COMMISSION DELEGATED REGULATION (EU) 2022/1645

of 14 July 2022

laying down rules for the application of Regulation (EU) 2018/1139 of the European Parliament and of the Council, as regards requirements for the management of information security risks with a potential impact on aviation safety for organisations covered by Commission Regulations (EU) No 748/2012 and (EU) No 139/2014 and amending Commission Regulations (EU) No 748/2012 and (EU) No 139/2014

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 19(1) point (g) and 39(1) point (b) thereof.

Whereas:

- (1) In accordance with the essential requirements set out in Annex II, point 3.1(b), to Regulation (EU) 2018/1139, design and production organisations are to implement and maintain a management system to manage safety risks.
- (2) In addition, in accordance with the essential requirements set out in Annex VII, points 2.2.1 and 5.2, to Regulation (EU) 2018/1139, aerodrome operators and organisations responsible for the provision of apron management services are to implement and maintain a management system to manage safety risks.
- (3) The safety risks referred to in recitals (1) and (2) may derive from different sources, including design and maintenance flaws, human performance aspects, environmental threats and information security threats. Therefore, the management systems implemented by the organisations as referred to in recitals (1) and (2), should take into account not only safety risks stemming from random events, but also safety risks deriving from information security threats where existing flaws may be exploited by individuals with a malicious intent. Those information security risks are constantly increasing in the civil aviation environment as the current information systems are becoming more and more interconnected, and increasingly becoming the target of malicious actors.
- (4) The risks associated with those information systems are not limited to possible attacks to the cyberspace, but encompass also threats which may affect processes and procedures as well as the performance of human beings.
- (5) A significant number of organisations already use international standards, such as ISO 27001, in order to address the security of digital information and data. These standards may not fully address all the specificities of civil aviation.
- (6) Therefore, it is appropriate to set out requirements for the management of information security risks with a potential impact on aviation safety.
- (7) It is essential that those requirements cover the different aviation domains and their interfaces since aviation is a highly interconnected system of systems. Therefore, they should apply to all the organisations that are already required to have a management system in accordance with the existing Union aviation safety legislation.
- (8) The requirements laid down in this Regulation should be consistently applied across all aviation domains, while creating a minimal impact on the Union aviation safety legislation already applicable to those domains.

- (9) The requirements laid down in this Regulation should be without prejudice to information security and cybersecurity requirements laid down in point 1.7 of the Annex to Commission Implementing Regulation (EU) 2015/1998 (²) and in Article 14 of Directive (EU) 2016/1148 of the European Parliament and of the Council (³).
- (10) The definition on information security used for the purposes of this legal act should not be interpreted as divergent from the definition of security of network and information systems laid down in Directive (EU) 2016/1148.
- (11) In order to avoid duplication of legal requirements, where organisations covered by this Regulation are already subject to security requirements arising from other Union acts referred to in recital (9), which are, in their effect equivalent to the provisions laid down in this Regulation, compliance with those security requirements should be considered to constitute compliance with the requirements laid down in this Regulation.
- (12) Organisations covered by this Regulation that are already subject to security requirements arising from Implementing Regulation (EU) 2015/1998 should also comply with the requirements of Annex I (Part IS.D.OR.230 'Information security external reporting scheme') to this Regulation as Implementing Regulation (EU) 2015/1998 does not contain any provisions related to external reporting of information security incidents.
- (13) Commission Regulations (EU) No 748/2012 (4) and (EU) No 139/2014 (5) should be amended in order to establish the link between the management systems prescribed in the regulations listed above and the information security management requirements prescribed by this Regulation.
- (14) In order to provide organisations with sufficient time to ensure compliance with the new rules and procedures introduced by this Regulation, this Regulation should apply from 3 years after the date of entry into force.
- (15) The requirements laid down by this Regulation are based on Opinion No 03/2021 (6), issued by the Agency in accordance with Article 75(2) points (b) and (c) and Article 76(1) of Regulation (EU) 2018/1139.
- (16) In accordance with Article 128(4) of Regulation (EU) 2018/1139, the Commission consulted experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making (7),

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation sets out the requirements to be met by the organisations referred to in Article 2 in order to identify and manage information security risks with potential impact on aviation safety which could affect information and communication technology systems and data used for civil aviation purposes and to detect information security events and identify those which are considered information security incidents with potential impact on aviation safety and respond to, and recover from, those information security incidents.

