

Aeronautical Services Advisory Memorandum (ASAM)

Focal Point: GEN

ASAM No: 004 Issue 13 Date 04.07.2025

Title

Guidance on the NSA/CA Audit Finding Corrective Action Process

### 1 Introduction

The objective of this document is to provide guidance to audited organisations, on the root cause and corrective action process to be followed in response to National Supervisory Authority (NSA) and Competent Authority (CA) audit findings. For information on the conduct and types of safety oversight audits undertaken by the CA please read ASAM No.34.

# 2 Scope

This document is applicable to ATM/ANS service providers (SP) and air traffic controller training provider organisations (TO), who fall within the scope of safety oversight audits conducted by the IAA in its role as the NSA/CA for Ireland under the applicable requirements of European Regulation (EU) 2018/1139 and its implementing rules, as well as applicable SES Regulations (EC) No 549/2004, (EC) No 550/2004 and (EC) No 551/2004 and hereafter referred to collectively as the CA.

### 3 Audits - General

ANSD oversight audit processes will, through appropriate audit sampling, verify:

- (a) compliance with applicable safety regulatory requirements prior to the issue of a certificate necessary to provide ATM/ANS services, including safety-related conditions attached to it.
- (b) compliance with applicable safety regulatory requirements prior to the issue or renewal of a certificate necessary to provide ATCO Training.
- (c) compliance with any safety-related obligations in the designation act issued in accordance with Article 8 of Regulation (EC) No 550/2004 (as amended).
- (d) ongoing compliance of certified organisations and for persons holding a licence, rating, or endorsement with applicable safety regulatory requirements.
- (e) implementation of safety, security and interoperability objectives, applicable requirements and other conditions identified in statements of compliance for ATM/ANS equipment.
- (f) technical and performance limitations and conditions identified in ATM/ANS equipment certificates and/or ATM/ANS equipment declarations.
- (g) safety measures, including ATM/ANS equipment directives mandated by EASA in accordance with point ATM/ANS.EQMT.AR.A.030 of Annex I to Delegated Regulation (EU) 2023/1768.
- (h) the implementation of applicable safety directives, corrective actions and enforcement measures.

# 4 Audit Finding and Corrective Action Requirements: Legislation

- 4.1 Commission Implementing Regulation (EU) 2017/373 (Reg 373) and Commission Regulation (EU) 2015/340 (Reg 340) identify several legal requirements specific to audit findings and corrective actions.
- 4.2 Reg 373 Part ATM/ANS.OR.A.055 'Findings and corrective actions' states

'After receipt of notification of findings from the competent authority, the service provider shall:

- (a) identify the root cause of the non-compliance.
- (b) define a corrective action plan that meets the approval by the competent authority.
- (c) demonstrate corrective action implementation to the satisfaction of the competent authority within the time period proposed by the service provider and agreed with that authority, as defined in point ATM/ANS.AR.C.050(e).'
- 4.3 Reg 340 Part ATCO.OR.B.030 'Findings' states

'After receipt of notification of findings issued by the competent authority in accordance with ATCO.AR.E.015, the training organisation shall:

- (a) identify the root cause of the finding.
- (b) define a corrective action plan; and
- (c) demonstrate the corrective action implementation to the satisfaction of the competent authority within the period agreed with that authority as defined in ATCO.AR.E.015.
- 4.4 Reg 373 AMC1 ATM/ANS.OR.A.055(b) 'Findings and corrective actions' states

The corrective action plan defined by the service provider should address the effects of the non-conformity and its root cause.

- 4.5 Reg 373 GM1 ATM/ANS.OR.A.055 'Findings and corrective actions' states
  - (a) Corrective action is the action taken to eliminate or mitigate the root cause(s) and prevent the recurrence of existing detected non-compliance or other undesirable condition or situation.
  - (b) The proper determination of the root cause is crucial for defining effective corrective actions.
- 4.6 Reg 340 GM1 ATCO.OR.B.030(a);(b) 'Findings' states
  - (a) Corrective action is the action to eliminate the root cause of a non-compliance in order to prevent its recurrence.
  - (b) Determination of the root cause is crucial for defining effective corrective actions.

