the MET systems are affected by the current regulatory requirements, which also supports the approach taken for the proposed set of AMC & GM; that is, to apply for all service providers of ATM/ANS, including AIS and MET providers, towards software assurance level standardisation.

comment	269 comment by: ASD/Thales Air Systems
	To not create confusion, it is very important to not mix standards for airborne systems like DO-178C and standards for ground systems like ED-109A. A unique list may be confusing for a Service Provider that is not aware about the techncal content of those standards and may require the compliance to DO-178C to ground systems manufacturers. This confusion between standards could create a climate of incomprehension that could hinder functional improvement initiatives in ATM systems. Moreover, safety management systems put in place by ATM ground manufacturers are based on ATM standards (e.g. ED-109A, ED-153), and it will represent a blocking industrial issue to comply with standards, such as DO-178C, not adapted to ATM ground systems.
	That is the reason why i t appears necessary to separate these 2 different categories of standards (airborne standards vs ground standards).
response	Not accepted
	It should be acknowledged that the scope of each document, i.e. standard, indicates the intended domain of applicability. This is especially relevant taking into account the possibility of identifying ATM/ANS systems with ground and space components.
comment	283 comment by: ASD/Thales Air Systems
	In the item (c), it is written that "The definition of the software assurance processes <u>may be</u> based on one of these industrial standards". From an industrial point of view, we know very well the technical content of these standards and we also know that requiring a compliance to provisions/requirements coming from different



	standards is a strong source of confusion. This is the reason why it appears useful to be more strict on this topic by writting for example: "The definition of the software assurance processes should be based on one of these industrial standards".
response	Not accepted
	Being guidance material and providing a non-exhaustive list of standards, the current wording is considered more suitable. It is acknowledged that there are other ANSPs that base the software assurance process on other standards (CMMI).
comment	318 comment by: UK CAA
	GM3 to AMC6 ATM/ANS.OR.C.005(a)(2) point (a)
	Equivalent coverage in EC 2017/373 text: N/A
	Comments: Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE. This section is out of context. The approval of processes is covered in ATM/ANS.OR.B.10 and its associated AMC/GM
response	Noted
	The comment is duly noted.
	It is preferred to keep this material linked to the functional system. It is noted that the software development process can also be established at system supplier level, supporting a special treatment for these processes.
comment	319 comment by: UK CAA
	GM3 to AMC6 ATM/ANS.OR.C.005(a)(2) point (c)
	Equivalent coverage in EC 2017/373 text: N/A
	Comments: Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE. This section is out of context. The approval of processes is covered in ATM/ANS.OR.B.10 and its associated AMC/GM
response	Noted
	The comment is duly noted.

AMC3 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system

p. 14

comment 70

comment by: CANSO



Remark: In item (a), in case of modifications to existing software, the existence of documented software assurance processes could not be systematically available, especially if the development was performed several years before. Additionally, the state of art at the moment for the previous development could be significantly different as the current standards. In these cases, the effective software experience could be claimed without any existence of documentation. It is noted that the software experience is already well addressed by the bullet (b), nevertheless, as written, it seems not being an

=> The following sentence is proposed for amendment:

alternative way to the bullet (a).

(a) When a change to a functional system includes the introduction of new software or modifications to existing software, the ATS provider should ensure the existence of documented software assurance processes necessary to produce evidence and arguments that demonstrate that the software behaves as intended (software requirements), with a level of confidence consistent with the criticality of the required application. In case of incomplete or absence to this expected documentation, the effective software experience, if exists, could be considered as a relevant alternative way.

response Not accepted

It is necessary to point out that as described in AMC6 ATM/ANC.OR.C.005(a)(2), (f), it is always possible to have specific software assurance processes for managing previously developed software and to use the technique that is mentioned in the comment. Based on the existence of this provision, it is not considered necessary to include the additional clarification proposed by the commentator.

comment	81 comment by: EUROCONTROL
	ATS.OR.205(a)(2) - Pages 14 to 19
	(Same comment as for ATM/ANS.OR.C.205(a)(2)).
	The EUROCONTROL Agency finds that there is no AMC/GM explaining how the criticality of the software (SWAL) is linked to the criticality of the application. This might lead, for the same functional system, to a situation with different SWAL allocations by different ANSPs, although for the same required application. It would be therefore beneficial at European level to rely on a standardised mechanism for SWAL allocation, depending on the criticality of the application.
response	Noted
	The comment is duly considered.
	It is agreed that there is a difference between the criticality of the software and the criticality of the particular application by an ANSP. The same software can be used in different contexts by several ANSPs. Nevertheless, the objective of the AMC & GM is



to address the software assurance aspects associated with the software, once the criticality of the application has been addressed by the ANSP.

On the other hand, EASA concurs with the idea of having a common European SWAL allocation matrix, as currently presented in some of the software standards. However, Regulation (EU) 2017/373 and the existing AMC & GM do not go in that direction regarding the severity classification scheme and risk classification scheme, where there is no harmonised severity classification scheme (as there is today under Regulation (EU) No 1035/2011). Then, this limits the possibility of establishing a common European SWAL allocation matrix.

comment	118 comment by: ENAV
	 In item (a), in case of modifications to existing software, the existence of documented software assurance processes could not be systematically available, especially if the development was performed several years before. Additionally, the state of art at the moment for the previous development could be significantly different as the current standards. In these cases, the effective software experience could be claimed without any existence of documentation. It is noted that the software experience is already well addressed by the bullet (b), nevertheless, as written, it seems not being an alternative way to the bullet (a). => The following sentence is proposed for amendment:
	(a) When a change to a functional system includes the introduction of new software or modifications to existing software, the ATS provider should ensure the existence of documented software assurance processes necessary to produce evidence and arguments that demonstrate that the software behaves as intended (software requirements), with a level of confidence consistent with the criticality of the required application. In case of incomplete or absence to this expected documentation, the effective software experience, if exists, could be considered as a relevant complementary way.
response	Not accepted
	It is necessary to point out that as described in AMC6 ATM/ANC.OR.C.005(a)(2), (f), it is always possible to have specific software assurance processes for managing previously developed software and to use the technique that is mentioned in the comment. Based on the existence of this provision, it is not considered necessary to include the additional clarification proposed by the commentator.
commont	168 comment by: DSNA
comment	
	In item (a), in case of modifications to existing software, the existence of documented software assurance processes could not be systematically available, especially if the development was performed several years before. Additionally, the state of art at the moment for the previous development could be significantly different as the current standards. In these cases, the effective software experience could be claimed without any



	existence of documentation. It is noted that the software experience is already well addressed by the bullet (b), nevertheless, as written, it seems not being an alternative way to the bullet (a). => The following sentence is proposed for amendment: "(a) When a change to a functional system includes the introduction of new software or modifications to existing software, the ATS provider should ensure the existence of documented software assurance processes necessary to produce evidence and arguments that demonstrate that the software behaves as intended (software requirements), with a level of confidence consistent with the criticality of the required application. In case of incomplete or absence to this expected documentation, the effective software experience, if exists, could be considered as a relevant alternative way."
response	Not accepted
·	It is necessary to point out that as described in AMC6 ATM/ANC.OR.C.005(a)(2), (f), it is always possible to have specific software assurance processes for managing previously developed software and to use the technique that is mentioned in the comment. Based on the existence of this provision, it is not considered necessary to include the additional clarification proposed by the commentator.
comment	201 comment by: AESA/DSANA
	As it is suggested for "AMC5 ATM/ANS.OR.C.005(a)(2)", the need of a "documented software assurance process" should be more evident and unambiguous. It is considered that requirements about defining and establishing SW safety assessment and assurance procedures should be stated as an AMC of ATM/ANS.OR.B.010 (a) "Change management procedures".
	The wording proposed for the previous comment is also applicable here.
response	Not accepted
·	It is preferred to keep this material linked to the functional system. It is also noted that the software development process can also be established at system supplier level, supporting a special treatment for these processes.
comment	202 comment by: AESA/DSANA
	AMC3 ATS.OR.205(a)(2) should include Software Assurance Levels (SWALs) instead of only "Assurance Levels"
	AMC3 ATS.OR.205(a)(2) paragraph (b) should include SWAL to be consistent with AMC5 ATM/ANS.OR.C.005(a)(2) paragraph (b). In general "Software Assurance Level"/SWAL is used as synonymous of "assurance level" in the NPA. Since Software Assurance Level (SWAL) has specific connotations in the ED-153, the wording should be reviewed in order to avoid misunderstanding.
response	Partially accepted

