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Annex to EASA Opinion No 01/2023

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

laying down technical requirements and administrative procedures for the approval of organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents

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laying down technical requirements and administrative procedures for the approval of organisations involved in the design and/or production of ATM/ANS systems and **ATM/ANS** constituents

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (1), and in particular Articles 43(1), 62(13)(f), 62(15)(c) thereof,

After consulting the Committee within the meaning of Regulation (EU) No 182/2011 (2),

Whereas:

- (1) Regulation (EU) 2018/1139 establishes common essential requirements to provide for a high uniform level of civil aviation safety in the Union; it requires the necessary detailed rules to be adopted, taking into account the objectives of Regulation (EU) 2018/1139 and the nature and risk of the particular activity concerned; it establishes the European Union Aviation Safety Agency (hereinafter referred to as the 'Agency').
- (2) In order to ensure the uniform implementation of and compliance with the essential requirements referred to in Article 40 of Regulation (EU) 2018/1139, for the provision of ATM/ANS referred to in point (g) of Article 2(1) of the same Regulation, the Commission should adopt implementing acts laying down detailed provisions concerning the rules and procedures for issuing, maintaining, amending, limiting, suspending or revoking the certificates for organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents referred to in point (b) of Article 42(1), and for the situations in which such certificates are to be required; the privileges and responsibilities of the holders of certificates referred to in point (b) of 42(1) thereof.
- (3) In accordance with Article 62(15)(c) of Regulation (EU) 2018/1139, the Commission should also adopt implementing acts laying down the provisions concerning the rules and procedures for the administration and management systems of the Agency relating to the exercise of the certification, oversight and enforcement tasks with respect to

implementing powers (OJ L 55, 28.2.2011, p. 13).

rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of

⁽¹⁾ OJ L 212, 22.08.2018, p. 1.

⁽²⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the

- organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents.
- **(4)** Maintenance is commonly understood as the act of keeping equipment in good condition by making repairs, correcting problems, etc. However, it could also be understood to refer to changes to equipment to reflect developments in requirements and standards. In order to cover these two potentially different meanings, this Regulation should differentiate routine maintenance from upgrades/evolution of existing equipment due to functional changes. Routine maintenance is considered the performance of those tasks that are necessary to ensure that ATM/ANS equipment can continue to operate correctly to fulfil its operational function. The principles of the new conformity assessment framework will result in that routine maintenance should only be performed in accordance with the instructions, guidance and requirements provided by the organisations involved in the design and/or production of ATM/ANS equipment in order to ensure the validity of the certificate or declaration of the particular ATM/ANS equipment. Such routine maintenance activities would be normally within the remit of ATM/ANS providers which perform them in accordance with the instructions of the relevant ATM/ANS equipment manufacturer.
- (5) The measures provided for in this Regulation are based on Opinion No xx/2023, issued by the European Union Aviation Safety Agency in accordance with Article 75(2)(b) and (c) and Article 76(1) of Regulation (EU) 2018/1139.
- (6) This implementing act is adopted in accordance with the examination procedure referred to in Article 127(3) of Regulation (EU) 2018/1139.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee within the meaning of Regulation (EU) No 182/2011,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down technical requirements and administrative procedures for the approval of organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents (ATM/ANS equipment).

Article 2

Definitions

For the purpose of this Regulation, 'ATM/ANS equipment' means ATM/ANS constituents as defined by Article 3(6) of Regulation (EU) 2018/1139, and ATM/ANS systems as defined by Article 3(7) of that Regulation, excluding airborne constituents.

Article 3

Competent authority requirements

1. For the purposes of this Regulation, the competent authority responsible for the issue of approvals to organisations involved in the design, and/or production of ATM/ANS

- equipment and for the oversight and enforcement in respect of those organisations, shall be the Agency pursuant to Article 80(1)(c) of Regulation (EU) 2018/1139.
- 2. The Agency shall fulfil the detailed requirements laid down in Annex II (Part-ATM/ANS.EQMT.AR) to Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment] when conducting certification, investigations, inspections, audits and other monitoring activities necessary to ensure the effective oversight of organisations involved in the design, and/or production of ATM/ANS equipment subject to this Regulation.

