Draft Annex
to draft Commission Implementing Regulation (EU) …/…
amending Commission Regulation (EU) No 748/2012 as regards the establishment of safety management systems for competent authorities

ANNEX I

Annex I (Part 21) to Commission Regulation (EU) No 748/2012 is amended as follows:

(1) the 'Contents' are replaced by the following:

'*Contents*

21.B.432 Oversight programme

21.B.433 Findings and corrective actions; observations

21.B.435 Changes to the design management system

SUBPART K — PARTS AND APPLIANCES

(SUBPART L — NOT APPLICABLE)

SUBPART M — REPAIRS

21.B.450 Type-certification basis and environmental protection requirements for a major repair design approval

21.B.453 Issue of a repair design approval

(SUBPART N — NOT APPLICABLE)

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

21.B.480 Issue of an ETSO authorisation

SUBPART P — PERMIT TO FLY

21.B.520 Investigation

21.B.525 Issue of a permit to fly

SUBPART Q — IDENTIFICATION OF PRODUCTS, PARTS AND APPLIANCES

Appendices

Appendix I — EASA Form 1 — Authorised Release Certificate

Appendix II – EASA Form 15a and 15c – Airworthiness Review Certificate

Appendix III — EASA Form 20a — Permit to Fly

Appendix IV — EASA Form 20b — Permit to Fly (issued by approved organisations)

Appendix V — EASA Form 24 — Restricted Certificate of Airworthiness

Appendix VI — EASA Form 25 — Certificate of Airworthiness

Appendix VII — EASA Form 45 — Noise Certificate

Appendix VIII — EASA Form 52 — Aircraft Statement of Conformity

Appendix IX — EASA Form 53 — Certificate of Release to Service

Appendix X — EASA Form 55 — Production Organisation Approval Certificate

Appendix XI — EASA Form 65 — Letter of Agreement for production without production organisation approval

Appendix XII — Categories of flight tests and associated flight test crew qualification.';

(2) point 21.1 is replaced by the following:

'**21.1 Competent authority**

For the purpose of this Annex, the 'competent authority' shall be:

(a) for Section A, Subpart A,

1. for design organisations, the Agency;
2. for production organisations that have their principal place of business in a territory for which a Member State is responsible under the Chicago Convention, the authority designated by that Member State or by another Member State in accordance with Article 64 of Regulation (EU) 2018/1139, or the Agency if the responsibility has been reallocated to the Agency in accordance with Article 64 or 65 of Regulation (EU) 2018/1139;
3. for production organisations that have their principal place of business outside a territory for which a Member State is responsible under the Chicago Convention, the Agency;

(b) for Section A, Subparts B, D, E, J, K, M, O and Q, the Agency;

(c) for Section A, Subparts F, G, H and I:

1. for organisations that have their principal place of business in a territory for which a Member State is responsible under the Chicago Convention, the authority designated by that Member State or by another Member State in accordance with Article 64 of Regulation (EU) 2018/1139, or the Agency if the responsibility has been reallocated to the Agency in accordance with Article 64 or, as regards Subpart G, Article 65 of Regulation (EU) 2018/1139;
2. for organisations that have their principal place of business outside a territory for which a Member State is responsible under the Chicago Convention, the Agency;

(d) for Section A, Subpart P:

1. for aircraft registered in a Member State, the authority designated by the Member State of registry;
2. for unregistered aircraft, the authority designated by the Member State which prescribed the identification marks;
3. for the approval of the flight conditions related to the safety of the design, the Agency.';

(3) the following point 21.2 is inserted:

'**21.2 Scope**

Section A of this Annex establishes the provisions that lay down the rights and obligations of the applicant for, and holder of, any certificate issued or to be issued in accordance with this Annex.

Section B of this Annex establishes the conditions for conducting the certification oversight and enforcement tasks as well as the administrative and management system requirements to be complied with by the competent authority that is responsible for the implementation of Section A of this Annex.';

(4) point 21.B.5 is deleted;

(5) the following points 21.B.10 and 21.B.15 are inserted:

‘**21.B.10 Oversight documentation**

The competent authority shall provide all the legislative acts, standards, rules, technical publications and related documents to the relevant personnel in order to allow them to perform their tasks and to discharge their responsibilities.

21.B.15 Information to the Agency

(a) The competent authority of the Member State shall notify the Agency in case of any significant problems with the implementation of Regulation (EU) 2018/1139 and its delegated and implementing acts within 30 days from the manifestation of such problems.