It is noted that the term 'SWAL' is not used in other standards (e.g. ED-109A). However, it is preferred to keep the assurance level term in a more generic way, at least, in this point, while in other points the term 'SWAL' is introduced.

comment	227 comment by: DSAC - FR NSA
	Which is the severity classification scheme refered to in this paragraph ? The service provider's SCS ? The SCS defines by the Competent Authority ?
response	Noted
	According to Regulation (EU) 2017/373, the severity classification scheme is defined/proposed by the service providers. This is further illustrated in the associated AMC & GM.
comment	320 comment by: UK CAA
	<u>Annex IV</u>
	AMC3 ATS.OR.205(a)(2)
	Equivalent coverage in EC 2017/373 text: ATS.OR.205 (a)(2)
	Comments: Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE. Most of these points (see below) are covered by AMC/GM related to ATM/ANS.OR.B.005, B.010 & ATS.OR.200 & 205
response	Noted
	It is preferred to keep this material linked to the functional system. It is noted that the software development process can also be established at system supplier level, supporting a special treatment for these processes.
comment	321 comment by: UK CAA
	AMC3 ATS.OR.205(a)(2), point (a)
response	Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.B.010 (a) ATS.OR.205 (a)(2)Comments: SW is part of a functional system. Before changing any part of a functional system the service provider must ensure that the procedures to be used are approved by the CA. This is covered in ATM/ANS.OR.B.010. Noted
response	Holey


The comment is duly noted.
322 comment by: UK CAA
AMC3 ATS.OR.205(a)(2) point (b)
Equivalent coverage in EC 2017/373 text: <u>ATM/ANS.OR.B.005 (a)(4), (c) & (d)</u> ATM/ANS.OR.B.010 (b) & (c) ATS.OR.200 (3)
Comments: The management system rules cover the reporting, analysis and correction of failures of the functional system and adequate performance of procedures. They cover the complete functional system and change management procedures and therefore, by definition, cover software.
Noted
The comment is duly noted.
EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.

AMC4 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system	p. 15-16
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comment	5 comment by: DFS Deutsche Flugsicherung GmbH
	The text of Regulation 482/2008 has not always been copied identically within the AMC, e.g. point AMC4 ATS.OR.205 (a) (2) ii) has been modified. ED-153 is in line with Regulation 482/2008, however is not with Regulation 2017/373 ATS.OR.205. GMs contain both copies from ED documents as well as additional and modified parts. This mixture between referencing, copying and modifying is not acceptable. When the requirements are being changed, then also the ED documents need to be modified as well. Previous means to comply become partially non-compliant by new GM. This creates legal confusion rather than clarity. Therefore, a complete revisiting of the IR and AMC/GM material is recommended.
response	Noted
The aim of the proposed set of AMC & GM is to provide means of compliance software assurance when introducing changes to the functional system. The ne this additional material regarding software assurance was expressed by s stakeholders, especially authorities, during the Comitology process that resu Regulation (EU) 2017/373. Other ways for demonstration of compliance a possible and need to be evaluated by the corresponding regulated parties.	
	On the other hand, EASA has established RMT.0719 on regular updates of the subject implementing measures. And based on standardisation and implementation



feedback, EASA will perform, on a regular basis, a review of identified or notified subjects, which could lead to amendments to the rules, and, where appropriate, may propose amendments to the IRs and/or AMC & GM.

comment	6 comment by: DFS Deutsche Flugsicherung GmbH
	The following contradiction should be removed or better explained under GM: The traceability as required by (a) (2) is not supported by ED-153, as ED-153 explicitly does not allow "derived requirements". GM3 to AMC4 ATS.OR.205 (a)(2) however refers to ED-153.
response	Noted
	There are two separate aspects that require attention:
	• Derived requirements are allowed by other software standards. Both approaches (ED-153 or ED-109A) would be acceptable, provided that they are applied according to the corresponding standard.
	• ED-153 is listed in GM3 to AMC4 as an example of the different alternatives.
comment	17 comment by: D Winship
	Software requirements "correct, complete and compliant with the upper level requirements" Use of "compliantupper level" requirements implies a multi-layered requirements set which may, or may not be, the case. The different levels of system/software requirements should be consistent, coherent and 'aligned with', rather than 'compliant with', each other (as compliance is normally verified <i>for</i> each requirement as opposed to <i>between</i> different levels of requirements). Replacing this text with "aligned with the system requirements" would appear to be more appropriate.
response	Not accepted
	Based on existing software standards (ED-153, ED-109A), it is preferred to maintain the term 'compliant'. Regarding the upper-level and system requirements, the use of the term 'upper level' gives the possibility to address a multi-layered software component, as it is the case in most of the software applications in the ATM/ANS domain.
comment	19 comment by: D Winship

section a(5)

"following verification methods...agreed with the CA" –

It is essential to recognise that the CA focus is on the adequacy of the verification results/assurance – it is neither practical, achievable or desirable for the CA to engage in approving "verification methods" for individual changes. In addition, the



	text as written doesn't take into account the reality that, in most projects, much of the software is not unique or custom designed specifically for a single service provider – some of the verification work on core functionality may have been completed long before the service provider and CA became involved (i.e. re-used software from other projects). Some of the results of this earlier verification activity could be permissible as evidence (e.g. 'core' algorithm testing) even though the CA hasn't been engaged in agreeing the "verification method". This text should be reconsidered – the original text from 482 (with NSA replaced by CA) appears more appropriate.
	"The EATMN software shall be adequately verified by analysis and/or testing and/or equivalent means, as agreed with the"
response	Accepted Considering the comment, the text has been amended.
comment	38 comment by: ENAIRE
	AMC4 ATS.OR.205 (a) is confuse. It should be explained in order to system requirements, software requirements, software design requirements. It is easier than talk in terms of "upper level requirements".
response	Partially accepted Considering the comment the text has been amended to promote clarity.
comment	43 comment by: CANSO
	The text of Regulation 482/2008 has not always been copied identically within the AMC, e.g. point AMC4 ATS.OR.205 (a) (2) ii) has been modified. ED-153 is in line with Regulation 482/2008, however is not with Regulation 2017/373 ATS.OR.205. GMs contain both copies from ED documents as well as additional and modified parts. This mixture between referencing, copying and modifying is not acceptable. When the requirements are being changed, then also the ED documents need to be modified as well. Previous means to comply become partially non-compliant by new GM. This creates legal confusion rather than clarity. Therefore, a complete revisiting of the IR and AMC/GM material is recommended.
response	Noted
	The aim of the proposed set of AMC & GM is to provide means of compliance for the software assurance when introducing changes to the functional system. The need for this additional material regarding software assurance was expressed by several stakeholders, especially authorities, during the Comitology process that resulted in Regulation (EU) 2017/373. Other ways for demonstration of compliance are also possible and need to be evaluated by the corresponding regulated parties.
	On the other hand, EASA has established RMT.0719 on regular updates of the subject implementing measures. And based on standardisation and implementation



feedback, EASA will perform, on a regular basis, a review of identified or notified subjects, which could lead to amendments to the rules, and, where appropriate, may propose amendments to the IRs and/or AMC & GM.