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#### 5 Corrective Action Process

5.1 The objective of the corrective action process is firstly to identify and then to eliminate or mitigate the "root cause" of a non-compliance identified by audit of an SP/TO organisation. The organisation should formulate a plan which will outline how the non-compliance will be rectified, and addressed such that it doesn't reoccur, and how long that will take to implement. This is documented in a corrective action plan (CAP) and forward to the CA for its acceptance.

# 5.2 Level 1 Finding

- 5.2.1 Reg 373 Part ATM/ANS.AR.C.050 (e) (1) states 'In the case of level 1 findings, the competent authority shall take immediate and appropriate action, and may, if appropriate, limit, suspend or revoke in whole or in part the certificate while ensuring the continuity of services provided that safety is not compromised.'.
- 5.2.2 Reg 340 Part ATCO.AR.E.015(d) states 'In the case of level 1 findings the competent authority shall take immediate and appropriate action to prohibit or limit activities, and if appropriate, it shall take action to revoke the certificate or to limit or suspend it in whole or in part, depending upon the extent of the finding, until successful corrective action has been taken by the training organisation.'
- 5.2.3 The SP/TO may be required to take immediate and appropriate action and may be required by the CA to limit or suspend in whole or in part their services, provided safety is not compromised. The measure(s) taken shall depend upon the extent of the finding and shall remain until successful corrective action has been taken by the service provider. To understand the risk posed by the noncompliance, the CA will require evidence from the audited organisation in the form of a risk assessment, and/or any other relevant data.
- 5.2.4 The SP/TO shall submit a proposed corrective action plan (CAP) as per Section 6, to the CA no later than 5 working days from the date the finding was issued (or sooner if required)
- 5.2.5 If the appropriate action outlined above is not taken, then a safety directive may be issued by the CA, mandating actions to be performed by the SP/TO and associated rationale, when evidence shows that aviation safety may otherwise be compromised (ref ATM/ANS.AR.A.030).

## 5.3 Level 2 Finding

- 5.3.1 Reg 373 Part ATM/ANS.AR.C.050 (e)(2)(i) states 'In the case of level 2 findings, the competent authority shall (i) grant the service provider a corrective action implementation period included in an action plan appropriate to the nature of the finding;'
- 5.3.2 Reg 340 AMC1 ATCO.AR.E.015(d)(2) states 'The corrective action implementation period included in an action plan granted by the competent authority initially should not exceed three months.'
- 5.3.3 No later than 3 working days after the closing meeting the audited SP/TO shall receive an individual NCR report form (OPS.ANS.F.237) for each finding. An SP/TO shall then submit a CAP (using appropriate section(s) of each OPS.ANS.F.237 NCR form) no later than 15 working days (3 weeks) commencing from the day after receipt of these written NCR reports.
- 5.3.4 The SP/TO CAP shall include a root cause, a proposed corrective action(s) and an implementation period by which the non-compliance shall be addressed. The SP/TO shall ensure that the proposed implementation period is sufficient to demonstrate that all proposed corrective actions(s) have been implemented, inclusive of any change related mandatory notification periods if applicable.
- 5.3.5 For a level 2 non-compliance associated with the functional system, the CA requires a risk assessment to identify the risk posed by the identified non-compliance and the exposure timeline until corrected i.e., the proposed CAP implementation period. See Section 6.1 which lists the elements required in a CAP.

5.3.6 Please note: for a Level 2 non-compliance, the auditee is not required to document an 'immediate action' (IA) unless their risk assessment identifies one or more is required. When the SP documents an IA(s) as part of their CAP, unless the CA requests otherwise, it is not required to present the IA evidence in the timeline they propose nor request a CAP implementation deadline extension. The IA evidence is submitted in line with the overall CAP deadline.