(b) Without prejudice to Regulation (EU) No 376/2014 and its delegated and implementing acts, the competent authority of the Member State shall provide the Agency as soon as possible with any safety-significant information stemming from the occurrence reports stored in the national database as specified in Article 6(6) of Regulation (EU) No 376/2014.’;

(6) point 21.B.20 is replaced by the following:

‘**21.B.20 Immediate reaction to a safety problem**

(a) Without prejudice to Regulation (EU) No 376/2014 and its delegated and implementing acts, the competent authority shall implement a system to appropriately collect, analyse and disseminate safety information.

(b) The Agency shall implement a system to appropriately analyse any relevant safety information received and, without undue delay, provide Member States and the European Commission with any information, including recommendations or corrective actions to be taken, that is necessary for them to react in a timely manner to a safety problem involving products, parts, appliances, persons or organisations that are subject to Regulation (EU) 2018/1139 and its delegated and implementing acts.

(c) Upon receiving the information referred to in points (a) and (b), the competent authority of the Member State shall take adequate measures to address the safety problem.

(d) The measures taken under point (c) shall immediately be notified to all persons or organisations which need to comply with them under Regulation (EU) 2018/1139 and its delegated and implementing acts. The competent authority of the Member State shall also notify those measures to the Agency and, when combined action is required, to the other Member States concerned.’;

(7) point 21.B.25 is replaced by the following:

‘**21.B.25 Management system**

(a) The competent authority shall establish and maintain a management system, including as a minimum:

1. documented policies and procedures to describe its organisation, the means and methods for establishing compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts. The procedures shall be kept up to date, and serve as the basic working documents within that competent authority for all its related tasks;

2. a sufficient number of personnel to perform its tasks and discharge its responsibilities. A system shall be in place to plan the availability of personnel in order to ensure the proper completion of all tasks;

3. personnel that are qualified to perform their allocated tasks and that have the necessary knowledge and experience, and receive initial and recurrent training to ensure continuing competency;

4. adequate facilities and office accommodation for personnel to perform their allocated tasks;

5. a function to monitor the compliance of the management system with the relevant requirements, and the adequacy of the procedures, including the establishment of an internal audit process and a safety risk management process. Compliance monitoring shall include a feedback system of audit findings to the senior management of the competent authority to ensure the implementation of corrective actions as necessary;

6. a person or group of persons having a responsibility to the senior management of the competent authority for the compliance monitoring function.

(b) The competent authority shall, for each field of activity, including the management system, appoint one or more persons with the overall responsibility for the management of the relevant task(s).

(c) The competent authority shall establish procedures for the participation in a mutual exchange of all necessary information and assistance with any other competent authorities concerned, whether from the same Member State or from other Member States, including on:

1. all findings raised and any follow-up actions taken as a result of the oversight of persons and organisations that carry out activities in the territory of a Member State, but certified by the competent authority of another Member State or by the Agency;

2. information stemming from mandatory and voluntary occurrence reporting as required by 21.A.3A.

(d) A copy of the procedures related to the management system of the competent authority of the Member State and their amendments shall be made available to the Agency for the purpose of standardisation.';

(8) point 21.B.30 is replaced by the following:

'**21.B.30 Allocation of tasks to qualified entities**

(a) The competent authority may allocate tasks related to the initial certification or to the continuing oversight of products and parts, as well as of natural or legal persons subject to Regulation (EU) 2018/1139 and its delegated and implementing acts to qualified entities. When allocating tasks, the competent authority shall ensure that it has:

1. put a system in place to initially and continuously assess whether the qualified entity complies with Annex VI 'Essential requirements for qualified entities' to Regulation (EU) 2018/1139. This system and the results of the assessments shall be documented;

2. established a written agreement with the qualified entity, approved by both parties at the appropriate management level, which defines:

(i) the tasks to be performed;

(ii) the declarations, reports and records to be provided;

(iii) the technical conditions to be met when performing such tasks;

(iv) the related liability coverage;

(v) the protection given to the information acquired when carrying out such tasks.

(b) The competent authority shall ensure that the internal audit process and safety risk management process required by point 21.B.25(a)(5) cover all the certification and continuing oversight tasks performed by the qualified entity on its behalf.';

(9) point 21.B.35 is replaced by the following:

'**21.B.35 Changes to the management system**

(a) The competent authority shall have a system in place to identify the changes that affect its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EU) 2018/1139 and its delegated and implementing acts. This system shall enable the competent authority to take action necessary to ensure that its management system remains adequate and effective.

