

Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

1. Introduction

This material outlines the procedures to enable an ATM/ANS service provider (hereafter referred to as the SP) to implement a change to their functional system, with or without prior notification to the competent authority (hereafter referred to as the CA), in accordance with the regulatory requirements of Commission Regulation (EU) 2017/373.

A functional system means a combination of procedures, human resources and equipment, including hardware and software, organised to perform a function within the context of ATM/ANS and other ATM network functions.

The SP shall define and document the scope of their functional system. When a SP does not clearly define the scope or extent of its functional system, (i.e. from those areas of service provision, management system(s), safety management system) the CA will consider all of the SPs procedures, human resources and equipment (including hardware and software) to constitute their functional system.

1.1. **Scope**

This ASAM applies to all SPs certified by the CA of Ireland, in accordance with the requirements of Commission Regulation (EU) 2017/373 and specifically addresses a change to the functional system or a change that affects the functional system.

For changes to the provision of service, the SP's management system and/or safety management system, that do not affect the functional system, SPs shall follow the steps outlined in ASAM No. 039, which can be accessed under the 'Publications' tab on the IAA website (https://www.iaa.ie/publications).

1.2. Responsible Person

The Irish Aviation Authority (IAA) is the CA for Ireland regarding Regulation (EU) 2018/1139, and Commission Implementing Regulation (EU) 2017/373.

The Manager, Air Navigation Services Division (ANSD) of the IAA has overall responsibility for this material.

2. References

- Commission Implementing Regulation (EU) No. 2017/373 as amended;
- Regulation (EU) 2018/1139 as amended;

ASAM No.38 Issue 8.0 Page 1 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

3. Changes to the functional system - Notification

- 3.1 ATM/ANS.OR.A.045 Changes to a functional system
 - (a) A service provider planning a change to its functional system shall:
 - (1) notify the CA of the change;
 - (2) provide the CA, if requested, with any additional information that allows the CA to decide whether or not to review the argument for the change;
 - (3) inform other SP and, where feasible, aviation undertakings affected by the planned change.
- 3.2 For changes to the functional system or that affect the functional system, which are not identified within the CA Change Management Procedures letter of approval (as per Section 13 routine changes), the SP shall notify the CA of the proposed change in advance of implementation, using the Notification of Change (NOC) online form on the IAA website as follows -

Classification of planned change where prior notification is required in advance of implementation

- 3.2.1 **Complex**; notification **no later** than 90 working days in advance of the proposed change implementation date. The likelihood of regulatory review is considered to be high. See section 4.
- 3.2.2 **Non-complex**; notification **no later** than 35 working days in advance of the proposed change implementation date. The likelihood of regulatory review should be medium to low. Where an approval by the regulation is directly mandated to be issued (e.g., Low Visibility Procedures, etc) then at a minimum this change is classed as a 'non-complex change' unless the approval letter states otherwise. See section 4.
- 3.2.3 **Common;** notification **no later** than 10 working days in advance of the proposed change implementation date. The SP considers that the planned change would not require regulatory review. See section 4.

ASAM No.38 Issue 8.0 Page 2 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

- Note Where it is found that an SP is submitting planned changes under the 'Common' classification, which require the CA to undertake an unreasonable level of reviews, then the CA may impose a limitation on the approval of the change management procedures, which suspends the use of the 'Common' classification.

 In such a scenario, the SP (or specific internal Unit therein) may be directed not to submit future changes under the 'Common' classification notification process. This will remain in place until such time that the SP can demonstrate their ability to adhere to correct classification of notifications, to the satisfaction of the CA.
- 3.2.4 **Unplanned**; notification sent to the CA in line with timeframes as documented under SP procedures which are approved by the CA. An unplanned change is any urgent change that the SP has assessed as being necessary to carry out in less than the minimum notification period outlined within this ASAM, in order to maintain the safety of the service. They are conducted in accordance with SP change management procedures approved by the CA i.e. where the SP has documented the scope of unplanned changes and associated procedure, which is listed in the CA approval letter. The SP scope of the change shall be attached to the notification. See section 12.
- 3.3 For changes that affect the functional system but are specifically listed under a CA change management procedures letter of approval, the SP is not required to notify the CA in advance of implementation. In such instances, the SP shall record the change in their change register and notify the CA post-implementation in accordance with agreed timelines i.e. as documented in the SP approved change management procedures. Such changes are classified as 'routine changes', see section 13.
- 3.4 Where the SP is in doubt regarding what specific NOC classification is applicable in relation to a planned change, then they should engage directly with the CA to seek guidance and feedback. It is recommended that if the SP determines that such engagement is required, then it should be undertaken in the early planning stages for a proposed change, to avoid the potential for any unnecessary delays.

4. Complex, Noncomplex and Common planned changes

4.1 A **complex change** can be the likelihood of the argument being complex and/or unfamiliar to the SP (and indeed the CA) and/or the severity of the possible consequences of the planned change is significant¹. It may also be the amount of

ASAM No.38 Issue 8.0 Page 3 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

safety assurance documentation being generated or updated such that the volume is significant and requires considerable time and due diligence by the SP and/or the CA.