Article 4

Organisations involved in the design, and/or production of ATM/ANS equipment

An organisation involved in the design and/or production of ATM/ANS equipment shall demonstrate its capability in this regard in accordance with the Annex (Part-DPO.OR) to this Regulation.

Article 5

Amendments to Regulations (EU) 2023/XXX and 2023/XXXX [on the basis of Opinion No 03/2021]

- 1. The following point (j) is added to Article 2(1):
 - '(j) approved organisations involved in the design and/or production of ATM/ANS equipment subject to (this) Regulation (EU) 2023/XXX COMMISSION IMPLEMENTING REGULATION (EU) .../... of XXX laying down technical requirements and administrative procedures for the approval of organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents.'
- 2. The following point (h) is added to Article 6(1):
 - '(h) with regard to organisations referred to in Article 2(1), point (j), the competent authority designated in accordance with Article 3(1), as applicable, of (this) Regulation (EU) 2023/XXX COMMISSION IMPLEMENTING REGULATION (EU) .../... of XXX laying down technical requirements and administrative procedures for the approval of organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents.'.

Article 6

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

For the Commission
The President
[...]

ANNEX

REQUIREMENTS FOR ORGANISATIONS INVOLVED IN THE DESIGN AND/OR PRODUCTION OF ATM/ANS EQUIPMENT

(Part-DPO.OR)

SUBPART A — GENERAL REQUIREMENTS (DPO.OR.A)

DPO.OR.A.001 Scope

This Annex establishes the common requirements as regards the rights and obligations of an applicant for, and a holder of, an organisation approval for the design and/or production of ATM/ANS equipment.

DPO.OR.A.005 Eligibility

Any natural or legal person who has demonstrated, or is in the process of demonstrating, their capability to design and/or produce ATM/ANS equipment in accordance with point DPO.OR.A.010, may apply for a design and/or production organisation approval under the conditions laid down in this Annex.

DPO.OR.A.010 Application for a design and/or production organisation approval and demonstration of capability

- (a) An application for an approval under this Regulation shall be made in a form and manner established by the Agency.
- (b) In order to obtain an approval, an organisation involved in the design and/or production of ATM/ANS equipment shall comply with the requirements set out in this Regulation where those requirements are applicable to the activities that the organisation involved in the design and/or production of ATM/ANS equipment performs or intends to perform.

DPO.OR.A.015 Organisation exposition

- (a) An organisation involved in the design and/or production of ATM/ANS equipment shall establish and maintain an exposition, which provides the following information:
 - (1) a statement signed by the accountable manager confirming that the organisation exposition and any associated manuals, which define the organisation's compliance with the requirements will be complied with at all times;
 - (2) the title(s) and name(s) of the key manager(s) as referred to in DPO.OR.B.020;
 - (3) the duties and responsibilities of the manager(s), including matters for which they may deal directly with the Agency on behalf of the organisation;
 - (4) an organisational chart showing lines of responsibility and accountability of the managers throughout the organisation, including a direct accountability of the accountable manager;
 - (5) a general description of the organisation's manpower resources;

- (6) a general description of the facilities located at each location specified in the organisation's approval;
- (7) a general description of the organisation's scope of work relevant to the terms of approval;
- (8) the procedure(s) for the verification and demonstration that the design of ATM/ANS equipment, or changes to it, complies with the applicable detailed specifications and requirements as established by Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment] and has no unsafe features, as applicable;
- (9) the procedure for the preparation and maintenance of the technical data and records, for each model of each piece of ATM/ANS equipment for which a certificate or declaration of design has been issued in accordance with Implementing Regulation (EU) .../... [implementing act on the approval of DPOs], as applicable;
- (10) the procedure(s) for the notification of organisational changes to the Agency;
- (11) the amendment procedure for the organisation's exposition;
- (12) a description, direct or by cross reference, of the organisation's management system and procedure(s);
- (13) a description, direct or by cross reference, of the contractors' management and oversight procedure(s) referred to in point DPO.OR.B.015 of this Annex.
- (b) The exposition shall be amended as necessary to remain an up-to-date description of the organisation, and a copy of it, including its amendments, shall be supplied to the Agency.
- (c) An application for a change approval referred to in point DPO.OR.B.005 of this Annex shall be based on the submission of the proposed changes to the exposition.