# 5.4 CA action on receipt of a CAP

- 5.4.1 Reg 373 Part ATM/ANS.AR.C.050 (e) (2) (ii) states the CA shall 'assess the corrective action and implementation plan proposed by the service provider and, if the assessment concludes that they are sufficient to address the non-compliance(s), accept them'.
- 5.4.2 If the CA accepts the CAP, it will inform the SP/TO. However, the CA may not accept all or part of a CAP proposal. The CA will communicate with the SP/TO in a timely manner with the intent to have a resolved CAP in place no later than 30 working days commencing from the day after the written NCR form OPS.ANS.F.237 is relayed to the SP/TO. Auditors will communicate either individually or through the lead auditor by email. Where it is indicated that action is needed regarding a particular CAP, the SP/TO will update their original corresponding OPS.ANS.F.237 form accordingly and resubmit this as their updated CAP, identifying the updated version number in the box provided in the bottom left corner of the form.
- 5.4.3 Where CAPs are accepted the corresponding NCR form OPS.ANS.F.237 does not need to be resubmitted.
- 5.4.4 Use of ANSD form OPS.ANS.F.239 (see sample at appendix C) At their discretion this excel form may be used by the auditor (or if consolidated by the audit lead) as a record to track the status of proposed CAPs. Following their assessment of the proposed CAP, the CA will populate and email it to the SP or TO. The SP/TO is not required to populate the excel form nor return it to the CA. Where it is indicated that action is needed regarding a particular CAP the SP/TO will update their original corresponding OPS.ANS.F.237 form accordingly (either adding to the original comment or replacing it altogether) and resubmit this as their updated CAP.
  Upon receipt of the updated OPS.ANS.F.237 NCR form the CA will update the OPS.ANS.F.239 with its reply and sent back until all items are accepted. Where CAPs are indicated as fully accepted the corresponding NCR does not need to be resubmitted.
- 5.4.5 Reg 373 Part ATM/ANS.AR.C.050 (e) (3) states 'In the case of level 2 findings, where the service provider fails to submit a corrective action plan that is acceptable to the competent authority in light of the finding, ... the finding may be raised to a level 1 finding, and action taken as laid down in point [(e)] (1).'
- 5.4.6 Reg 340 Part ATCO.AR.E.015 (d)(3) states 'Where a training organisation fails to submit an acceptable corrective action plan, ... the finding shall be raised to a level 1 finding, and action shall be taken as laid down in point (d)(1).'
- 5.4.7 Where the SP/TO fails to submit a corrective action plan that is acceptable to the CA or doesn't submit a CAP at all, the CA may raise the finding to a level 1 classification. However, pursuant to Regulation (EU) 2018/1139 Article 62(2)(d), Commission Implementing Regulation (EU) 2017/373 Article 5(4) and in accordance with the IAA Enforcement Policy LEG.ENF.10, where appropriate a SP /TO can be formally put on notice of enforcement action i.e., of the intent to raise a finding from a level 2 to a level 1 classification. Formal action will commence with a requirement in writing from the IAA to the SP/TO directing them to resolve the matter within a specified time period. If the SP/TO does not address the action set down by the CA as outlined in the enforcement letter, then the finding shall be raised to a level 1 classification.

# 5.5 CAP monitoring

5.5.1 During the CAP implementation period, each SP/TO is responsible for tracking the progress of its CAPs for each audit finding and take appropriate steps to ensure it adheres to CA agreed timelines. Each SP/TO should have documented organisational procedures for root cause analysis, defining a corrective action plan and demonstrating corrective action implementation within the period agreed with the CA.