comment	71 comment by: CANSO
	Remark: As stated in item (a)(1)(ii), one may understand that the demonstration is covering all the software. Actually, the demonstration should only cover the scope of the change. => The following sentence is proposed for amendment:
	(a)(1)(ii) specify in the scope of the change, the functional behaviour, in nominal and downgraded modes, timing performances, capacity, accuracy, software resource usage on the target hardware, robustness to abnormal operating conditions and overload tolerance, as appropriate, of the new software or modified software part.
response	Not accepted
	It must be highlighted that the requirement refers to features requested in the software assurance process. They can be applied for a particular change but the processes should be change-independent.
comment	72 comment by: CANSO
	Remark: Sentence of item (2)(i) seems to be ambiguous and clarification is expected. => The following sentence is proposed for amendment:
	(i) Each software requirement introduced at each level in the design lifecycle should be traced to the same level of design lifecycle at which its satisfaction is demonstrated.
response	Partially accepted
	Considering the comment, the text has been amended to promote clarity.
	However, it should be noted that the proposed solution was different from the original text and the intent of the rule.
comment	 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)
	Part a 1 Provides a clear link between software assurance and safety assessment of changes good!
response	Noted



comment	119 comment by: ENAV
	The text of Regulation 482/2008 has not always been copied identically within the AMC, e.g. point AMC4 ATS.OR.205 (a) (2) ii) has been modified. ED-153 is in line with Regulation (EC) No 482/2008; however, it is not with Regulation (EU) 2017/373 ATS.OR.205. GM contain both copies from ED documents as well as additional and modified parts. This mixture between referencing, copying and modifying is not acceptable. When the requirements are being changed, then also the ED documents need to be modified as well. Previous means to comply become partially non-compliant by new GM. This creates legal confusion rather than clarity. Therefore, a complete revisiting of the IR and AMC & GM is recommended.
response	Noted
	The aim of the proposed set of AMC & GM is to provide means of compliance for the software assurance when introducing changes to the functional system. The need for this additional material regarding software assurance was expressed by several stakeholders, especially authorities, during the Comitology process that resulted in Regulation (EU) 2017/373. Other ways for demonstration of compliance are also possible and need to be evaluated by the corresponding regulated parties.
	On the other hand, EASA has established RMT.0719 on regular updates of the subject implementing measures. And based on standardisation and implementation feedback, EASA will perform, on a regular basis, a review of identified or notified subjects, which could lead to amendments to the rules, and, where appropriate, may propose amendments to the IRs and/or AMC & GM.
comment	120 comment by: ENAV
	Remark: Sentence of item (2)(i) seems to be ambiguous and clarification is expected. => The following sentence is proposed for amendment: (i) Each software requirement introduced at each level in the design lifecycle should be traced to the same level of design lifecycle at which its satisfaction is demonstrated.
response	Partially accepted
	Considering the comment, the text has been amended to promote clarity.
	However, it should be noted that the proposed solution was different from the original text and the intent of the rule.
comment	137 comment by: ISAVIA ohf.
	Comment to AMC4 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system (page 15-16):



		(EU) 2017/373 there is no requirement to safety risk assessment. The text should be
response	Accepted	
	Considering the comment, the text has be	een amended.
comment	169	comment by: DSNA
	all the software. Actually, the demonstr change. => The following sentence "(a)(1)(ii) specify in the scope of the change downgraded modes, timing performance usage on the target hardware, robustne	erstand that the demonstration is covering ation should only cover the scope of the is proposed for amendment: ge, the functional behaviour, in nominal and es, capacity, accuracy, software resource ess to abnormal operating conditions and
		new software or modified software part."
response	Not accepted It must be highlighted that the requirement refers to features requested in the software assurance process. They can be applied for a particular change but the processes should be change-independent.	
comment	172	comment by: DSNA
	Sentence of item (2)(i) seems to be ambiguous and clarification is expected. => The following sentence is proposed for amendment: "(i) Each software requirement introduced at each level in the design lifecycle should be traced to the same level of design lifecycle at which its satisfaction is demonstrated."	
response	Partially accepted	
	Considering the comment, the text has be	een amended to promote clarity.
	However, it should be noted that the poriginal text and the intent of the rule.	proposed solution was different from the
comment	207 The comment by:	European Transport Workers Federation - ETF
	p10 : non-ATS services AMC6 (a)(2)(ii) Each software requirement [] should be traced to an upper level requirement [] p15 : ATS services : AMC4 (a)(2)(ii) Each software requirement [] is traced to an upper level requirement []	Is the difference intended ? From a regulatory perspective, it does not seem to create any difference in the provision or at least we do not understand it.

**** ency of the European Union

response	Accepted	
	The text has been amended to addres	s the inconsistency.
comment	208 * comment	t by: European Transport Workers Federation - ETF
	p11 : non-ATS services : AMC6 (f) [] If no sufficient assurance can be provided [] p16 : ATS services : AMC4 (e) [] If no sufficient assurance may be provided []	Is the difference intended ? From a regulatory perspective, it does not seem to create any difference in the provision or at least we do not understand it.
response	Accepted	
	The text has been amended to addres	s the inconsistency.
comment	228	comment by: <i>DSAC - FR NSA</i>
	In paragraph (3), The demonstration that the software implementation contains no functions which adversely affect safety may be difficult to achieve especially for COTS. This paragraph may be rephrased as "the functions contained in the software implementation do not adversely affect safety".	
response	Partially accepted	
	highlighted in point (f) of the AMC. Th considered equivalent to the wording	s can be defined by the service provider as e reference to the software implementation is ng and covers the case of the COTS where ssed from the potential impact on safety or
comment	239	comment by: NATS
connent		ion of the software" seems too imprecise; the



	Suggest: rewording to "the executable version of the software which is to be deployed into operation"
response	Not accepted
	The verification activities can be based on several (known) versions of the software, without mandatorily being the last one. An assessment of the versions evolutions might allow to take credit of the verification in previous versions of particular requirements, subject to a non-regression policy.
comment	255 comment by: NATS
	para (a) (1) (ii) and (a) (4) Although a straight copy of the EC 482/2008 requirement the concept of "software resource usage on target hardware" is not required. It could be argued that to meet the other software requirements as stated (such as performance and overload tolerance) "software resource usage" must be met.
	 Issue: Difficult to specify and meet especially for software deployed within a virtualised environment. Suggest the removal of the statement "software resource usage on target hardware" from the list.
response	Accepted
comment	256 comment by: NATS
comment	Para (a) (5) Its unclear as to the scope of the agreement with respect to verification with the CA i.e. is the intention a strategy or a requirement by requirement verification method or selection from an agreed set of verification methods? Issue: Potential inconsistency of application. Effort required from CA associated with agreeing software verification approach. Suggested resoultion; Clarification dependent upon the intention of the statement.
response	Accepted
	The text has been updated to promote clarity in order to avoid this potential misunderstanding.
comment	257 comment by: NATS
	 Para (b) As written there is no means to use arguments or evidence from previous versions of software if suitably justified. Impact: Unnecessary re-generation of assurance evidence, with associated cost. Suggested Resolution: Modify (3) to read "that have been used in the production of that version, or can be justified as applicable to that version.'
response	Accepted
comment	258 comment by: NATS