Most complex changes will require project management. The CA will require the project (change) sponsor and appropriate experts to present to the affected IAA divisions in advance, so that the CA can -

- gain an understanding of the planned change,
- the actions required to be undertaken,
- the CA resource needed,
- to alert the project to any regulatory issues,
- provide feedback on proposed timelines and
- In general, ensure that project expectations are understood and to agree notification and submission timelines.

Therefore, for a complex change the SP shall inform the Manager ANSD in advance of submitting a notification for the planned change via the NOC portal, who will then coordinate a date and time for the aforementioned presentation to be made to the affected IAA internal divisions.

The SP should plan to present the following at a minimum in advance of the meeting

- Change/Project plan (to include the safety plan i.e. the plan for implementing the safety elements of the change under the SP approved management of change procedures).
- Change/Project Scope.
- Change/Project timelines.
- Change/Project milestones.
- Change/Project dependencies (includes list of other affected stakeholders).
- Change/Project lags and leads.
- 4.2 A **non-complex change**, unlike a complex change, should not have the potential to result in a high risk or a high impact on service provision.

For a non-complex change

- The SP is familiar with the full scope of the planned change and the formulation of the associated necessary argument; however thorough consideration is required.
- the severity of the possible consequences of the change is deemed not to be significant¹

ASAM No.38 Issue 8.0 Page 4 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

For guidance, one or more of the following may pertain -

- The planned change is **familiar** to the SP (i.e., it can be demonstrated that most of the change elements (approx. 75%) have been assessed before and within the last 365 calendar days approx.).
- Involves significant coordination with other SP(s) or aviation undertaking(s) in advance of implementing the planned change, which results in a significant amount of safety assessment and/or assurance documentation being generated to support the planned change (e.g., requires a joint safety assessment which identifies additional safety mitigations to be put in place by the SP to reach an acceptable level of safety, or additional time for the other organisation(s) to assess and, if necessary, put in place safety mitigations because of the identified potential impact of the planned change.)
- Involves a new contracted activity or a change to a previously assessed contracted activity.
- May require another CA to be notified in advance of implementation.
- The CA has already advised the SP in advance of notifying the planned change, that it will likely be subject to a review based on the CA decision making criteria.

Note¹ - Severity of the consequences of the change may be determined as a result of the Preliminary Safety Assessment conducted in accordance with GM1 ATM/ANS.OR.A.045(a) 'Changes to a functional system'.

4.3 For a **common change**, the following criteria must be met -

- The SP is very familiar with the full scope of the planned change and the formulation of the associated necessary argument.
- the severity of the possible consequences of the change is not significant¹
- The amount of safety assurance documentation being generated or updated such that the volume is not significant.
- The CA has <u>not</u> advised the SP in advance of notifying the planned change, that it will likely be subject to regulatory review based on CA decision making criteria.

For guidance, one or more of the following may pertain -

 It's very familiar to the SP (i.e., it can be demonstrated that all of the change elements have been assessed before and within the last 365 calendar days approx.

ASAM No.38 Issue 8.0 Page 5 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

- Coordination with other SPs or aviation undertakings is necessary in advance of implementing the planned change and involves a joint safety assessment to be undertaken as part of the coordination phase. However, the joint safety assessment does not identify that any additional safety mitigations are required to be put in place by the SP or the other organisation(s), to reach an acceptable level of safety for the planned change.
- Involves no new contracted activity or no change to a previously assessed contracted activity.

An example of a 'common change' could be a minor software upgrade to deploy security/performance patches, and other equipment changes that do not add any additional system functionality.

- 4.4 Complex, noncomplex, and common changes need to be notified as early as possible to prevent any potential delay in their implementation. Therefore, it is advisable that the NOC form is submitted as soon as possible, and that the description of the change includes a sufficient level of detail, to provide the CA with an initial understanding of the planned change. Wherever necessary, additional information should be provided by means of references to supporting documentation and attached to the NOC form.
- 4.5 Regarding detail within the notification, the SP should place emphasis on inputting as much detail as possible on
 - (1) Purpose of the planned change.
 - (2) Reasons for the planned change.
 - (3) Detailed description of the planned change.
 - (4) Place of implementation.
 - (5) New/modified functions/services brought about by the planned change.
 - (6) High-level identification of the constituents of the functional system being changed and what is modified in their functionality.
 - (7) Consequence of the change (i.e., the harmful effects of the hazards associated with the change see definition of 'risk' in Regulation (EU) 2017/373 Annex I (85)).
- 4.6 For air traffic services (ATS) providers, the consequences of the change specified in 4.5 (7) above, should be expressed in terms of the harmful effects of the change, i.e. the effects of the hazards associated with safety risks. These could be the result of a preliminary safety assessment, if available, or an early hazard analysis that concentrates on the service level effects. For SP other than ATS providers, the

ASAM No.38 Issue 8.0 Page 6 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

consequences should be expressed in terms of what aspects of the performance of the service are potentially impacted by the change.