⁽²⁾ Commission Implementing Regulation (EU) 2015/1998 of 5 November 2015 laying down detailed measures for the implementation of the common basic standards on aviation security (OJ L 299, 14.11.2015, p. 1).

⁽³⁾ Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (OJ L 194, 19.7.2016, p. 1).

⁽⁴⁾ Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1).

⁽⁵⁾ Commission Regulation (EU) No 139/2014 of 12 February 2014 laying down requirements and administrative procedures related to aerodromes pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 44, 14.2.2014, p. 1).

⁽⁶⁾ https://www.easa.europa.eu/document-library/opinions

⁽⁷⁾ OJ L 123, 12.5.2016, p. 1.

Article 2

Scope

- 1. This Regulation applies to the following organisations:
- (a) production organisations and design organisations subject to Subparts G and J of Section A of Annex I (Part 21) to Regulation (EU) No 748/2012, except design and production organisations that are solely involved in the design and/or production of ELA2 aircraft as defined in Article 1(2), point (j) of Regulation (EU) No 748/2012;
- (b) aerodrome operators and apron management service providers subject to Annex III 'Part Organisation Requirements (Part-ADR.OR)' to Regulation (EU) No 139/2014.
- 2. This Regulation is without prejudice to information security and cybersecurity requirements laid down in point 1.7 of the Annex to Implementing Regulation (EU) 2015/1998 and in Article 14 of Directive (EU) 2016/1148.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

- (1) 'information security' means the preservation of confidentiality, integrity, authenticity and availability of network and information systems;
- (2) 'information security event' means an identified occurrence of a system, service or network state indicating a possible breach of the information security policy or failure of information security controls, or a previously unknown situation that can be relevant for information security;
- (3) 'incident' means any event having an adverse effect on the security of network and information systems as defined in Article 4(7) of Directive (EU) 2016/1148;
- (4) 'information security risk' means the risk to organisational civil aviation operations, assets, individuals, and other organisations due to the potential of an information security event. Information security risks are associated with the potential that threats will exploit vulnerabilities of an information asset or group of information assets;
- (5) 'threat' means a potential violation of information security which exists when there is an entity, circumstance, action or event that could cause harm;
- (6) 'vulnerability' means a flaw or weakness in an asset or a system, procedures, design, implementation, or information security measures that could be exploited and results in a breach or violation of the information security policy.

Article 4

Requirements arising from other Union legislation

- 1. Where an organisation referred to in Article 2 complies with security requirements laid down in Article 14 of Directive (EU) 2016/1148 that are equivalent to the requirements laid down in this Regulation, compliance with those security requirements shall be considered to constitute compliance with the requirements laid down in this Regulation.
- 2. Where an organisation referred to in Article 2 is an operator or an entity referred to in the national civil aviation security programmes of Member States laid down in accordance with Article 10 of Regulation (EC) No 300/2008 of the European Parliament and of the Council (8), the cybersecurity requirements contained in point 1.7 of the Annex to Implementing Regulation (EU) 2015/1998 are considered to be equivalent to the requirements laid down in this Regulation, except as regards point IS.D.OR.230 of the Annex to this Regulation that shall be complied with.

⁽⁸⁾ Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).

3. The Commission, after consulting EASA and the Cooperation Group referred to in Article 11 of Directive (EU) 2016/1148, may issue guidelines for the assessment of the equivalence of requirements laid down in this Regulation and Directive (EU) 2016/1148.