	 Para (e) It is not necessarily true that "generic assurance processes cannot be applied" to COTS, NDS or PDS. It is however unlikely. Issue: Remove the inference that generic assurance approach is not applicable to these types of software. Suggested resolution: Modify "generic assurance processes cannot be applied" to "generic assurance processes may not be applicable"
response	Not accepted
	The intent of the current wording is to highlight the impossibility to apply the generic assurance process. There would be some COTS or NDS where the generic assurance process is possible and can be provided by the COTS supplier.
comment	259 comment by: NATS
	Para (e) Modify last sentace for readability - it requires clarity Suggestion: Modify to read "If sufficient assurance cannot be provided, complementary"
response	Accepted
comment	260 comment by: NATS
	 Para (e) In themselves neither "existing service level experience" nor "monitoring" are a "mitigation means aiming at decreasing the impact of specific failure modes of this type of software", whereas software/system architectural considerations are. Issue: Confusion between failure mode mitigation and means of addressing assurance shortfalls. General clarity Suggestion: Reword preceding test to read "If sufficient assurance cannot be provided, complementary mitigation should be applied. This may include but is not limited to:"
response	Not accepted
	It should be noted that the three cases presented would belong to the mitigation of specific failure modes pre- and post-implementation.
comment	286 * comment by: ASD/Thales Air Systems
	In the item (a)(1)(ii), it is mentionned "specify the functional behaviour in downgraded modes" and later " robustness to abnormal operating conditions". What is the difference between the 2 points? It seems that these 2 points are redundant o at least linked since requirements on "downgraded modes" cover "robustness to abnormal operating conditions". May be the last part of the sentence could be used as an example of downgraded mode.
response	Noted



Downgraded modes might correspond to a situation in which the software provides lower performances but works under normal operating conditions. Then, both concepts are separate and would need to be maintained in this way.

commont.	323 comment by: UK CAA
comment	323 comment by: UK CAA AMC4 ATS.OR.205(a)(2)
	Comments: Not specific to software. Removal of the SW related terms would have no effect or the meaning of the text and would broaden it to include PPE. Most of these points (see below) are covered by AMC/GM related to ATS.OR.205 This section is out of context. Processes are dealt with in ATM/ANS.OR.B.010 and its associated AMC/GM. This section of the IR and its associated AMC/GM deals with
	the criteria for safety assurance cases and not the processes that created a safety case.
response	Noted
comment	324 comment by: UK CAA
	AMC4 ATS.OR.205(a)(2), point (a)(1)(i)
	Equivalent coverage in EC 2017/373 text: AMC2 ATS.OR.205 (a)(2) (b), (c), (d)
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	325 comment by: UK CAA
	AMC4 ATS.OR.205(a)(2), point (a)(1)(ii)
	Equivalent coverage in EC 2017/373 text: ATS.OR.205 (a)(1)(v) <u>GM3 ATS.OR.205(a)(2) (</u> a)
response	Noted
	The comment is duly noted.



EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.

comment	326 comment by: UK CAA
	AMC4 ATS.OR.205(a)(2), point (a)(2)(i)
	Equivalent coverage in EC 2017/373 text: AMC2 ATS.OR.205(a)(2) (d)
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
omment	327 comment by: UK CAA
	AMC4 ATS.OR.205(a)(2), point (a)(2)(ii)
	Equivalent coverage in EC 2017/373 text: AMC2 ATS.OR.205(a)(2) (d)
esponse	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
omment	328 comment by: UK CAA
	AMC4 ATS.OR.205(a)(2), point (a)(3)
	Equivalent coverage in EC 2017/373 text: <u>ATS.OR.205 (</u> a)(2) & (b)(2)(ii) AMC2 ATS.OR.205 (a)(2) (a) & (c)
esponse	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.

comment 329

comment by: UK CAA



	AMC4 ATS.OR.205(a)(2) point (a)(4)
	Equivalent coverage in EC 2017/373 text: ATS.OR.205 (a)(5)(ii) AMC2 ATS.OR.205(a)(2) (c) & (e)
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	330 comment by: UK CAA
	AMC4 ATS.OR.205(a)(2), point (a)(5)
	Equivalent coverage in EC 2017/373 text: ATS.OR.205 (a)(2), (b)(1) AMC1 ATS.OR.205 (b)(5)
	Comments: The procedures for verification are covered in ATM/ANS.OR.B.010 and its associated AMC/GM and will have been agreed with the CA prior to their use.
response	Noted
	It should be noted that software verification procedures may also be available at system supplier level. Therefore, the link to these procedures to the functional system change is considered also relevant.
comment	331 comment by: UK CAA
	AMC4 ATS.OR.205(a)(2), point (b)
	Equivalent coverage in EC 2017/373 text: AMC2 ATS.OR.205 (a)(2) (f)
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	332 comment by: UK CAA



	AMC4 ATS.OR.205(a)(2) point (c)
	See also: GM1 to AMC4 ATS.OR.205(a)(2)
	(Text identical to GM1 to AMC6 ATM/ANS.C.005(a)(2))
	GM2 to AMC4 ATS.OR.205(a)(2) points (a), (b) & (c)
	(Text the same as GM2 to AMC6 ATM/ANS.C.005(a)(2))
	Equivalent coverage in EC 2017/373 text: N/A
	Comments: The concept of rigour is not used in the IR, confidence is used. Assurance levels are used in Regulation (EC) No 482/2008 to determine 'the rigour to which the assurances are established'. This can only be understood as a means to provide the required level of confidence. Hence this clause is incorrect.
response	Accepted
	Considering the comment, the text has been amended.
comment	333 comment by: UK CAA
	AMC4 ATS.OR.205(a)(2), point (d)(1)
	Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.B.030 (a), (b) & (c) AMC2 ATS.OR.205 (a)(2) (f)
response	Noted
	The comment is duly noted.
	EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.
comment	334 comment by: UK CAA
	AMC4 ATS.OR.205(a)(2), point (d)(2)
	Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.B.005 (a)(4), (c) & (d) ATM/ANS.OR.B.030 (a), (b) & (c)
	Comments: The management system rules cover the reporting, analysis and correction of failures of the functional system.
response	Noted



The comment is duly noted. EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities. comment 335 comment by: UK CAA AMC4 ATS.OR.205(a)(2), point (d)(3) See also: AMC6 ATM/ANS.OR.C.005(a)(2), point (e)(3) Equivalent coverage in EC 2017/373 text: ATM/ANS.OR.B.030 (a), (b) & (c) Comments: Not specific to software. Noted response The comment is duly noted. EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities. comment 336 comment by: UK CAA AMC4 ATS.OR.205(a)(2), point (e) Equivalent coverage in EC 2017/373 text: None **Comments:** Incorrect. The requirement for assurance (ATS.OR.205(a)(2)) applies to all parts of the functional system and therefore includes software, no matter whether it is bespoke, COTS or previously developed. This is GM not AMC. The rule itself is adequate, it covers this and is not specific to software. response Noted The comment is duly noted. EASA believes that the aspects identified in the AMC & GM are not covered in the existing AMC & GM with the necessary level of detail, taking into account the particularities and specificities of the software-related activities.