- 4.7 Useful information can be found in the following guidance material, to provide an insight into the CA decision making process, when determining the need to conduct a review of a notified change -
 - (1) GM1 ATM/ANS.AR.C.035(b) Decision to review a notified change to the functional system: Selection criteria for reviewing a notified change to the functional system
 - (2) GM1 ATM/ANS.AR.C.035(c) Decision to review a notified change to the functional system: Other selection criteria.
- 4.8 The decision to review a change will be based, in most circumstances, on the content of the submitted NOC form. Exceptions to this are cases where the CA is not familiar with the type of change, or the complexity of the change requires a more thorough consideration.
- 4.9 The SP should consider that an early, clear and accurate change notification will assist the CA in determining the need for a review and may prevent any inconvenience such as:
 - (1) the CA having to request more information about the planned change in order to make its decision as required in ATM/ANS.OR.A.045(a)(2);
 - (2) the CA deciding to review a change unnecessarily because the NOC form contains unclear information in relation to the planned change; or
 - (3) the delay in the CA deciding whether to review a change, caused by the lack of information, having an impact on the proposed date of entry into service.

5. Notification - Planned changes

- 5.1 For a planned change to the functional system the SP shall notify the CA using the NOC <u>online form</u> on the IAA website, in advance of the proposed change no later than -
 - 5.1.1 Complex 90 working days;
 - 5.1.2 Non-complex 35 working days;
 - 5.1.3 Common 10 working days.

ASAM No.38 Issue 8.0 Page 7 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

Note: the CA considers the day after receipt of the notification as the first day for counting purposes.

- 5.2 The SP shall provide the CA with the following at a minimum in relation to a planned change to the functional system;
 - o A completed online NOC form and as appropriate -
 - A copy of the associated safety (support) case and any supporting documentation (as applicable) in relation to the planned change, and
 - The SP shall include in the NOC submission, all relevant draft documentation which is affected by the planned change, clearly identifying where change(s) have been made.
 - Where planned updates to such documentation will have an impact on demonstration of compliance with Regulation (EU) 2017/373 requirements, the SP shall submit an updated version of each impacted compliance matrix document* (or extracts of) to reflect the planned change, which assists in tracking organisational compliance with the regulatory requirements. In such instances, the SP shall ensure that the 'Doc list' tab in each compliance matrix is updated accordingly and in advance of submitting as part of the NOC. (*or alternative SP compliance tracking document(s) agreed for use by the CA)
- 5.3 Where information required to be filled in on the form is not available at the time of submission of the NOC, SPs shall insert a note in the appropriate field indicating when that information will be available.
- 5.4 The SP shall notify the CA, when the information provided in a previous notification is no longer valid (e.g. NOC cancellation, change in description, change in scope, etc) or when the information previously missing becomes available. This notification shall be by means of an updated NOC form using the same reference number but with a new version number.
- 5.5 Where additional information in relation to a submitted NOC is requested by the CA (i.e., additional to the NOC information already sent in), then an update of the NOC is required to submit this additional information, using the same reference number with a new version number.
- 5.6 As a contingency, where there are issues with the online form an SP may use the PDF form OPS.ANS.F.267 available on the IAA NOC portal, attach it to an email and

ASAM No.38 Issue 8.0 Page 8 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

send to ansdinfo@iaa.ie to notify of the planned change, providing information regarding the issues experienced when attempting to use the online NOC form.

- 5.7 For notified planned changes, the SP may plan to implement the planned change on or after the identified implementation date, following receipt of the CA automated email. If there is a lack of clarity regarding the content of the NOC (i.e. unclear or missing information) then the CA may contact the SP to advise that there may be a potential delay to the planned implementation date, until such time that the CA has received all required information to determine if a review is required. Therefore, the onus is on the SP to be as accurate and complete with regard to the information contained within the NOC, at the time of initial submission. The CA reserves the right to review any NOC submission and delay its implementation if the change and its potential impact are not clear.
- 5.8 For complex changes as the likelihood of CA review is high, the SP should plan for the introduction of the planned change but in the knowledge that the CA will most likely carry out a review. As such, there could be an impact on the identified planned implementation date, if the overall NOC submission is not complete and clear. Also, if the change is new to the SP and/or to the CA this may also have an impact on the identified planned implementation date, so SPs should not rely on the minimum notification period when submitting the NOC, but rather submit it in enough time to ensure there is contingency included for potential unknowns.