Article 5

Competent authority

- 1. The authority responsible for certifying and overseeing compliance with this Regulation shall be:
- (a) with regard to organisations referred to in Article 2, point (a), the competent authority designated in accordance with Annex I (Part 21) to Regulation (EU) No 748/2012;
- (b) with regard to organisations referred to in Article 2, point (b), the competent authority designated in accordance with Annex III (Part-ADR.OR) to Regulation (EU) No 139/2014.
- 2. Member States, may for the purposes of this Regulation, designate an independent and autonomous entity to fulfil the assigned role and responsibilities of the competent authorities referred to in paragraph 1. In that case, coordination measures shall be established between that entity and the competent authorities, as referred to in paragraph 1, to ensure effective oversight of all the requirements to be met by the organisation.

Article 6

Amendment to Regulation (EU) No 748/2012

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

- (1) the Table of Contents is amended as follows:
 - (a) the following heading is inserted after heading 21.A.139:
 - '21.A.139A Information security management system';
 - (b) the following heading is inserted after heading 21.A.239:
 - '21.A.239A Information security management system';
- (2) the following point 21.A.139A is inserted after point 21.A.139:

'21.A.139A Information security management system

In addition to the production management system required by point 21.A.139, the production organisation shall establish, implement and maintain an information security management system in accordance with Commission Delegated Regulation (EU) 2022/1645 (*) in order to ensure the proper management of information security risks which may have an impact on aviation safety.

- (*) Commission Delegated Regulation (EU) 2022/1645 of 14 July 2022 laying down rules for the application of Regulation (EU) 2018/1139 of the European Parliament and of the Council, as regards requirements for the management of information security risks with a potential impact on aviation safety for organisations covered by Commission Regulations (EU) No 748/2012 and (EU) No 139/2014 and amending Commission Regulations (EU) No 748/2012 and (EU) No 139/2014 (OJ L 248, 26.9.2022, p. 18).';
- (3) the following point 21.A.239A is inserted after point 21.A.239:

'21.A.239A Information security management system

In addition to the design management system required by point 21.A.239, the design organisation shall establish, implement and maintain an information security management system in accordance with Commission Delegated Regulation (EU) 2022/1645 in order to ensure the proper management of information security risks which may have an impact on aviation safety.'.

Article 7

Amendment to Regulation (EU) No 139/2014

Annex III (Part-ADR.OR) to Regulation (EU) No 139/2014 is amended as follows:

(1) the following point ADR.OR.D.005A is inserted after point ADR.OR.D.005:

'ADR.OR.D.005A Information security management system

The aerodrome operator shall establish, implement and maintain an information security management system in accordance with Delegated Regulation (EU) 2022/1645 (*) in order to ensure the proper management of information security risks which may have an impact on aviation safety.

- (*) Commission Delegated Regulation (EU) 2022/1645 of 14 July 2022 laying down rules for the application of Regulation (EU) 2018/1139 of the European Parliament and of the Council, as regards requirements for the management of information security risks with a potential impact on aviation safety for organisations covered by Commission Regulations (EU) No 748/2012 and (EU) No 139/2014 and amending Commission Regulations (EU) No 748/2012 and (EU) No 139/2014 (OJ L 248, 26.9.2022, p. 18).';
- (2) point ADR.OR.D.007 is replaced by the following:

'ADR.OR.D.007 Management of aeronautical data and aeronautical information

- (a) As part of its management system, the aerodrome operator shall implement and maintain a quality management system covering the following activities:
 - (1) its aeronautical data activities;
 - (2) its aeronautical information provision activities.
- (b) As part of its management system, the aerodrome operator shall establish a security management system to ensure the security of operational data it receives, or produces, or otherwise employs, so that access to that operational data is restricted only to those authorised.
- (c) The security management system shall define the following elements:
 - (1) the procedures relating to data security risk assessment and mitigation, security monitoring and improvement, security reviews and lesson dissemination;
 - (2) the means designed to detect security breaches and to alert personnel with appropriate security warnings;
 - (3) the means of controlling the effects of security breaches and of identifying recovery action and mitigation procedures to prevent reoccurrence.
- (d) The aerodrome operator shall ensure the security clearance of its personnel with respect to aeronautical data security.
- (e) The aspects related to information security shall be managed in accordance with point ADR.OR.D.005A.';
- (3) the following point ADR.OR.F.045A is inserted after point ADR.OR.F.045:

'ADR.OR.F.045A Information security management system

The organisation responsible for the provision of AMS shall establish, implement and maintain an information security management system in accordance with Delegated Regulation (EU) 2022/1645 in order to ensure the proper management of information security risks which may have an impact on aviation safety.'.