AMC4 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system p. 16-17



comment	7 comment by: DFS Deutsche Flugsicherung GmbH
	GM1 to AMC4 The structure of the GM is misleading, since the classification criteria in sub-para (c) (2) (i)-(iii) are always applicable, not only for multiple SWALs. We suggest to restructure the paragraph to avoid misunderstanding.
response	Not accepted
	It should be noted that the considerations included in this point are only applicable where there are several SWALs covered by the same set of software assurance processes.
comment	21 comment by: D Winship
	Para (c) "The use of multiple SWALsseveral criticalities of softwareby same set of software assurance processes". This text is potentially misleading as the software assurance system may be designed to invoke more comprehensive and rigorous processes for more critical code – in other words not employing the same set of processes.
response	Noted
	It should be noted that the processes are written in general terms. Typically, software suppliers have a unique set of software development process that are able to cope with several software assurance levels, depending on the activities carried out.
comment	22 comment by: D Winship
	Para (c) "processes are intended to rely on several software assurance levels". Suggest replace 'intended to rely on' with 'employ'. Assurance processes don't ' rely' on SWALs, assurance evidence rigour is driven by the software's designated SWAL(s).
response	Accepted
comment	45 comment by: CANSO
	GM1 to AMC4 The structure of the GM is misleading, since the classification criteria in sub-para (c) (2) (i)-(iii) are always applicable, not only for multiple SWALs. We suggest to restructure the paragraph to avoid misunderstanding.
response	Not accepted
	It should be noted that the considerations included in this point are only applicable where there are several SWALs covered by the same set of software assurance process.



comment	121 comment by: ENAV
	GM1 to AMC4 The structure of the GM is misleading, since the classification criteria in sub-para (c) (2) (i)-(iii) are always applicable, not only for multiple SWALs. We suggest to restructure the paragraph to avoid misunderstanding
response	Not accepted
	It should be noted that the considerations included in this point are only applicable where there are several SWALs covered by the same set of software assurance process.
comment	131 comment by: Avinor Air Navigation Services (Avinor Flysikring AS)
	Comment to GM1 to AMC4 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the fundtional system (c)(2)(i) required to be achieved with independence;
	It should be more precisely described what is required by the term "independence" for requirements which needs to be achieved with independence.
	Justification: The term "independence" is vaguely described in ED-153.
response	Noted
	It should be noted that 'independence' is defined in ED-109A as 'Verification independence is achieved when the verification activity is performed by a person(s) other than the developer of the item being verified'. ED-109A Standard is considered within the standards list.
comment	229 comment by: DSAC - FR NSA
	Paragraph (d) doesn't provide added guidance to AMC4 ATS.OR.205(a)(2) - € regarding the "alternative means [] to demonstrate", therefore it could be removed.
response	Accepted
comment	261 comment by: NATS
	 Para (d) It is not necessarily true that "generic assurance processes cannot be applied" to COTS, NDS or PDS. It is however unlikely. Issue: Remove the inference that generic assurance approach is not applicable to these types of software. Suggestion: Modify "generic assurance processes cannot be applied" to "generic assurance processes may not be applicable"
response	Not accepted



It should be noted that the current wording intends to highlight the impossibility to apply the generic assurance process. There would be some COTS or NDS where the generic assurance process is possible and can be provided by the COTS supplier.

comment 337 comment by: UK (CAA
GM1 to AMC4 ATS.OR.205(a)(2)	
(Text nearly the same as GM1 to AMC6 ATM/ANS.C.005(a)(2))	
See also: AMC4 ATS OR $205(a)(2)$ point (a)	
AMC4 ATS.OR.205(a)(2) point (c) GM1 to AMC4 ATS.OR.205(a)(2)	
(Text identical to GM1 to AMC6 ATM/ANS.C.005(a)(2))	
Equivalent coverage in EC 2017/373 text: N/A	
The ATM IR does not define assurance levels. It allows their use but points out to	
there can be many different types and that their use does not imply satisfaction requirement	n of
See GM2 ATS.OR.205(a)(2)	
Comments:	
Not specific to software. Removal of the SW related terms would have no effect the meaning of the text and would broaden it to include PPE. Assurance levels can be used in other fields as well e.g. DALs, HWALs	t on
The relationship between confidence and SWALs is not defined and so introduce SWALs should not be done until there is some solid underpinning evidence for so a relationship	•
response Noted	
The comment has been duly considered.	
comment 338 comment by: UK of	CAA
GM1 to AMC4 ATS.OR.205(a)(2) points (a)	
Equivalent coverage in EC 2017/373 text: ATS.OR.205(a)(2)	
Comments:	
Incorrect ref – should be ATS.OR.205(a)(2)	
Tautology – This simply says that the assurance should be provided with the requ level of confidence.	ired
response Not accepted	
]
comment 339 comment by: UK C	CAA
GM1 to AMC4 ATS.OR.205(a)(2) points (b)	



response	Noted
	EASA believes that the aspects identified in the AMC & GM are not covered in the
	existing AMC & GM with the necessary level of detail, taking into account the
	particularities and specificities of the software-related activities.
comment	340 comment by: UK CAA
	GM1 to AMC4 ATS.OR.205(a)(2) points (c)
	Equivalent coverage in EC 2017/373 text: None
response	Noted
	EASA believes that the aspects identified in the AMC & GM are not covered in the
	existing AMC & GM with the necessary level of detail, taking into account the
	particularities and specificities of the software-related activities.
comment	341 comment by: UK CAA
	GM1 to AMC4 ATS.OR.205(a)(2) points (d)
	Equivalent coverage in EC 2017/373 text: None
response	Noted
	EASA believes that the aspects identified in the AMC & GM are not covered in the
	existing AMC & GM with the necessary level of detail, taking into account the
	particularities and specificities of the software-related activities.

GM2 to AMC4 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional	p. 17
system	p. 17

comment	48 comment by: CANSO
	(b) "The allocated SWALs should be commensurate with the most severe effect that software malfunctions or failures may cause, according to the used severity classification scheme. It should, in particular, take into account the risks associated with software malfunctions or failures and the architecture and/or procedural defences identified."
	Clarify if the architecture and/or procedural defences identified are existing defences, defences that have to be implemented (Safety Requirement) or both of them.
response	Accepted



Considering the comment and the intent to correspond to 'both of cases', the text has been amended accordingly to promote clarity.

comment	73 comment by: CANSO
	Remark:
	Item (c):Partitioning between several software components with distinct SWAL
	should be acceptable taken into account the integrity control between data
	exchanged. It could be an alternative way to reduce SWAL from some sub-
	components.
	Space and timing partitioning consideration should be demonstrated depending on
	the SWAL criticality.
	=> The following sentence is proposed for amendment:(c) The software components that cannot be shown to be independent of one another
	should be allocated to the SWAL of the most critical of the dependent components.
	In case of integrity control of data exchanges between software components or in
	case of with space and timing partitioning argumentation, distinct SWAL could be
	considered
response	Not accepted
	It should be noted that that the integrity control between data exchanged is only
	valid when there is design and implementation independence between the control
	component and the controlled component. Then, point (c) would not be applicable.
comment	122 comment by: ENAV
	(b) "The allocated SWALs should be commensurate with the most severe effect that
	software malfunctions or failures may cause, according to the used severity
	classification scheme. It should, in particular, take into account the risks associated
	with software malfunctions or failures and the architecture and/or procedural
	defences identified."
	Clarify if the architecture and/or procedural defences identified are existing
	defences, defences that have to be implemented (Safety Requirement) or both of
	them
response	Accepted
	Considering the comment and the intent to correspond to 'both of cases', the text
	has been amended accordingly to promote clarity.
	······································
comment	130 comment by: Avinor Air Navigation Services (Avinor Flysikring AS)
	Comment to (b):
	Worst effect should be replaced with worst <i>credible</i> effect and other mitigations in
	place should be taken into account.