# 5.6 CAP implementation deadline extensions

- 5.6.1 Reg 373 Part ATM/ANS.AR.C.050 (e) (3) states 'In the case of level 2 findings... where the service provider fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding may be raised to a level 1 finding, and action taken as laid down in point [(e)] (1).'
- 5.6.2 Reg 340 Part ATCO.AR.E.015 (d)(3) states 'Where a training organisation fails to... perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to a level 1 finding, and action shall be taken as laid down in point (d)(1).'
- 5.6.3 The CA shall be notified where it becomes apparent to an audited organisation that the accepted CAP deadline will not be met. The audited organisation may request an extension citing the reason for not achieving the accepted timescales and the risk posed by continued non-compliance. To support its decision to grant an extension, the CA may require evidence in the form of a risk assessment, or any other relevant data. See Section 6.2 which lists the elements required in a CAP extension request.
- 5.6.4 An auditor may grant one CAP extension per finding but no more. For any further extensions, the manager ANSD must give approval.
- 5.6.5 Where the SP/TO fails to perform the corrective action within the period accepted or extended by the CA, the finding can be raised to a level 1 finding. However, pursuant to Regulation (EU) 2018/1139 Article 62(2)(d), Commission Implementing Regulation (EU) 2017/373 Article 5(4) and in accordance with the IAA Enforcement Policy LEG.ENF.10, where appropriate a SP /TO can be formally put on notice of enforcement action i.e., of the intent to raise a non-compliance classification from a level 2 to a level 1. Formal action will commence with a requirement in writing from the IAA to the SP/TO directing them to resolve the matter within a specified period. If the SP/TO does not address the action set down by the CA as outlined in the enforcement letter, then it shall be raised to a level 1 finding.
- 5.6.6 Where ANSD receive an extension request it will be recorded. The amount of extension requests received from an organisation, whether granted or not, will be monitored as an ANSD safety performance metric. This metric maybe used as an indicator of other potential issues within an SP/TO organisation which could warrant ANSD examination. Therefore, a CAP extension request should be the exception and not the norm to a CAP process.
- 5.6.7 For Level 2 findings, CAP extension requests not submitted in a timely\* manner, may be raised to a level 1 finding. An auditor will consult with the manager ANSD who must give approval. This will be communicated to the SP/TO.
  - \* Timely in this context is receipt by the CA of a CAP extension request at least ten (10) working days before the CAP closure date. This allows the CA to review the request, seek additional information and relay acceptance or non-acceptance. It also demonstrates to some level SP/TO organisational monitoring of their CAP.

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#### 5.7 CAP closure evidence

- 5.7.1 SP/TOs shall coordinate with the CA in advance of implementing CAP related changes, to determine in advance if they will be sufficient to demonstrate that the CAP has been satisfactorily addressed. SP/TOs are advised to consider such coordination as part of the CAP implementation plan and associated timeline(s).
- 5.7.2 Any SP/TO identified planned changes to address the accepted CAP shall be marked 'draft', submitted to the CA and receive CA acceptance, before they are implemented by the SP/TO.
- 5.7.3 The SP/TO shall ensure that any changes (including unplanned change) required to demonstrate that the accepted CAP has been fully implemented are notified i.a.w their approved change management process and the auditor advised.
- 5.7.4 The CA 'NOC check' step may be expedited upon request to facilitate earlier introduction than mandatory notification timelines, with the agreement of the CA.
- 5.7.5 The SP/TO shall ensure that an NCR closure request submission address each of the accepted CAP action(s) and includes associated supporting evidence to demonstrate that they have been satisfactorily addressed and any associated change(s) implemented. It is not appropriate for the CA to have to search or interpret where CAP related evidence is located within the submitted documentation. Therefore, as part of the NCR closure request, the SP/TO should clearly identify where CAP related evidence is located within the supporting evidence.

## 6 Summary

## 6.1 Elements required in a Corrective Action Plan (CAP).

- 6.1.1 For each finding, an SP/TO shall carry out a corrective action to eliminate (or mitigate) the root cause of a non-compliance to prevent its reoccurrence. This they shall document such action(s) in a CAP (using the associated Non-Compliance report (NCR) form OPS.ANS.F.237) which, at a minimum, shall include the following components:
  - (a) What was/is the root cause? (AMC)
  - (b) What was/is the effect of the non-conformity? (AMC)
  - (c) How was the root cause identified? (should be in line with org procedures)
  - (d) Confirmation and evidence that the root cause was identified by an appropriate subject matter expert (SME) (Safety assurance & traceability)
  - (e) Independent organisational confirmation that the appropriate root cause was identified (Safety assurance & traceability)
  - (f) Date of when the root cause was identified. (org traceability)
  - (g) Immediate action for a level 1 non-compliance or as identified by a risk assessment for Level 2 FS non-compliance.
  - (h) The corrective action taken, or propose to take, to eliminate or mitigate the root cause of a non-compliance in order to prevent its recurrence. (AMC; safety assurance & traceability)
  - (i) The completion date (if already completed by time of the CAP drafting) or proposed timeline for corrective action implementation. (AMC; safety assurance & traceability)
  - (j) A risk assessment for any level 1 or a level 2 non-compliance associated with the functional system.