 As per ATM/ANS.OR.A.045(d) requirement, when a planned change is subject to CA review, the SP shall only allow the parts of the change for which the CA has approved the argument, to enter into operational service.
- 5.9 For <u>all</u> classes of change, should the SP wish to introduce the planned change in advance of the notified planned implementation date, it may request the CA to expedite the 'NOC check' (see section 8), providing supporting rationale for the request and justification for the inability to adhere to the minimum notification periods. All such requests should be forwarded to the CA email address identified in section 15 and the relevant CA Inspectors who have been allocated to the SP. Note that the above expedite provision should only be requested in exceptional cases and is without prejudice to the minimum notification periods set out in section 3.2. The CA will endeavour to facilitate the SP request to expedite the 'NOC check' but reserves the right to refuse the request without justification. Therefore, the SP should plan the notification of all changes i.a.w the minimum notification periods set out in section 3.2

ASAM No.38 Issue 8.0 Page 9 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

- 5.10 The CA may, as part of the change process, conduct audits and inspections including, as appropriate, unannounced inspections of the SP prior to, during and/or after implementation of a change.
- 5.11 In the continuous oversight process, the CA may assess the information provided in a NOC to verify whether the actions taken comply with the approved procedures and applicable requirements. In case of any non-compliance, the CA will:
 - (1) notify the SP of the non-compliance and request further changes.
 - (2) in case of level 1 and level 2 findings, act in accordance with point ATM/ANS.AR.C.050.

6. Notification to users of the service (General)

- 6.1 Having notified a change, the SP shall:
 - (1) individually inform all other SPs identified as potentially affected by the notified planned change; and
 - (2) inform all aviation undertakings potentially affected by the planned change, where feasible, either individually or via a representative body of aviation undertakings, or by publishing details of the planned change in a dedicated publication of the SP or aeronautical information publications such as an aeronautical information circular (AIC).
- 6.2 Having notified a change, the SP shall inform the relevant SPs and aviation undertakings whenever the information provided in accordance with point 6.1 is materially modified.
- 6.3 When a change affects other SPs and/or aviation undertakings, as identified in point 6.1, the initiating SP and other identified SPs potentially affected by the planned change, in coordination, shall determine:
 - (1) the dependencies with each other and, where feasible, with the affected aviation undertakings;
 - (2) the assumptions and risk mitigations that relate to more than one SP or aviation undertaking.
- 6.4 Those SPs affected by the assumptions and risk mitigations referred to in point 6.3 (2) shall only use, in their argument for the planned change, agreed and aligned

ASAM No.38 Issue 8.0 Page 10 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

assumptions and risk mitigations with each other and, where feasible, with aviation undertakings.

7. Action upon receipt of notification

- 7.1 Upon receipt of a NOC in accordance with point ATM/ANS.OR.A.045(a)(1), or upon receipt of modified information in accordance with point ATM/ANS.OR.A.045(b), the CA will through its 'NOC Check' and 'Decision to Review' processes, determine the need for a review of the planned change. The CA may request any additional information that it deems necessary from the SP to support this determination process and subsequent decision.
- 7.2 The CA will acknowledge receipt of the online NOC form, by automated email response which will include a copy of the submitted NOC form. The SP shall keep a copy of this email as evidence of notification to the CA.
- 7.3 If for some reason the SP doesn't receive the CA automated email response, then it must contact the CA directly via email at ansdinfo@iaa.ie identifying the issue. The CA will reply within 05 working days from the date it receives this email providing an acknowledgement to the notification. The planned change shall not take place until a CA response is received.
- 7.4 Once the SP has notified the CA of its planned change in accordance with the procedures of this ASAM, it can implement the planned change as notified and following the minimum notification period unless -
 - (1) it receives communication from the CA that it has determined the need to conduct a review of the planned change; or
 - (2) through the 'NOC Check' process, the CA indicates the SP cannot proceed with the planned change.

8. The CA 'NOC Check' process

- 8.1 The 'NOC Check' process will identify -
 - (1) what planned change will not need review (will fall within the annual safety oversight audit scope); or

ASAM No.38 Issue 8.0 Page 11 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

- (2) what planned change need further examination to determine if a review is needed (step 1.2 in the review process flow diagram at appendix B); or
- (3) what planned changes definitively need to be reviewed* (step 1.3 in process flow diagram appendix B)
- 8.2 When the SP has submitted its NOC, the CA will check the submission for correctness and completeness. The NOC must contain enough detail about the planned change and its potential impact for the CA to determine if a review is required.
 - 8.2.1 If the NOC is complete and the safety argument is accepted*, the CA will close the NOC in its database and the SP can implement the planned change as notified.
 - * Note The exception to point 8.2.1 is where the combination of the likelihood of the argument is complex or unfamiliar to the SP (or the CA) and the severity of the possible consequences of the planned change is significant. The CA is mandatorily required to conduct a review in such a scenario. Therefore, the CA will notify the SP and conduct a review (step 1.3 in the process flow diagram appendix B) before the SP can implement the planned change.
 - 8.2.2 If the NOC is complete but the safety argument lacks clarity, the CA will go to step 1.2 in the process flow diagram (appendix B) (i.e., the decision to review process). If the CA determines a review is required, the SP shall be notified of same.
 - 8.2.3 If the NOC is incomplete, (not enough information provided in the information fields) or the associated documentation is incorrect/lacking clarity, the CA will do either of the following:
 - (1) Regarding insufficient information, where the change is not considered to be risk critical, its scope is limited and the ability of the CA to understand the planned change is not impinged, then the CA may decide that it can proceed as notified. In this scenario, the main issue is not in the understanding the scope of the planned change or its risk level, but it is to get the additional information so that the AMC1 ATM/ANS.OR.A.045(a) is demonstrated to be met.