(b) The competent authority shall update in a timely manner its management system to reflect any changes to Regulation (EU) 2018/1139 and its delegated and implementing acts so as to ensure its effective implementation.

(c) The competent authority of the Member State shall notify the Agency of any changes affecting its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EU) 2018/1139 and its delegated and implementing acts.';

(10) in point 21.B.40, point (b) is deleted;

(11) point 21.B.45 is deleted;

(12) point 21.B.55 is replaced by the following:

'**21.B.55 Record-keeping**

(a) The competent authority shall establish a record-keeping system that allows the adequate storage, accessibility and reliable traceability of:

1. the management system's documented policies and procedures;
2. the training, qualifications and authorisation of its personnel;
3. the allocation of tasks, covering the elements required by point 21.B.30, as well as the details of tasks allocated;
4. certification processes and continuing oversight of certified organisations, including:
   (i) the application for a certificate, approval, authorisation and letter of agreement;
   (ii) the competent authority's continuing oversight programme, including all the assessments, audits and inspection records;
   (iii) the certificates, approvals, authorisations and letters of agreement issued, including any changes to them;
   (iv) a copy of the oversight programme, listing the dates when audits are due and when audits were carried out;
   (v) copies of all formal correspondence;
   (vi) recommendations for the issue or continuation of a certificate, an approval authorisation or a letter of agreement, detail of findings and actions taken by the organisations to close these, including the date of closure, enforcement actions and observations;
   (vii) any assessment, audit and inspection report issued by another competent authority pursuant to points 21.B.120(d), 21.B.221(c) or 21.B.431(c);

(viii) copies of all the organisation expositions, handbooks or manuals, and of any amendments to them;

(ix) copies of any other documents approved by the competent authority;

5. Statements of Conformity (EASA Form 52, see Appendix VIII) and Authorised Release Certificates (EASA Form 1, see Appendix I) that it has validated for organisations that produce products, parts or appliances without a production organisation approval certificate according to Subpart F of Section A of this Annex.

(b) The competent authority of the Member State shall include in the record-keeping:

1. the evaluation and notification to the Agency of any alternative means of compliance proposed by organisations, and the assessment of any alternative means of compliance issued by the competent authority itself;

2. safety information in accordance with point 21.B.15 and follow-up measures;

3. the use of safeguard and flexibility provisions in accordance with Articles 71(1) and 76(4) of Regulation (EU) 2018/1139.

(c) The competent authority shall maintain a list of all the certificates, approvals, authorisations and letters of agreement it has issued.

(d) All the records referred to in points (a), (b) and (c) shall be kept for a minimum period of 5 years, subject to applicable data protection law.

(e) All the records referred to in points (a), (b) and (c) shall be made available, upon request, to a competent authorities of another Member State or to the Agency.';

(13) point 21.B.60 is deleted;

(14) the following point 21.B.65 is added:

'**21.B.65 Suspension, limitation and revocation**

The competent authority shall:

(a) suspend a certificate, approval, permit to fly, authorisation or letter of agreement when it considers that there are reasonable grounds that such action is necessary to prevent a credible threat to aircraft safety;

(b) suspend, revoke or limit a certificate, approval, permit to fly, authorisation or letter of agreement if such action is required pursuant to points 21.B.125, 21.B.225 or 21.B.433;

(c) suspend or revoke a certificate of airworthiness or a noise certificate upon evidence that some of the conditions specified in points 21.A.181(a) or 21.A.211(a) are not met;

(d) suspend or limit in whole or in part a certificate, approval, permit to fly, authorisation or letter of agreement if unforeseeable circumstances outside the

control of the competent authority prevent its inspectors from discharging their oversight responsibilities over the oversight planning cycle.';

(15) the following point 21.B.115 is added:

'**21.B.115 Alternative means of compliance**

(a) Alternative means of compliance may be used to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.

(b) The competent authority shall establish a system to consistently evaluate that all the alternative means of compliance used by itself or by organisations under its oversight allow for the establishment of compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.

(c) The competent authority shall evaluate all the alternative means of compliance proposed by an organisation in accordance with point 21.A.124A by analysing the documentation provided and, if considered necessary, by conducting an inspection of the organisation.