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- 6.1.2 The SP/TO shall forward the CAP to the CA in line with those timelines documented in this notice. It shall then track the progress of the CAP to ensure it is implemented in accordance with the CA agreed schedule.
- 6.1.3 All of the above should be supported by organisational procedures to ensure personnel follow a standard, complete and correct process for root cause analysis and elimination/mitigation of a non-compliance.

# 6.2 Elements required in a CAP implementation deadline extension request.

- 6.2.1 Where an extension request is made it must:
  - (a) be submitted at least 10 working days before the accepted CAP implementation deadline.
  - (b) include an updated CAP (using the associated Non-Compliance report (NCR) form OPS.ANS.F.237), with the requested amendment to the implementation deadline identified.
  - (c) Include the reason why it is being sought; (why the SP/TO cannot adhere to the agreed implementation deadline).
  - (d) include the actions that will be taken to ensure a further CAP extension won't be sought.
  - (e) For a non-compliance associated with the functional system (level 1 or 2), if it has been requested in accordance with para 5.6.3, submit the safety risk assessment to provide assurance that an acceptable level of safety will be maintained
  - (f) for a non-compliance associated with the non-functional system a safety assessment may be required whilst the non-compliance remains open.

## 7 References

- 7.1 Regulation (EU) 2018/1139, the Basic Regulation.
- 7.2 Commission Implementing Regulation (EU) 2017/373 laying down common requirements for providers of ATM/ANS and their oversight, as amended.
- 7.3 Commission Regulation (EU) 2015/340 ATCO Licensing and Training Organisations, as amended.

### 8 Further Information

8.1 Requests for further information on the contents of this notice should be addressed to <a href="mailto:ansdinfo@iaa.ie">ansdinfo@iaa.ie</a>

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### **Annex A: Audit Findings Classification Scheme:**

Service Providers Reg (EU) 2017/373; ATM/ANS.AR.C.050

(c) A level 1 finding shall be issued by the competent authority when any serious non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis as well as Regulations (EC) No 549/2004, (EC) No 550/2004 and (EC) No 551/2004 and their implementing rules, with the ATM/ANS provider's procedures and manuals, with the terms and conditions of the certificate, with the designation act, if applicable, or with the content of a declaration which poses a significant risk to flight safety or otherwise calls into question the service provider's capability to continue operations.

Level 1 findings shall include but not be limited to:

- (1) promulgating operational procedures and/or providing a service in a way which introduces a significant risk to flight safety;
- (2) obtaining or maintaining the validity of the service provider's certificate by falsification of submitted documentary evidence;
- (3) evidence of malpractice or fraudulent use of the service provider's certificate;
- (4) the lack of an accountable manager.
- (d) A level 2 finding shall be issued by the competent authority when any other non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on its basis, as well as Regulations (EC) No 549/2004, (EC) No 550/2004 and (EC) No 551/2004 and their implementing rules, with the ATM/ANS provider's procedures and manuals or with the terms and conditions of the certificate, or with the content of the declaration.
- (e)(3) In the case of level 2 findings, where the service provider fails to submit a corrective action plan that is acceptable to the competent authority in the light of the finding, or where the service provider fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding may be raised to a level 1 finding, and action shall be taken as laid down in point (1).
- (g) For those cases not requiring level 1 and 2 findings, the competent authority may issue observations.