The CA will notify the SP via a Type A email notification with 'CA NOC feedback to SP – 'Type A' in the subject line.

ASAM No.38 Issue 8.0 Page 12 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

The onus is on the SP to provide the requested information in advance of the notified implementation date of the planned change, unless otherwise notified by the CA inspector. The CA inspector will outline if an updated NOC is required to be resubmitted and if so, it will be with the same reference number but with a new version number;

or

- (2) Regarding insufficient information which inhibits the CAs ability to understand the planned change, its impact, its extent, its risk level etc, the CA will require the SP to provide the missing information, or to update the notification material prior to allowing the planned change take place. The CA will notify the SP by an email with 'CA NOC feedback to SP 'Type B' in the subject line and a CA feedback form 'OPS.ANS.F.254' attached with specific information, in order for the SP to understand what is being required of it.
- 8.2.4 In follow up to an initial NOC submission, if the CA does not receive the information it requests in a timely manner, the SP runs the risk of the CA rejecting the NOC submission and advising that the planned change cannot go ahead¹. The SP will be notified in such a scenario, which shall reset the notification timelines².
- 8.2.5 Please refer to IAA ASAM No.45 for further information and guidance material in relation to the CA 'NOC Check' process.

Explanatory note 1

If this is the case, it is because the flow of information is impacting on review and notification timelines and the CA will not be able to remain inside the published process. Therefore, some control is required to keep discipline and structures of notification in place for the benefit of all SPs and the CA.

Explanatory Note 2

The CA works within the timelines for notification of a review to the SP and that time period from notification to assess whether a review is needed or not, is impinged on if the initial 'NOC Check' following notification identifies deficiencies in the NOC. Remember the timelines are minimum to allow the SP to prepare its case and undertake its planned change as soon as possible, but also allowing the CA to meet its regulatory monitoring and oversight requirements. Therefore, when working to notification timeline minimums there is little room for manoeuvre, so it is incumbent on the management systems of a SP to ensure that material submitted is quality, compliance and safety checked (at a minimum) before submitted for regulatory check.

ASAM No.38 Issue 8.0 Page 13 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

- 9. CA decision to review a notified change (ATM/ANS.AR.C.035)
- 9.1 Following completion of the CA 'NOC Check' process, the decision to review process is the next step to determine whether a CA review of the planned change will be undertaken.
- 9.2 The CA will determine the need for a review based on specific, valid and documented selection criteria that, as a minimum, ensure that the notified planned change is reviewed if the combination of the likelihood of the argument being complex or unfamiliar to the SP (or the CA) and the severity of the possible consequences of the change is significant. Other reasons for review are continuous oversight sampling, training of CA staff or other reasons which will be provided if requested at the time of review.
- 9.3 It is important to note for a correct and proper functioning change process where review and approval is required, the SP must ensure the CA is provided with mature safety arguments complete with (c/w) relevant supporting documentation in a timely manner. These documents must have evidence of SP organisational review and approval at the appropriate management level, to indicate to the CA that they have complied with the regulatory and organisational requirements and as such are being presented as being fit for regulatory approval.
- 9.4 It is not appropriate for submissions to be received by the CA which lack SP organisational review, compliance, or which require extensive CA comment. This in some cases, can call into question the effectiveness of an SPs management system (e.g. quality, safety, security, compliance etc.). If it is apparent from an initial CA review that due care and attention was not given to the submission, the SP runs the risk of the CA rejecting the argument contained within the NOC submission outright and the planned change not being approved for implementation in the timeframe requested.
- 9.5 Should the CA decide to review a change it will -
 - (1) inform the SP of its decision to review by email -
 - for complex and non-complex changes no later than 20 working days following receipt of the NOC.
 - for common changes no later than 10 working days following receipt of the NOC.

(See appendix B for process flow diagrams)

The CA will provide the associated rationale to the SP upon request.

ASAM No.38 Issue 8.0 Page 14 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

- (2) coordinate its activities with other CAs whenever necessary.

 (Note this must be done before issuing a change approval if one is issued)
- 9.6 Where the CA has advised that a planned change is subject to a review, the SP shall only allow the parts of the planned change for which the CA has approved the argument to enter into operational service.

10. Regulatory baseline & CA submission requirements

ATM/ANS.AR.C.040 Review of a notified change to the functional System

- (a) When the **competent** authority reviews the argument for a notified change, it shall:
- (1) assess the validity of the argument presented with respect to point ATM/ANS.OR.C.005(a)(2) or ATS.OR.205(a)(2);

ATS.OR.205 Safety assessment and assurance of changes to the functional system

- (a) For any change notified in accordance with point ATM/ANS.OR.A.045(a)(1), the air traffic services provider shall:
 - (2) provide assurance, with sufficient confidence, via a complete, documented and valid argument that the safety criteria identified via the application of point ATS.OR.210 are valid, will be satisfied and will remain satisfied.