When the competent authority finds that the alternative means of compliance are in accordance with Regulation (EU) 2018/1139 and the its delegated and implementing acts, it shall without undue delay:

1. notify the applicant that the alternative means of compliance may be implemented and, if applicable, amend the letter of agreement of the applicant accordingly;

2. notify the Agency of their content, and include copies of all the relevant documentation.

(d) If the competent authority itself uses alternative means of compliance to achieve compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts, it shall:

1. make them available to all the organisations and persons under its oversight;

2. notify the Agency without undue delay.

The competent authority shall provide the Agency with a full description of the alternative means of compliance, including any revisions to procedures that may be relevant, as well as an assessment demonstrating that they comply with Regulation (EU) 2018/1139 and its delegated and implementing acts.';

(16) point 21.B.120 is replaced by the following:

'**21.B.120 Initial certification procedure**

(a) Upon receiving an application for the issue of a letter of agreement for the purpose of demonstrating conformity of the individual products, parts and appliances, the

competent authority shall verify the applicant's compliance with the applicable requirements.

(b) The competent authority shall record all the findings issued, closure actions as well as recommendations for the issue of the letter of agreement.

(c) The competent authority shall confirm to the applicant in writing all the findings raised during the verification. For initial certification, all findings must be corrected to the satisfaction of the competent authority before the letter of agreement can be issued.

(d) When satisfied that the applicant complies with the applicable requirements, the competent authority shall issue the letter of agreement (EASA Form 65, see Appendix XI).

(e) The letter of agreement shall contain the scope of the agreement, a termination date and, where applicable, the appropriate limitations.

(f) The duration of the letter of agreement shall not exceed 1 year.';

(17) point 21.B.125 is replaced by the following:

'**21.B.125 Findings and corrective actions; observations**

(a) The competent authority shall have a system in place to analyse findings for their safety significance.

(b) 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 its delegated and implementing acts, with the organisation's procedures and manuals, or with the terms of the letter of agreement which lowers safety or seriously endangers flight safety.

The level 1 findings shall also include:

1. any failure to grant the competent authority access to the organisation's facilities as defined in point 21.A.9 during normal operating hours and after two written requests;

2. obtaining the letter of agreement or maintaining its validity by falsification of the submitted documentary evidence; and

3. any evidence of malpractice or fraudulent use of the letter of agreement.

(c) A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the terms of the letter of agreement which is not classified as a level 1 finding..

(d) 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

(EU) 2018/1139 and its delegated and implementing acts, communicate in writing the finding to the organisation and request corrective action to address the non-compliance(s) identified. If a level 1 finding directly relates to an aircraft, the competent authority shall inform the competent authority of the Member State in which the aircraft is registered.

1. If there are any level 1 findings, the competent authority shall take immediate and appropriate action to prohibit or limit the activities of the organisation involved and, if appropriate, it shall take action to revoke the letter of agreement or to limit or suspend it in whole or in part, depending upon the extent of the level 1 finding, until successful corrective action has been taken by the organisation.

2. If there are any level 2 findings, the competent authority shall:

   (i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, and that in any case shall initially not be more than 3 months. The period shall commence from the date of the written communication of the finding to the organisation, requesting corrective action to address the non-compliance(s) identified. At the end of this period, and subject to the nature of the finding, the competent authority may extend the 3-month period provided that a corrective action plan has been agreed by the competent authority;

   (ii) assess the corrective action and implementation plan proposed by the organisation, and if the assessment concludes that they are sufficient to address the non-compliance(s), accept these;

   (iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to level 1 and action shall be taken as laid down in point (f)(1)(i).

(e) For those cases that do not require level 1 or level 2 findings, the competent authority may issue observations:

1. for any item whose performance has been assessed to be ineffective;

2. when it has been identified that an item has the potential to cause a non-compliance under points (b) or (c); or

3. when suggestions or improvements are of interest for the overall safety performance of the organisation.

The observations issued under this point shall be communicated in writing to the organisation and recorded by the competent authority.';

(18) points 21.B.130, 21.B.145 and 21.B.150 are deleted;

(19) the following point 21.B.215 is inserted:

‘**21.B.215 Alternative means of compliance**

(a) Alternative means of compliance may be used to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.

(b) The competent authority shall establish a system to consistently evaluate that all the alternative means of compliance used by itself or by organisations under its oversight allow for the establishment of compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.

(c) The competent authority shall evaluate all the alternative means of compliance proposed by an organisation in accordance with point 21.A.134A by analysing the documentation provided and, if considered necessary, by inspecting the organisation.