DPO.OR.A.020 Means of compliance

- (a) Alternative means of compliance to the acceptable means of compliance (AMC) adopted by the Agency may be used by an organisation involved in the design and/or production of ATM/ANS equipment to establish and demonstrate compliance with Regulation (EU) 2018/1139 and this Regulation.
- (b) When an organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the Agency with a full description of that alternative means of compliance. The description shall include any revisions to manuals or procedures that may be relevant, as well as an assessment that demonstrates compliance with Regulation (EU) 2018/1139 and this Regulation.

An organisation involved in the design and/or production of ATM/ANS equipment may use any alternative means of compliance subject to prior approval by the Agency and upon receipt of the notification as provided for in point (d) to point ATM/ANS.EQMT.AR.A.015 of Annex II (Part-ATM/ANS.EQMT.AR) to Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment].

DPO.OR.A.025 Duration, continued validity and privileges of an organisation approval

- (a) An organisation's approval shall remain valid for an unlimited period of time provided that:
 - (1) the organisation remains compliant with Regulation (EU) 2018/1139 and its applicable delegated and implementing acts;
 - (2) the approval has not been surrendered by the organisation or suspended or revoked by the Agency.
- (b) Upon revocation or surrender of the approval, if issued in a paper format, it shall be returned to the Agency without delay.
- (c) The holder of an organisation approval shall be entitled, within the scope of its terms of approval and under the relevant procedures of the design management system:
 - (1) to classify changes to an ATM/ANS equipment as 'major' or 'minor';
 - (2) to approve minor changes to an ATM/ANS equipment certificate(s) and/or declaration(s);
 - (3) to approve certain major changes to an ATM/ANS equipment certificate issued under COMMISSION DELEGATED REGULATION (EU) .../...of XXX laying down common technical requirements and administrative procedures for the conformity assessment of ATM/ANS systems and ATM/ANS constituents;
 - (4) to issue certain ATM/ANS equipment declarations under COMMISSION DELEGATED REGULATION (EU) .../...of XXX laying down common technical requirements and administrative procedures for the conformity assessment of ATM/ANS systems and ATM/ANS constituents and approve certain major changes to those declarations; and
 - (5) to issue certain ATM/ANS equipment statements of compliance under COMMISSION DELEGATED REGULATION (EU) .../...of XXX laying down common technical requirements and administrative procedures for the conformity assessment of ATM/ANS systems and ATM/ANS constituents.

DPO.OR.A.030 Facilitation and cooperation

- (a) An organisation involved in the design and/or production of ATM/ANS equipment shall facilitate the inspections and audits performed by the Agency or by a qualified entity that acts on its behalf, and it shall cooperate as necessary for the efficient and effective exercise of the powers of the Agency.
- (b) An organisation involved in the design and/or production of ATM/ANS equipment shall cooperate with and support the ATM/ANS providers using its ATM/ANS equipment in their compliance demonstration process to the competent authorities concerned.

DPO.OR.A.035 Findings and corrective actions

Following the receipt of the notification of findings from the Agency, the organisation involved in the design and/or production of ATM/ANS equipment shall:

- (a) identify the root cause of the non-compliance;
- (b) define a corrective action plan; and

(c) demonstrate the implementation of the corrective action to the satisfaction of the Agency within the time period proposed and approved by the Agency, as defined in point (e)(2) of point ATM/ANS.EQMT.AR.C.050 of Annex II (Part-ATM/ANS.EQMT.AR) to Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment].