ATM/ANS.AR.C.005 Certification, declaration, and verification of service providers' compliance with the requirements

"(a)(4) the implementation of safety, security and interoperability objectives, applicable requirements and other conditions identified in the statement of compliance for ATM/ANS equipment; technical and performance limitations and conditions identified in ATM/ANS equipment certificates and/or ATM/ANS equipment declarations; and of safety measures, including ATM/ANS equipment directives mandated by the Agency in accordance with point ATM/ANS.EQMT.AR.A.030 of Annex I to Delegated Regulation (EU) 2023/1768;"

ASAM No.38 Issue 8.0 Page 15 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

- 10.1 The CA email notification to the SP advising of the decision to conduct a review may include the CA form OPS.ANS.F.256SP 'Changes to the FS Checklist'. When provided by the CA, this checklist is to be used by -
 - (1) ATS providers, for changes to its functional system, to document where it meets compliance in respect to ATS.OR.205(a)(2), ATS.OR.210 and with ATM/ANS ground equipment conformity assessment framework if required;
 - (2) For ATM/ANS providers (who are non-ATS providers), for changes to its functional system, to document where it meets compliance in respect to <u>ATM/ANS.OR.C.005(a)(2)</u> and with ATM/ANS ground equipment conformity assessment framework if required;
 - (3) To expedite the regulatory review.
- 10.2 Where provided by the CA, the checklist shall be submitted as part of each subsequent SP submission to track compliance.
- 10.3 The SP must ensure the CA is provided with mature safety arguments c/w relevant supporting documentation, in a timely manner after being notified of the CAs decision to review.
- 10.4 For review of submissions which do not have a complete set of supporting documentation, SPs should factor into their planned change implementation plan, the time needed for follow-up action following an initial CA review and consequently for any further CA comment that may be generated following submission of the remaining documentation.
- 10.5 Where a complete set of supporting documentation isn't provided, the CA may indicate that it will start its review but reserves the right to suspend it at any time until it has <u>all</u> evidence needed to assess the validity of the argument presented for the planned change.

Explanatory note 3

It is not ideal if evidence gathering is still being performed during the CA review in the lead up to the planned 'O-date'. This leads to tight timelines for the SP to ensure the safety argument is valid and erodes contingency time to react, should the CA generate comment when undertaking its review. It also shortens CA review time

ASAM No.38 Issue 8.0 Page 16 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

which places a high burden on CA inspectors to carry out a hurried review, thus raising the potential of missing non-compliance related issues.

However, it is recognised that on occasion it is necessary. Good project management through appropriate planning and early consultation with affected organisations is vital to ensure that a planned 'O-date' remains on track. Therefore, when the CA review period runs consecutively up to the planned 'O-date' and the SP needs to use some of that period for evidence gathering e.g. SAT testing, ATCO training etc, then it shall consult and get agreement in writing from the CA before it notifies it of the change.

No associated dates, appointments, training or any other activity outside of the control of the SP, should be made with third party organisations in such circumstances, until the CA is consulted with. The CA will require a rationale from the SP and seek assurance from the SPs change plan that this encroachment on the minimum CA review period is justified. This supporting documentation shall form part of the SP notification material to the CA under the NOC procedure.

Where evidence gathering/submission is not complete within 30 days of the planned 'O-date' -

As part of this consultation, the CA will need to ensure it has resources available (impacts for example, other regulatory tasks; leave periods; training courses; contingency issues {sickness; State security etc.}). It should also allow the CA to understand the amount of outstanding supporting documentation that is required to be reviewed to better understand the impact on the overall safety argument submission.

Where an SP gets agreement to submit remaining supporting documentation within the review period leading up to O-date, should unexpected issues arise (e.g., the evidences are more complex or higher in quantity than estimated at consultation; the SP has not adhered to agreed timelines; the CA priority tasking has changed, or any other reason deemed justifiable to the CA) the CA reserves the right to delay the planned change, until it has reviewed all the outstanding supporting documentation and reaches a determination in relation to the assessment of the overall argument.

11. The CA Review and Approval/Rejection Process

- 11.1 The following (1), (2) or (3) are the possible outcomes of an initial CA review -
 - (1) The CA will close its review and without delay indicate that the planned change

ASAM No.38 Issue 8.0 Page 17 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

can go ahead as notified, outlining any associated conditions or limitations, and as soon as practical will issue an approval letter to reflect same.

Or

(2) The SP will receive a notification via email that the CA will continue its review and, if not already attached, will forward either the OPS.ANS.F.256SP form or a Comment Response Document (CRD) OPS.ANS.F.257 in due course. The SP may continue to plan to implement the planned change on or after the notified implementation date. This is on the understanding that the SP will get all matters outlined in the OPS.ANS.F.256SP form or CRD, resolved in sufficient time to demonstrate same to the CA before the planned 'O-date'.

Therefore -

(a) If all identified matters are satisfactorily resolved, the CA will close its review and indicate that the planned change can go ahead as notified, outlining any associated conditions or limitations, and as soon as practical will issue an approval letter to reflect same.