When the competent authority finds that the alternative means of compliance are in accordance with Regulation (EU) 2018/1139 and the its delegated and implementing acts, it shall without undue delay:

1. notify the applicant that the alternative means of compliance may be implemented and, if applicable, amend the approval of the applicant accordingly;

2. notify the Agency of their content, including copies of all the relevant documentation.

(d) If the competent authority itself uses alternative means of compliance to achieve compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts, it shall:

1. make them available to all the organisations and persons under its oversight;

2. notify the Agency without undue delay.

The competent authority shall provide the Agency with a full description of the alternative means of compliance, including any revisions to procedures that may be relevant, as well as an assessment demonstrating that they comply with Regulation (EU) 2018/1139 and its delegated and implementing acts.’;

(20) point 21.B.220 is replaced by the following:

‘**21.B.220 Initial certification procedure**

(a) Upon receiving an application for the initial issue of a production organisation approval certificate, the competent authority shall verify the applicant’s compliance with the applicable requirements.

(b) A meeting with the accountable manager of the applicant shall be convened at least once during the investigation for initial certification to ensure that this person understands his or her role and accountability.

(c) The competent authority shall record all the findings issued, closure actions as well as the recommendations for the issue of the production organisation approval certificate.

(d) The competent authority shall confirm to the applicant in writing all the findings raised during the verification. For initial certification, all findings must be corrected to the satisfaction of the competent authority before the certificate can be issued.

(e) When satisfied that the applicant complies with the applicable requirements, the competent authority shall issue the production organisation approval certificate (EASA Form 55, see Appendix X).

(f) The certificate reference number shall be included on the EASA Form 55 in a manner specified by the Agency.

(g) The certificate shall be issued for an unlimited duration. The privileges and the scope of the activities that the organisation is approved to conduct, including any limitations as applicable, shall be specified in the terms of approval attached to the certificate.';

(21) the following points 21.B.221 and 21.B.222 are added:

'**21.B.221 Oversight principles**

(a) The competent authority shall verify:

1. compliance with the requirements that are applicable to organisations, prior to issuing the production organisation approval certificate;

2. continued compliance with the applicable requirements of the organisations it has certified;

3. the implementation of appropriate safety measures mandated by the competent authority according to points 21.B.20(c) and (d).

(b) This verification shall:

1. be supported by documentation specifically intended to provide personnel responsible for oversight with guidance to perform their functions;

2. provide the organisations concerned with the results of oversight activities;

3. be based on assessments, audits, inspections and, if needed, unannounced inspections;

4. provide the competent authority with the evidence needed in case further action is required, including the measures provided for in point 21.B.225.

(c) The competent authority shall establish the scope of the oversight defined in points (a) and (b) taking into account the results of past oversight activities and the safety priorities.

(d) If the facilities of an organisation are located in more than one State, the competent authority, as defined in point 21.1, may agree to have the oversight tasks performed by the competent authority(ies) of the Member State(s) where the facilities are located, or by the Agency for facilities that are located outside a territory for which Member States are responsible under the Chicago Convention. Any organisation that is subject to such an agreement shall be informed of its existence and of its scope.

(e) For any oversight activities that are performed at facilities located in a Member State other than where the organisation has its principal place of business, the competent authority, as defined in point 21.1, shall inform the competent authority of that Member State before performing any on-site audit or inspection of the facilities.

(f) The competent authority shall collect and process any information deemed necessary for performing oversight activities.

21.B.222 Oversight programme

(a) The competent authority shall establish and maintain an oversight programme covering the oversight activities required by point 21.B.221(a).

(b) The oversight programme shall take into account the specific nature of the organisation, the complexity of its activities, the results of past certification and/or oversight activities, and it shall be based on the assessment of the associated risks. It shall include, within each oversight planning cycle:

1. assessments, audits and inspections, including, as appropriate:
   (i) management system assessments and process audits;
   (ii) product audits of a relevant sample of the products, parts and appliances that are within the scope of the organisation;
   (iii) sampling of the work performed; and
   (iv) unannounced inspections;
2. meetings convened between the accountable manager and the competent authority to ensure that both parties remain informed of all significant issues.

(c) An oversight planning cycle that does not exceed 24 months shall be applied.