DPO.OR.A.040 Immediate reaction to a safety and interoperability problem

An organisation involved in the design and/or production of ATM/ANS equipment shall implement any safety and security measures, including ATM/ANS equipment directives, mandated by the Agency in accordance with point ATM/ANS.EQMT.AR.A.050 of Annex II to Delegated Regulation (EU) .../... [delegated act on the attestation of ATM/ANS equipment].

DPO.OR.A.045 Failures, malfunctions, and defects

- (a) The holder of an approval issued in accordance with this Regulation shall:
 - (1) establish and maintain a system for collecting, investigating and analysing reports of and information on failures, malfunctions, defects or other occurrences which have caused or might cause adverse effects on the continuing compliance of the ATM/ANS equipment with the applicable requirements; and
 - (2) inform all known users of the ATM/ANS equipment concerned and, on request, any person mandated under other associated regulations about the system established in accordance with point (a)(1) and on how to provide such reports of and information on failures, malfunctions, defects or other occurrences.
- (b) For organisations that have their principal place of business in a Member State, the system established in accordance with point (a)(1) shall include provisions for mandatory and voluntary occurrence reporting and follow-up that meet the requirements of Regulation (EU) No 376/2014 and of Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on their basis.
- (c) The approval holder shall report to the Agency any failure, malfunction, defect or other occurrence of which it is aware, and which has resulted or may result in an unsafe or underperformance condition.
- (d) For approval holders that do not have their principal place of business in a Member State, reports shall be made in a form and manner established by the Agency, as soon as practicable and in any case submitted not later than 72 hours after the person or organisation has become aware of the particular occurrence, unless exceptional circumstances prevent this.
- (e) The approval holder shall investigate an occurrence that has been reported under point (c), including the deficiencies that have led to that occurrence, and report to the Agency the results of its investigation and any action it intends to take or proposes to take to correct these deficiencies.

DPO.OR.A.050 Approval transferability

An organisation approval is not transferable, except only as a result of a change in the ownership of the organisation.

SUBPART B — MANAGEMENT (DPO.OR.B)

DPO.OR.B.001 Management system

- (a) An organisation involved in the design and/or production of ATM/ANS equipment shall implement and maintain a management system that includes the following:
 - (1) clearly defined lines of responsibility and accountability throughout its organisation, including a direct accountability of the accountable manager;
 - (2) a description of the overall philosophy and principles of the organisation, collectively constituting a policy, signed by the accountable manager;
 - (3) the means to verify the performance of the organisation in the light of the performance indicators and performance targets of the management system;
 - (4) a process to identify changes within the organisation and the context in which it operates, which may affect established processes, procedures and products and, where necessary, change the management system to accommodate those changes;
 - (5) a process to identify the scope of changes to the ATM/ANS equipment and the associated risk;
 - (6) a process to review the management system, identify the causes of substandard performance of the management system, determine the implications of such substandard performance, and eliminate or mitigate such causes;
 - (7) a process to ensure that the personnel of the organisation are trained and competent to perform their duties in a safe, efficient, continuous and sustainable manner; in this context, the organisation shall establish policies for the recruitment and training of its personnel;
 - (8) a formal means for communication which ensures that all personnel of the organisation are fully aware of the management system that allows critical information to be communicated and that makes it possible to explain why particular actions are taken and why procedures are introduced or changed;
 - (9) as regards design activities:
 - (i) procedure(s) for the design of ATM/ANS equipment, and for changes to its design;
 - (ii) assurance that the design of ATM/ANS equipment, or the changes to its design, comply with the applicable specifications, including independent checking function of the demonstration of compliance on the basis of which the organisation submits compliance statements and associated documentation to the Agency; and
 - (iii) procedure(s) for the verification of the acceptability of the elements of the ATM/ANS equipment designed, or the tasks performed, by the contracted organisations referred to in point DPO.OR.B.015;
 - (iv) staff involved in the design of ATM/ANS equipment are of sufficient numbers and are trained and competent, and have been authorised to discharge their allocated responsibilities;
 - (v) assurance that there is close and efficient coordination between departments and within departments;