Or

(b) If the OPS.ANS.F.256SP form is used and five non-compliances are identified or the CRD reaches the threshold numbers outlined hereunder, the CA <u>may</u> suspend its review and send back either. This is on the understanding that enough issues have been identified that demonstrates the NOC submission is not at a sufficient level of maturity for regulatory approval and warrants further review and update by the SP.

The SP shall address the OPS.ANS.F.256SP / CRD comments and demonstrate that it has carried out a full review* to ensure no other issues are contained within its submission that could affect the regulatory approval being issued. This may have the potential to affect the planned implementation date and the SP should plan accordingly.

CRDs may not extend to more than the following before being addressed by the SP -

5 Major

(See appendix A for definition of each classification)

The SP shall submit their OPS.ANS.F.256SP or CRD response and updated docs (with organisational review/approval evidence*) using the NOC form with the same reference number but with a new version number.

ASAM No.38 Issue 8.0 Page 18 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

If the identified matters are not being resolved to the CAs satisfaction, e.g. a second or third OPS.ANS.F.256SP or CRD review is suspended, or where the CRD is issued and the SP fails to return it in a timely manner, the CA reserves the right to close the review and reject the NOC outright. In such a scenario, the CA will issue a rejection letter (with justification) and the change as proposed shall not go ahead. See point 11.2.

*Note - Updated documents with a record of the chapters reviewed, the changes made to each and the name of the person who carried out the review, is one way the SP can declare demonstrates evidence that a full review was carried out.

Or

- (3) The CA will close its review and issue a rejection letter (with justification). See point 11.2.
- 11.2 Regarding point 11.1 '(2) b)' and '(3)' where a rejection letter is issued: Should the SP wish to resubmit the change it must first address the issues outlined by the CA and then start the notification process again, by sending in a new NOC form with a new reference number and a new version number. The notification process will start again from the beginning as if it is a first-time submission.
- 11.3 The CA may prescribe conditions under which the SP may operate when implementing planned changes, which may include allowing the SP to partially implement a planned change whilst the regulatory review is ongoing.
- 11.4 Depending on the planned change, the CA approval may take the form of a new or amended certificate, a new or amended approval letter, or an electronic mail, setting out terms of approval if appropriate.
- 11.5 Where it is found that the SP implements planned changes (or parts thereof) that are subject to CA review, without having received CA approval in advance (as referred to in ATM/ANS.OR.A.045(d)), the CA will take immediate and appropriate action, without prejudice to any additional enforcement measures. Note; Appropriate action by the CA may include suspension, limitation or revocation of the SP's certificate.

12. Unplanned changes

ASAM No.38 Issue 8.0 Page 19 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

An unplanned change is any change that the SP has safety assessed as being necessary to carry out in less than the CA minimum 10 working days notification period and is not listed as a routine change in the CA letter of approval. These include responding immediately to a safety problem as required in ATM/ANS.OR.A.060 or when an emergency arises in which the SP must take immediate action to ensure the safety of the services provided.

An unplanned change must still follow an SPs process for change, i.e., at a minimum a safety assessment of the change is carried out before the change is introduced and a notification sent to the CA in line with approved timeframes, as documented under approved SP change management procedures.

The safety assessment must demonstrate the urgent need for the change to be implemented and justify why -

• it cannot adhere to the CA minimum 10 working days notification period. This type of change significantly reduces the time for the CA to assess whether to review the change or not before implementation thus reducing the effectiveness of oversight.

or

 where a NOC has been submitted in accordance with a planned change; the SP has subsequently determined that the introduction of this change needs to be brought forward in a timeframe less than the minimum notification period, to ensure the safety of the services provided.

Important: The procedure(s) for unplanned changes must be submitted by the SP and approved by the CA prior to use.

13. Routine changes

In accordance with ATM/ANS.OR.B.010(b), the SP "shall use procedures to manage, assess and, if necessary, mitigate the impact of changes to its functional systems in accordance with points ATM/ANS.OR.A.045, ATM/ANS.OR.C.005, ATS.OR.205 and ATS.OR.210."

For 'routine changes', the notification to the CA may be done in a simpler manner and post-implementation of the change.

The SP may choose to compile a list of what it considers to be 'routine changes' and submit it as part of the overall set of change management procedure(s) to the CA for consideration during the regulatory review and approval process. The SP shall

ASAM No.38 Issue 8.0 Page 20 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

submit the associated safety assurance documentation under a 'non-complex change' NOC for consideration by the CA.

Where CA approval is granted for a list of 'routine changes', the SP may implement any of the listed changes in accordance with the approved change management procedures and are not required to notify the CA in advance of the implementation of the planned change.

The SP shall record all 'routine changes' in a change register and provide notification to the CA, at specific intervals identified in their approved change management procedure. The period of notification may vary from SP to SP (and possibly subunits within complex SPs), and influencing factors may be the SP size, number of changes, complexity of operations, risk profile, adherence to correct change management procedures, etc.

The change register shall at a minimum include the following information -

- SP unique change number reference and version number;
- Title of the change:
- FS or NFS:
- Name and reference number of the CA approved change management procedure, which the 'routine change' was conducted under;
- Date of implementation
- Name of change initiator
- Name of change sponsor
- Name of person who filled in the change information in the register.
- Date the information was entered into the change register.