Note - For a full understanding of the regulatory requirements please check the regulation and its specific acceptable means of compliance (AMCs) and guidance material (GM).

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### **Annex B: Audit Findings Classification Scheme:**

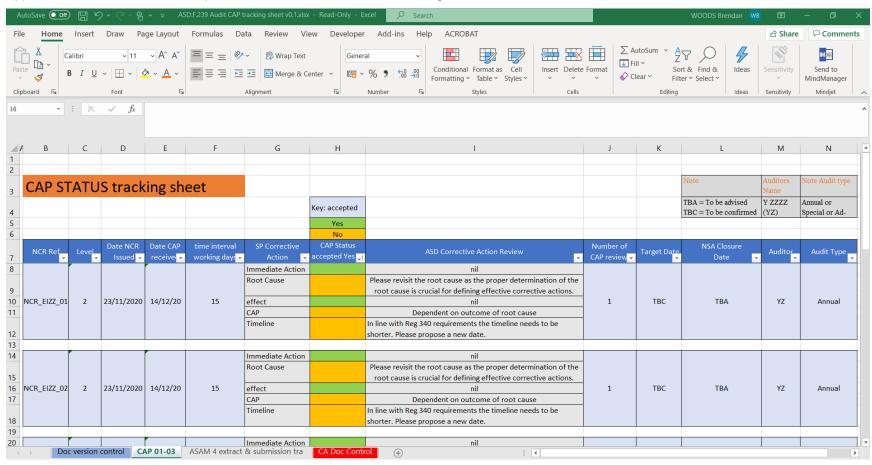
Training Organisations – Commission Regulation (EU) 2015/340 Part ATCO.AR.E.015

- 1. A level 1 finding shall be issued by the competent authority when any significant non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and this Regulation, with the certificate and/or its terms of approval and privileges, which poses a significant risk to flight safety and/or otherwise calls into question the training organisation's capability to continue the training provision.
- 2. A level 1 finding shall include, but shall not be limited to:
  - (a) providing training in a way which introduces a significant risk to flight safety;
  - (b) failure to give the competent authority access to the training organisation's facilities as defined in point ATCO.OR.B.025 during normal operating hours and after two written requests;
  - (c) obtaining or maintaining the validity of the training organisation certificate by falsification of submitted documentary evidence;
  - (d) evidence of malpractice or fraudulent use of the training organisation certificate; and
  - (e) the lack of an accountable manager.
- 3. A level 2 finding shall be issued by the competent authority when any other non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and this Regulation, with the training organisation's procedures and manuals or with the type(s) of training provided or certificate(s).
- 4. When a finding is detected during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by Regulation (EC) 2018/1139 and Commission Regulation (EU) 2015/340, communicate the finding to the training organisation in writing and request corrective action to address the non-compliance(s) identified.
  - (a) In the case of level 1 findings the competent authority shall take immediate and appropriate action to prohibit or limit activities, and if appropriate, it shall take action to revoke the certificate or to limit or suspend it in whole or in part, depending upon the extent of the finding, until successful corrective action has been taken by the training organisation.
  - (b) In the case of level 2 findings the ASD shall:
    - (i) grant the training organisation a corrective action implementation period included in an action plan appropriate to the nature of the finding; and
    - (ii) assess the corrective action and implementation plan proposed by the training organisation and, if the assessment concludes that they are sufficient to address the non-compliance(s), accept these.
  - (c) Where a training organisation fails to submit an acceptable corrective action plan, or to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to a level 1 finding, and action shall be taken as laid down in point 4(a).
- 5. The corrective action implementation period included in an action plan granted by the competent authority, initially should not exceed three months. At the end of this period, and subject to the nature of the finding, the ANSD may extend the three-month period subject to a satisfactory corrective action plan.

- 6. For those cases not requiring level 1 and 2 findings, the competent authority may issue observations.
- 7. For a full understanding of the regulatory requirements please check the regulation and its specific acceptable means of compliance (AMCs) and guidance material (GM).

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Appendix C - Print screen of sample OPS.ANS.F.239 CAP status tracking sheet



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