- (10) as regards production activities, procedures for:
 - (i) the issue and approval of documents, or changes to them;
 - (ii) assessment audits and the control of contracted organisations referred to in point DPO.OR.B.015;
 - (iii) verifying that incoming products, parts, materials and equipment, including the supply of new items or items used by product buyers, are as specified in the applicable design data;
 - (iv) verifying that ATM/ANS equipment conforms to the applicable design data;
 - (v) identification and traceability;
 - (vi) organisation processes;
 - (vii) inspection and testing;
 - (viii) calibration of tools, jigs, and test equipment;
 - (ix) the control of non-conforming items;
 - (x) the coordination with the applicant for, or holder of, the design approval;
 - (xi) the completion and retention of records of work carried out;
 - (xii) the issue of release documents;
 - (xiii) the handling, storage and packing of ATM/ANS equipment.
- (b) An organisation involved in the design and/or production of ATM/ANS equipment shall document all key management system processes, including a process for making personnel aware of their responsibilities, and the procedure for amending those processes.
- (c) An organisation involved in the design and/or production of ATM/ANS equipment shall establish a function to monitor its compliance with the applicable requirements and the adequacy of the established procedures. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure the effective implementation of corrective actions, as necessary.
- (d) The management system shall be proportionate to the size of the organisation involved in the design and/or production of ATM/ANS equipment and the complexity of its activities, taking into account the hazards and associated risks inherent in those activities.
- (e) In addition to the management system referred to in point (a), the organisation involved in the design and/or production of ATM/ANS equipment shall establish, implement and maintain an information security management system in accordance with Implementing Regulation (EU) 202X/XXXX [on the basis of Opinion No 03/2021] in order to ensure the proper management of information security risks which may have an impact on aviation safety.

DPO.OR.B.005 Change management

(a) Following the issue of an organisation's approval, any change to the management system that is significant shall be approved by the Agency before being implemented unless such a change is notified and managed in accordance with a procedure approved by the Agency.

- The organisation shall submit to the Agency an application for approval demonstrating continuous compliance with the applicable requirements.
- (b) Each change to ATM/ANS equipment shall be notified to and approved by the Agency before being implemented unless such a change is managed in accordance with a change management procedure approved by the Agency, defining the classification of the changes to the ATM/ANS equipment and describing how such changes will be notified and managed.

DPO.OR.B.010 Facility requirements

An organisation involved in the design and/or production of ATM/ANS equipment shall ensure that its facilities and equipment, including testing facilities and equipment, are adequate and suitable to perform and manage all its tasks and activities in accordance with the applicable requirements.

DPO.OR.B.015 Contracted activities

- (a) Contracted activities include all those activities that are within the scope of the organisation's activities, in accordance with the terms of the certificate, which are performed by other organisations either themselves certified to carry out such activities or, if not certified, working under the organisation's supervision. An organisation involved in the design and/or production of ATM/ANS equipment shall ensure that when it contracts any part of its activities to or when it purchases any part of its activities from external organisations, the contracted or purchased activity, as applicable, conforms with the applicable requirements.
- (b) When an organisation involved in the design and/or production of ATM/ANS equipment contracts any part of its activities to an organisation that is not itself certified in accordance with this Regulation to carry out such activities, it shall ensure that the contracted organisation works under its supervision. An organisation involved in the design and/or production of ATM/ANS equipment shall ensure that the Agency is given access to the contracted organisation to determine its continued compliance with the applicable requirements of this Regulation.

DPO.OR.B.020 Personnel requirements

- (a) An organisation involved in the design and/or production of ATM/ANS equipment shall appoint an accountable manager who has the authority to ensure that all activities may be financed and carried out in accordance with the applicable requirements of this Regulation. The accountable manager shall be responsible for establishing and maintaining an effective management system.
- (b) The authority, duties, and responsibilities of the nominated postholders, in particular of management personnel in charge of safety-, quality-, security-, finance- and human-resources-related functions, as applicable, shall also be defined.