The above list is non-exhaustive and the SP may add more information as it deems necessary. The SP is required to have safety assessment records and associated assurance evidence available for completed changes, on request by the CA.

The list hereafter includes examples of the type of changes that may fall under the SP scope of 'routine changes', which the CA could approve under the SP change management procedures letter of approval.

- Changes to maintenance routines, except those that may potentially impact service provision.
- Equipment modifications/manufacturer upgrades that do not affect the operating parameters or do not introduce new functionality into the system.

ASAM No.38 Issue 8.0 Page 21 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

 Document changes, typos, formats etc. that do not impact on the content of management systems, change management systems or service provision. (Note: Where a management system document has been changed it should be sent to the CA as an update to the previously submitted documents under an approved NOC process.)

The SP shall not implement any proposed 'routine change' process until a CA letter of approval is issued in relation to same. Where CA approval has not been issued, the SP shall continue to notify the planned change in accordance with the appropriate timeline identified in Section 5.1 of this ASAM.

Note: The change management procedure(s) for 'routine changes' must be notified under a non-complex change and approved by the CA prior to implementation.

14. Exemption to deviate from approved procedures

(ATM/ANS.OR.B.010 Change management procedures refers)

If an SP identifies that a CA approved change management procedure(s) is not suitable for a particular planned change, the SP shall:

- (1) make a request to the CA for an exemption to deviate from the approved change management procedure(s);
- (2) provide the details of the deviation and the justification for its use to the CA;
- (3) not use the deviation before being approved by the CA.

15. Further Information

Any queries or requests for further information should be addressed to the following CA email address: ansdinfo@iaa.ie

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ASAM No.38 Issue 8.0 Page 22 of 24



Focal Point: ANSP

ASAM

No: 38

Issue 8.0

Date 30.05.2025

Title

Changes by a service provider certified in accordance with the requirements of Commission Regulation (EU) 2017/373 that affects the functional system

Appendix A

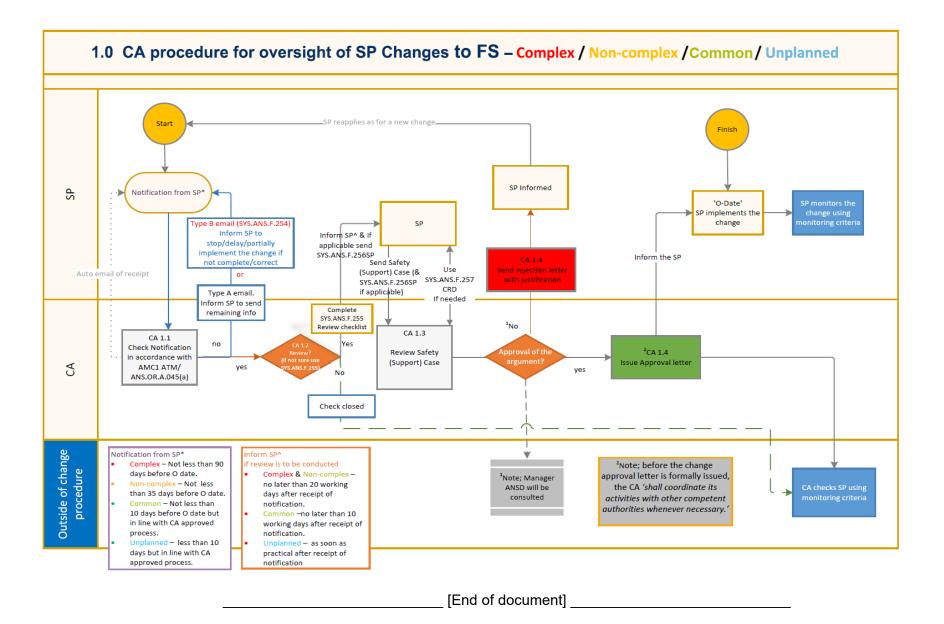
Re section 11.1 (2) b) remarks in CRDs classified to the following categories:

- **Major:** A comment on a critical issue ANSD considers significant enough to prevent regulatory approval of the proposed change(s) unless resolved by the service provider (e.g. a non-conformity to applicable regulatory requirements, or non-adherence to an organisation's own requirement, or an important problem that shall be resolved by the organisation).
- Minor: A comment on other issues indirectly affecting the compliance demonstration, which ANSD considers are necessary to address before proceeding. Whilst not solely preventing regulatory approval of the proposed change(s) the accumulation of these issues can lead to the prevention of regulatory approval of the proposed change(s).
- Question: The question may be associated to an issue that requires clarification. However, upon receipt of further information the CRD question classification will change to a Closed, Minor or Major classification.
- **Editorial:** Observations on missing information or editorials of a nature which are needed to provide clarity or ensure no ambiguity exists by the absence of that information.

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ASAM No.38 Issue 8.0 Page 23 of 24

Appendix B



ASAM No.38 Issue 8.0 Page 24 of 24