	Justification: One of the weaknesses with SWAL is the likelihood x most severe effect. Most severe effect will most likely be very serious (using worst case effect, instead of worst credible, and not taking other mitigations into account), and the definitions of likelihood is very vague, resulting in that the outcome/derived SWAL level can be whatever the people working on it wants it to be.
response	Accepted
	Considering the comment, the text has been amended accordingly.
comment	170 comment by: DSNA
	Item (c):Partitioning between several software components with distinct SWAL should be acceptable taken into account the integrity control between data exchanged. It could be an alternative way to reduce SWAL from some subcomponents. Space and timing partitioning consideration should be demonstrated depending the SWAL criticality. => The following sentence is proposed for amendment: "(c) The software components that cannot be shown to be independent of one another should be allocated to the SWAL of the most critical of the dependent components. In case of integrity control of data exchanges between software components or in case of with space and timing partitioning argumentation, distinct SWAL could be considered."
response	Not accepted
	It should be noted that that the integrity control between data exchanged is only valid when there is design and implementation independence between the control component and the controlled component. Then, point (c) would not be applicable.
comment	230 comment by: DSAC - FR NSA
	Only ED-153 provides a methodology to allocate SWAL and it is not sufficiently detailed and "constraining" to assure that SWAL will be allocated on the same way by all users. A more detailed GM would help to harmonize SWAL allocation.
response	Noted
	There are some particularities depending on the way that the safety (support) assessment is applied by each ANSP. It is noted that the current AMC & GM on changes to functional system does not have a reference severity classification scheme for hazard effects different from accident (catastrophic). This aspect will be considered for future rulemaking activity.
comment	262 comment by: NATS
	Para (c) "The use of multiple SWALs would also allow the possibility of managing several criticalities of the different software components within the system by the



	same set of software assurance processes." Where this is the case, appropriate partitioning needs to be demonstrated Issue : Suggests it is OK to have components of different criticality in the same system without partitioning. Suggestion: Reword to "The use of multiple SWALs would also allow the possibility of managing several criticalities of the different software components within the system (with appropriate partitioning) by the same set of software assurance processes."
response	Accepted
	Considering the comment, the text has been amended accordingly.
comment	274 comment by: German NSA (BAF)
	From the industrial standards only ED-153 use the term "SOFTWARE ASSURANCE LEVELS (SWAL)". If this term is used in the NPA it should be made clear whether it is used in the meaning of ED-153 levels or as general designation.
response	Noted
	The diversity of terms used in the different software standards is acknowledged. The term 'SWAL' has been used without a particular link to ED-153.
comment	292 comment by: ASD/Thales Air Systems
	GM2 to AM4 (b): regarding the sentence " and the architecture and/or procedural defences identified", it appears useful to be more detailed in the guidance explaining that mitigation measures are divided into 2 classes, preventive mitigations which decrease the probability of occurence of the hazard and protective mitigations which reduce the severity of the end effect of the hazard. And that the SWAL allocation done by ATS providers should take into account existing mitigations means to allocate the appropriate SWAL to a software equipment of the the ATM system.
response	Not accepted
	Despite that, this information could be considered useful. It is preferred to keep the provision at a higher level of abstraction rather to enter in other domains safety assessment techniques.
comment	342 comment by: UK CAA
	GM2 to AMC4 ATS.OR.205(a)(2)
	Equivalent coverage in EC 2017/373 text: N/A
	The ATM IR does not define assurance levels. It allows their use but points out that there can be many different types and that their use does not imply satisfaction of requirement See GM2 ATS.OR.205(a)(2)
	Comments:



	Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE. Assurance levels can be used in other fields as well e.g. DALs, HWALs The relationship between confidence and SWALs is not defined and so introducing SWALs should not be done until there is some solid underpinning evidence for such a relationship
response	Noted
	An analysis of the requirements has shown that there is no overlap. The commented GM is introduced to illustrate the intent of AMC4 ATS.OR.205(a)(2).
comment	343 comment by: UK CAA
	GM2 to AMC4 ATS.OR.205(a)(2) point (a)
	Equivalent coverage in EC 2017/373 text: N/A
response	Noted
	An analysis of the requirements has shown that there is no overlap. The commented GM is introduced to illustrate the intent of AMC4 ATS.OR.205(a)(2).
comment	344 comment by: UK CAA
	GM2 to AMC4 ATS.OR.205(a)(2) point (b)
	Equivalent coverage in EC 2017/373 text: N/A
response	Noted
	An analysis of the requirements has shown that there is no overlap. The commented GM is introduced to illustrate the intent of AMC4 ATS.OR.205(a)(2).
comment	345 comment by: UK CAA
	GM2 to AMC4 ATS.OR.205(a)(2) point (c)
	Equivalent coverage in EC 2017/373 text: N/A
response	Noted
	An analysis of the requirements has shown that there is no overlap. The commented GM is introduced to illustrate the intent of AMC4 ATS.OR.205(a)(2).
	346 comment by: UK CAA
comment	
comment	GM2 to AMC4 ATS.OR.205(a)(2) point (d)



Comments: Out of scope/context. This section deals with ATSPs only.

response Noted

An analysis of the requirements has shown that the commented provision is relevant. The commented GM is introduced to illustrate the intent of AMC4 ATS.OR.205(a)(2).

GM3 to AMC4 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional p. 17-18 system

comment	25 comment by: D Winship
	 para (c) "The definition of the software assurance processes may be based on one of these industrial standards without" The intent of this statement requires consideration – there is no reason why the service provider can't utilise best practices from a number of the relevant standards. The sentence as currently written could be interpreted as stating they can only select one due to the use of "without combining provisions for different standards". Please clarify intent of this paragraph and consider revision.
response	Partially accepted
	It would not be considered as a good practice to combine objectives from different standards as they were developed separately under different considerations and there could be some internal compensation means (one objective is less demanding in a particular standard because another objective is more demanding). On the other hand, the use of the verb 'may' allows the service provider to use the best practices to complement one of the standards or to define the full set of software assurance processes. No change is derived from this comment. However, considering the comment, the text has been amend to promote clarity.
comment	174 comment by: DSNA
	Even if the service provider may be able to validate pre-defined/standard additional software assurance processes, it may not be always able to define them because it requires a high level of expertise on the subject which may not be its core business.
response	Noted
	It should be highlighted that Regulation (EC) No 482/2008 is currently applicable and the ANSPs are required to implement a software assurance system.
comment	175 comment by: DSNA
	In item (b), the ED-12C/DO-178C should be removed too due to the fact that the ED- 109A/DO-278A already covers same assumptions for ATM context.