DPO.OR.B.025 Record-keeping

- (a) An organisation involved in the design and/or production of ATM/ANS equipment shall establish a record-keeping system that allows for the adequate storage of records and the reliable traceability of all its activities, covering in particular all the elements indicated in point DPO.OR.B.001 of this Annex.
- (b) The format and the retention period of the records referred to in point (a) shall be specified in the organisation's management system procedures.
- (c) Records shall be stored in a manner that ensures their protection against damage, alteration, and theft.
- (d) An organisation involved in the design and/or production of ATM/ANS equipment shall maintain a register of the ATM/ANS users that deploy its ATM/ANS equipment.

SUBPART C — TECHNICAL REQUIREMENTS (DPO.OR.C)

DPO.OR.C.001 Organisations involved in the design and/or production of ATM/ANS equipment

- (a) An applicant for, and a holder of, a design and/or production organisation approval for ATM/ANS equipment shall be entitled to hold or apply to be issued a certificate for the design and/or production of ATM/ANS equipment or issued a declaration of design compliance for certain ATM/ANS equipment, as applicable.
- (b) As regards design activities, an organisation shall:
 - (1) issue a declaration of design compliance for the ATM/ANS equipment, as applicable;
 - (2) issue data and information under its authority within the scope of its terms of approval as established by the Agency with the following statement: 'The technical content of this document is approved under the authority of EASA.AOA.GND.[XXXX]';
 - (3) prepare and maintain, for each model of each product for which an ATM/ANS equipment declaration has been issued, a current file of complete technical data and records.
- (c) As regards production activities, an organisation shall:
 - (1) manufacture each article ensuring that the completed product conforms to its design data and is safe for installation;
 - (2) prepare and maintain, for each model of each product for which an ATM/ANS equipment declaration has been issued, a current file of complete technical data and records:
 - (3) prepare, maintain and update the master copies of all manuals required by the applicable declaration specifications for the particular product;
 - (4) make available to the users of the product, and to the Agency on request, those instructions for continued suitability necessary for the use and maintenance of the product, and changes to those instructions;
 - (5) mark each article;

- (6) continue to comply with the applicable requirements laid down in this Regulation.
- (d) In addition to point (c), an organisation involved in the production of ATM/ANS equipment shall be entitled to, within the scope of its terms of approval, determine that each completed ATM/ANS equipment conforms with the applicable design data and is in a condition for safe operation before issuing a statement of conformity that the ATM/ANS equipment it has manufactured has been produced in accordance with the applicable requirements of this Regulation and with the applicable design data.
- (e) The statement of conformity referred to in point (d) for each ATM/ANS equipment manufactured shall contain at least the following information:
 - (1) a description of the ATM/ANS equipment;
 - (2) its part number;
 - (3) its serial number;
 - (4) a statement that the ATM/ANS equipment has been manufactured in conformity to the applicable design data and is in a condition for safe operation;
 - (5) a reference to the declaration of design.

DPO.OR.C.005 Coordination

An organisation involved in the design and/or production of ATM/ANS equipment shall ensure:

- (a) the satisfactory coordination, with the appropriate arrangements, between design and production activities, as appropriate;
- (b) the satisfactory coordination with and proper support to the relevant ATM/ANS providers and aviation undertaking(s) as regards the continued suitability of the ATM/ANS equipment, as applicable;
- (c) the proper support to the ATM/ANS equipment design activity with regard to its continued suitability of the ATM/ANS equipment.

DPO.OR.C.010 ATM/ANS equipment directives

When an ATM/ANS equipment directive has to be issued by the Agency, the organisation involved in the design and/or production of ATM/ANS equipment shall:

- (a) propose an appropriate corrective action and submit it together with details to the Agency for approval;
- (b) following the approval by the Agency of the proposal referred to in point (a), make available to all known users or owners of ATM/ANS equipment appropriate descriptive data and accomplishment instructions and, on request, to any person required to comply with the ATM/ANS equipment directive.