(d) Notwithstanding point (c), the oversight planning cycle may be extended to 36 months if the competent authority has established that during the previous 24 months:

1. the organisation has demonstrated that it can effectively identify aviation safety hazards and manage the associated risks;

2. the organisation has continuously demonstrated compliance with points 21.A.147 and 21.A.148 and it has full control over all changes to the production management system;

3. no level 1 findings have been issued;

4. all corrective actions have been implemented within the time period that was accepted or extended by the competent authority as defined in point 21.B.225.

Notwithstanding point (c), the oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the conditions provided in points (1) to (4) above, the organisation has established, and the competent authority has approved, an effective continuous system for reporting to the competent authority on the safety performance and regulatory compliance of the organisation itself.

(e) The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation has decreased.

(f) The oversight programme shall include records of the dates when assessments, audits, inspections and meetings are due, and when assessments, audits, inspections and meetings have been effectively carried out.

(g) At the completion of each oversight planning cycle, the competent authority shall issue a recommendation report on the continuation of the approval, reflecting the results of the oversight.';

(22) point 21.B.225 is amended as follows:

'**21.B.225 Findings and corrective actions; observations**

(a) The competent authority shall have a system in place to analyse findings for their safety significance.

(b) 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 its delegated and implementing acts, with the organisation's procedures and manuals, or with the certificate including the terms of approval which lowers safety or seriously endangers flight safety.

The level 1 findings shall also include:

1. any failure to grant the competent authority access to the organisation's facilities as defined in point 21.A.9 during normal operating hours and after two written requests;

2. obtaining the production organisation approval certificate or maintaining its validity by falsification of the submitted documentary evidence;

3. any evidence of malpractice or fraudulent use of the production organisation approval certificate; and

(4) the lack of an accountable manager.

(c) A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the certificate including the terms of approval which is not classified as a level 1 findingmay lower safety or endanger flight safety.

(d) 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 (EU) 2018/1139 and its delegated and implementing acts, communicate in writing the finding to the organisation and request corrective action to address the non-compliance(s) identified. If a level 1 finding directly relates to an aircraft, the competent authority shall inform the competent authority of the Member State in which the aircraft is registered.

1. If there are any level 1 findings, the competent authority shall take immediate and appropriate action to prohibit or limit the activities of the organisation involved and, if appropriate, it shall take action to revoke the production organisation approval certificate or to limit or suspend it in whole or in part, depending upon the extent of the level 1 finding, until successful corrective action has been taken by the organisation.

2. If there are any level 2 findings, the competent authority shall:

(i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, and that in any case shall initially not be more than 3 months. The period shall commence from the date of the written communication of the finding to the organisation requesting corrective action to address the non-compliance(s) identified. At the end of this period, and subject to the nature of the finding, the competent authority may extend the 3-month period provided that a corrective action plan has been agreed by the competent authority;

(ii) assess the corrective action and implementation plan proposed by the organisation, and if the assessment concludes that they are sufficient to address the non-compliance(s), accept these;

(iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to level 1 and action shall be taken as laid down in point (d)(1).

(e) For those cases not requiring level 1 or level 2 findings, the competent authority may issue observations:

1. for any item whose performance has been assessed to be ineffective; or
2. when it has been identified that an item has the potential to cause a non-compliance under points (b) or (c); or
3. when suggestions or improvements are of interest for the overall safety performance of the organisation.

The observations issued under this point shall be communicated in writing to the organisation and recorded by the competent authority.';

(23) points 21.B.230 and 21.B.235 are deleted;

(24) point 21.B.240 is amended as follows:

'**21.B.240 Changes to the production management system**

(a) Upon receiving an application for a significant change to the production management system, the competent authority shall verify the organisation's compliance with the applicable requirements before issuing the approval.

(b) The competent authority shall establish the conditions under which the organisation may operate during the change unless the competent authority determines that the production organisation approval certificate needs to be suspended.

(c) When it is satisfied that the organisation complies with the applicable requirements, the competent authority shall approve the change.

(d) Without prejudice to any additional enforcement measures, if the organisation implements a significant change to the production management system without having received the approval of the competent authority pursuant to point (c), the competent authority shall consider the need to suspend, limit or revoke the organisation's certificate.

(e) For non-significant changes to the production management system, the competent authority shall include the review of such changes in its continuing oversight in accordance with the principles set forth in point 21.B.221. If any non-compliance is found, the competent authority shall notify the organisation, request further changes and act in accordance with point 21.B.225.';

(25) points 21.B.245, 21.B.260, 21.B.330, 21.B.345, 21.B.530 and 21.B.545 are deleted.