	Note also that DO-278B doesn't exist yet, and should be replaced by DO-278A. Finally, ED109 should be considered as it is a standard currently used in industry right now (not all software development have switched from ed109 to ed109A).
response	Partially accepted
	The comments are duly considered.
	It should be acknowledged that still some European ANSPs are making use of ED-12C/DO-178C to facilitate the software assurance process. Considering the nature of the commented GM, the referenced standard remains.
comment	231 comment by: DSAC - FR NSA
	The same reference as in the array "RTCA DO-178C" and "RTCA DO-278B" should be used.
response	Accepted
comment	263 comment by: NATS
	Para (b) "When tools are used during the software development lifecycle". It is difficult to imagine a software development lifecycle that does not include at least one tool (such as a compiler or development environment). In those terms "Tool Qualification" always exists for a software development lifecycle. Issue: Clarify that tool qualification it not 'optional' as implied by the statement. Suggestion: Add ED-215 to the list of ED-109A related supplements
response	Accepted
	As regards the tools qualification, EASA agrees that tools are widely used for software development and verification. Nevertheless, it might be possible that the tools do not require qualification because the output is verified independently. It is preferred to keep the proposed text.
comment	269 The comment by: ASD/Thales Air Systems
	To not create confusion, it is very important to not mix standards for airborne systems like DO-178C and standards for ground systems like ED-109A. A unique list may be confusing for a Service Provider that is not aware about the techncal content of those standards and may require the compliance to DO-178C to ground systems manufacturers. This confusion between standards could create a climate of incomprehension that could hinder functional improvement initiatives in ATM systems. Moreover, safety management systems put in place by ATM ground manufacturers are based on ATM standards (e.g. ED-109A, ED-153), and it will represent a blocking industrial issue to comply with standards, such as DO-178C, not adapted to ATM ground systems.
	That is the reason why i t appears necessary to separate these 2 different categories of standards (airborne standards vs ground standards).



response	Not accepted
	It should be acknowledged that the scope of each document, i.e. standard, indicates the intended domain of applicability. This is especially relevant taking into account
	the possibility of identifying ATM/ANS systems with ground and space components.
comment	283 * comment by: ASD/Thales Air Systems
	In the item (c), it is written that "The definition of the software assurance processes <u>may be</u> based on one of these industrial standards". From an industrial point of view, we know very well the technical content of these standards and we also know that requiring a compliance to provisions/requirements coming from different standards is a strong source of confusion. This is the reason why it appears useful to be more strict on this topic by writting for example: "The definition of the software assurance processes should be based on one of these industrial standards".
response	Not accepted
	Being guidance material and providing a non-exhaustive list of standards, the current
	wording is considered more suitable. It is acknowledged that there are other ANSPs
	that base the software assurance process on other standards (CMMI).
comment	347 comment by: UK CAA
	GM3 to AMC4 ATS.OR.205(a)(2) point (a)
	Equivalent coverage in EC 2017/373 text: N/A
	Comments:
	Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE. This section is out of context. The approval of processes is covered in
	ATM/ANS.OR.B.10 and its associated AMC/GM
response	Noted
comment	348 comment by: UK CAA
	GM3 to AMC4 ATS.OR.205(a)(2) point (c)
	Equivalent coverage in EC 2017/272 to $t \in \mathbb{N}/A$
	Equivalent coverage in EC 2017/373 text: N/A
	Comments: Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE. This section is out of context. The approval of processes is covered in ATM/ANS.OR.B.10 and its associated AMC/GM
response	Noted



2. Individual comments and responses

GM4 to AMC4 system	ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional p. 18-19
comment	8 comment by: DFS Deutsche Flugsicherung GmbH
	 (a) The second sentence is not clear: "This requirement applies also to software assurances" – The whole subject is on software assurance, so please be more concrete which requirement is meant ??
	Better, we suggest to remove the second sentence. (It also contradicts e.g. the next paragraph where it says that non-ATS-providers may have different software assurance processes.)
response	Partially accepted
	Considering the comment, the text has been amended to promote clarity.
comment	26 comment by: D Winship
	para (a) "applies also to software assurancesas mitigation means against software design failures" Consideration should be given to rewording this sentence re "software assurances".
	Also scope for mitigations may not only be limited to "software design failures".
	Suggested revision "This requirement is also applicable to software assurance evidence which may include information on the mitigation measures established to address software failures or unintended behaviours."
response	Accepted
	Considering the comment, the text has been amended.
comment	46 comment by: CANSO
	(a) The second sentence is not clear: "This requirement applies also to software assurances" – The whole subject is on software assurance, so please be more concrete which requirement is meant ??
	Better, we suggest to remove the second sentence. (It also contradicts e.g. the next paragraph where it says that non-ATS-providers may have different software assurance processes.)
response	Partially accepted



Considering the comment, the text has been amended to promote clarity. comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, comment 78 Luftfartsavdelningen) part a The responsability is clear, avoids the current practice to rely on industry. Noted response The comment is duly noted. 123 comment comment by: ENAV (a) The second sentence is not clear: "This requirement applies also to software assurances" - The whole subject is on software assurance, so please be more concrete which requirement is meant ?? Better, we suggest to remove the second sentence. (It also contradicts e.g. the next paragraph where it says that non-ATS-providers may have different software assurance processes.) Partially accepted response Considering the comment, the text has been amended to promote clarity. comment 264 comment by: NATS Para (b) This bullet implies that a non-ATS provider may have an equivalent SWAL scheme (especially if the ATS provider is using SWAL allocation). **Impact:** Implication that the non-ATS provider may require a SWAL scheme. Suggestion: Modify statement to "ATS and non-ATS providers may rely on different sets of software assurance processes and if applicable, different sets of SWALs." Accepted response Considering the comment, the text has been amended accordingly. comment 265 comment by: NATS Para (d) This bullet implies that a non-ATS provider may have an equivalent SWAL scheme (especially if the ATS provider is using SWAL allocation). Issue: Implication that the non-ATS provider may require a SWAL scheme. Suggestion: Modify statement to "If SWALs are used, the ATS provider should....."



response	Accepted
	Considering the comment, the text has been amended accordingly.
comment	293 comment by: ASD/Thales Air Systems
	GM4 to AMC4 (a): in practice there are many cases where ATS providers rely on non- ATS providers expertise to define an appropriate mitigation strategy to solve bloking issues. For example, based on the safety objectives allocated by the ATS provider, an equipement provider may recommend to a ATS provider to implement specific procedures to manage a specific risk identified during the training phase. Regarding software assurance, it is important to distinguish the target SWAL allocation done by ATS provider and the implemented SWAL which depends on the design of the software and the architecture of the system where this software is integrated (e.g. software implemented using diversification or using a fallback solution, etc.).
response	Noted
	It should be pointed out that the comment addresses the necessary interactions between ATS and non-ATS provider in order to ensure that the non-ATS service is consistent with the intended use. This coordination is also necessary for the safety and safety support assessments.
	Considering the comment, the commented GM will remain as initially proposed without modifications.
comment	349 comment by: UK CAA
	GM4 to AMC4 ATS.OR.205(a)(2)
	Equivalent coverage in EC 2017/373 text: General GM Section 2.4 & 3.3
	Comments: Not specific to software. Removal of the SW related terms would have no effect on the meaning of the text and would broaden it to include PPE. All of this is covered to a greater depth in the general GM- on multi actor changes – Section 2.4 and Service provider centric view – Section 3.3
response	<i>Noted</i> The comment is duly noted.

6. Appendix p. 22-23 comment 74 comment by: CANSO Page 23 Remark:



	Cross reference table seems to give some wrong references and needs to be corrected as this gives troubles in comparing with EC 482/2002 E;g AMC6 ATM/ANS.OR.C.005(a)(2), point (1)(a) refers to (a)(1), etc (letters and figures seem inverted in the NPA referenced points) => References shall be updated.
response	Accepted
comment	75 comment by: CANSO
	Remark: There are some differences between NPA and current regulation (e.g consideration about derived requirements, safety requirements vs requirements etc.), so a transition period for projects that have started before the entry into force of the regulation needs to be addressed. => EC 482/2002 - Article 7 " Entry into force " can't be to N/A and because it should be considered for projects which have already started software developments or under call for tender process
response	Noted
	It should be noted that Regulation (EC) No 482/2008 entered into force in 2010 and, hence, after several years of application, it is understood that the concept of software legacy does not require a particular treatment. Consequently, any new software or modifications to existing software should follow the software assurance processes.
comment	124 comment by: ENAV
	Page 23 Remark: Cross reference table seems to give some wrong references and needs to be corrected as this gives troubles in comparing with EC 482/2002 E;g AMC6 ATM/ANS.OR.C.005(a)(2), point (1)(a) refers to (a)(1), etc (letters and figures seem inverted in the NPA referenced points) => References shall be updated.
response	Accepted
comment	125 comment by: ENAV
	Remark: There are some differences between NPA and current regulation (e.g consideration about derived requirements, safety requirements vs requirements etc.), so a transition period for projects that have started before the entry into force of the regulation needs to be addressed. => EC 482/2002 - Article 7 " Entry into force " can't be to N/A and because it should be considered for projects which have already started software developments or under call for tender process
response	Noted



It should be noted that Regulation (EC) No 482/2008 entered into force in 2010 and, hence, after several years of application, it is understood that the concept of software legacy does not require a particular treatment. Consequently, any new software or modifications to existing software should follow the software assurance processes.

comment	171 comment by: DSNA
	There are some differences between NPA and current regulation (e.g consideration about derived requirements, safety requirements vs requirements etc.), so a transition period for projects that have started before the entry into force of the regulation needs to be adressed. => EC 482/2002 - Article 7 " Entry into force " can't be to N/A and because it should be considered for projects which have already started software developments or under call for tender process
response	Noted
	It should be noted that Regulation (EC) No 482/2008 entered into force in 2010 and, hence, after several years of application, it is understood that the concept of software legacy does not require a particular treatment. Consequently, any new software or modifications to existing software should follow the software assurance processes.
comment	203 comment by: AESA/DSANA
	Errata in number of NPA references. Please consider to review the following NPA references in the cross reference table Regulation (EC) No 482/2008 and this NPA: Article 3.1 is missing. In the reference table it should say Article 3(1) > N/A Article 4 >ATM/ANS.OR.B.010(a)(a) instead of ATM/ANS.OR.B.010(a)(1) Article 4(1) > AMC5 ATM/ANS.OR.C.005(a)(2), point (a) and AMC3 ATS.OR.205(a)(2), point (a) instead of AMC5 ATM/ANS.OR.C.005(a)(2), point (1) and AMC3 ATS.OR.205(a)(2), point (1) Art. 3(2)(a) > AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(1) and AMC4 ATS.OR.205(a)(2), point (a) (1) instead of AMC6 ATM/ANS.OR.C.005(a)(2), point (1)(a) and AMC4 ATS.OR.205(a)(2), point (1)(a) Article 3(2)(b) > AMC6 ATM/ANS.OR.C.005(a)(2), point (a) (2) and AMC4 ATS.OR.205(a)(2), point (a)(2) instead of AMC6 ATM/ANS.OR.C.005(a)(2), point (1)(b) and AMC4 ATS.OR.205(a)(2), point (1)(b) Article 3(2)(c) > AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(3) and AMC4 ATS.OR.205(a)(2), point (1)(b) Article 3(2)(c) > AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(3) and AMC4 ATS.OR.205(a)(2), point (1)(b) Article 3(2)(c) > AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(3) and AMC4 ATS.OR.205(a)(2), point (1)(b) Article 3(2)(c) > AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(3) and AMC4 ATS.OR.205(a)(2), point (1)(b) Article 3(2)(c) > AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(3) and AMC4 ATS.OR.205(a)(2), point (1)(b) Article 3(2)(c) > AMC6 ATM/ANS.OR.C.005(a)(2), point (a)(3) and AMC4 ATS.OR.205(a)(2), point (a)(3) instead of AMC6 ATM/ANS.OR.C.005(a)(2), point (1)(c) and AMC4 ATS.OR.205(a)(2), point (1)(c)

Article 3(2)(d) > AMC5 ATM/ANS.OR.C.005(a)(2), point (a) and AMC3 ATS.OR.205(a)(2), point (a) instead of AMC5 ATM/ANS.OR.C.005(a)(2), point (1) and AMC3 ATS.OR.205(a)(2), point (1)



Article 3(2)(e) > AMC6 ATM/ANS.OR.C.005(a)(2), point (b) and AMC4 ATS.OR.205(a)(2), point (b) instead of AMC6 ATM/ANS.OR.C.005(a)(2), point (2)
and
AMC4 ATS.OR.205(a)(2), point (2)
Art. 4(3)(a) Annex II — Part A > AMC6 ATM/ANS.OR.C.005(a)(2), points (a)(1)(i)
and (ii) AMC4 ATS.OR.205(a)(2), points (a)(1)(i) and (ii) instead of AMC6
ATM/ANS.OR.C.005(a)(2), points (1)(a)(i) and (ii) and AMC4 ATS.OR.205(a)(2),
points (1)(a)(i) and (ii)
Art. 4(3)(b) Annex II — Part B > AMC6 ATM/ANS.OR.C.005(a)(2), points (a)(4)
and (5) and AMC4 ATS.OR.205(a)(2), points (a)(4) and (5) instead of AMC6
ATM/ANS.OR.C.005(a)(2), points (1)(d) and (e) and AMC4 ATS.OR.205(a)(2), points
(1)(d) and (e)
Art. 4(3)(c) Annex II — Part C > AMC6 ATM/ANS.OR.C.005(a)(2), point (d) and
AMC4 ATS.OR.205(a)(2), point (d) instead of AMC6 ATM/ANS.OR.C.005(a)(2),
point (4) and AMC4 ATS.OR.205(a)(2), point (4)
Art. 4(3)(d) Annex II — Part D > AMC6 ATM/ANS.OR.C.005(a)(2), points (a)(1)((i)
and (ii) and AMC4 ATS.OR.205(a)(2), points (a)(2) (i) and (ii) instead of AMC6
ATM/ANS.OR.C.005(a)(2), points (1)(b)(i) and (ii) and AMC4 ATS.OR.205(a)(2),
points (1)(b)(i) and (ii)
Art. 4(4) > Mainly addressed in NPA 2014-13; In this NPA, the software elements
are dealt with in: AMC6 ATM/ANS.OR.C.005(a)(2), point (c) instead of : Mainly
addressed in NPA 2014-13; In this NPA, the software elements are dealt with
in:AMC6 ATM/ANS.OR.C.005(a)(2), point (3) and AMC4 ATS.OR.205(a)(2), point (3)
Article 4(5)> AMC5 ATM/ANS.OR.C.005(a)(2), point (b) AMC3 ATS.OR.205(a)(2),
point (b) instead of:AMC5 ATM/ANS.OR.C.005(a)(2), point (2) and AMC3
ATS.OR.205(a)(2), point (2)
Art. 5 > Mainly addressed in NPA 2014-13; In this NPA the software elements
are: AMC6 ATM/ANS.OR.C.005(a)(2), point (e) and AMC4 ATS.OR.205(a)(2),
point (e) instead of Mainly addressed in NPA 2014-13; In this NPA the software
elements are: AMC6 ATM/ANS.OR.C.005(a)(2), point (5) and AMC4
ATS.OR.205(a)(2), point (5)
Asserted

response Accepted



3. Attachments

Z<u>20171207CommentFormExternal.pdf</u> Attachment #1 to comment <u>#350</u>

20171117UK CAA Table of Detailed Comments for Comment No 1 on NPA 2017-10.pdf Attachment #2 to comment <u>#350</u>

20171117UK CAA Table of Detailed Comments for Comment No 1 on NPA 2017-10.pdf Attachment #3 to comment <u>#236</u>