Article 8

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, 14 July 2022.

For the Commission The President Ursula VON DER LEYEN

ANNEX

INFORMATION SECURITY - ORGANISATION REQUIREMENTS

[PART-IS.D.OR]

IS.D.OR.100	Scope
IS.D.OR.200	Information security management system
IS.D.OR.205	Information security risk assessment
IS.D.OR.210	Information security risk treatment
IS.D.OR.215	Information security internal reporting scheme
IS.D.OR.220	Information security incidents – detection, response, and recovery
IS.D.OR.225	Response to findings notified by the competent authority
IS.D.OR.230	Information security external reporting scheme
IS.D.OR.235	Contracting of information security management activities
IS.D.OR.240	Personnel requirements
IS.D.OR.245	Record-keeping
IS.D.OR.250	Information security management manual (ISMM)
IS.D.OR.255	Changes to the information security management system

IS.D.OR.100 Scope

IS.D.OR.260 Continuous improvement

This Part establishes the requirements to be met by the organisations referred to in Article 2 of this Regulation.

IS.D.OR.200 Information security management system (ISMS)

- (a) In order to achieve the objectives set out in Article 1, the organisation shall set up, implement and maintain an information security management system (ISMS) which ensures that the organisation:
 - (1) establishes a policy on information security setting out the overall principles of the organisation with regard to the potential impact of information security risks on aviation safety;
 - (2) identifies and reviews information security risks in accordance with point IS.D.OR.205;
 - (3) defines and implements information security risk treatment measures in accordance with point IS.D.OR.210;
 - (4) implements an information security internal reporting scheme in accordance with point IS.D.OR.215;
 - (5) defines and implements, in accordance with point IS.D.OR.220, the measures required to detect information security events, identifies those events which are considered incidents with a potential impact on aviation safety except as permitted by point IS.D.OR.205(e), and responds to, and recovers from, those information security incidents;
 - (6) implements the measures that have been notified by the competent authority as an immediate reaction to an information security incident or vulnerability with an impact on aviation safety;
 - (7) takes appropriate action, in accordance with point IS.D.OR.225, to address findings notified by the competent authority;
 - (8) implements an external reporting scheme in accordance with point IS.D.OR.230 in order to enable the competent authority to take appropriate actions;
 - (9) complies with the requirements contained in point IS.D.OR.235 when contracting any part of the activities referred to in point IS.D.OR.200 to other organisations;

- (10) complies with the personnel requirements laid down in point IS.D.OR.240;
- (11) complies with the record-keeping requirements laid down in point IS.D.OR.245;
- (12) monitors compliance of the organisation with the requirements of this Regulation and provides feedback on findings to the accountable manager or, in the case of design organisations, to the head of the design organisation, in order to ensure effective implementation of corrective actions;
- (13) protects, without prejudice to applicable incident reporting requirements, the confidentiality of any information that the organisation may have received from other organisations, according to its level of sensitivity.
- (b) In order to continuously meet the requirements referred to in Article 1, the organisation shall implement a continuous improvement process in accordance with point IS.D.OR.260.
- (c) The organisation shall document, in accordance with point IS.D.OR.250, all key processes, procedures, roles and responsibilities required to comply with point IS.D.OR.200(a) and establish a process for amending that documentation. Changes to those processes, procedures, roles and responsibilities shall be managed in accordance with point IS.D.OR.255.
- (d) The processes, procedures, roles and responsibilities established by the organisation in order to comply with point IS.D. OR.200(a) shall correspond to the nature and complexity of its activities, based on an assessment of the information security risks inherent to those activities, and may be integrated within other existing management systems already implemented by the organisation.
- (e) Without prejudice to the obligation to comply with the reporting requirements contained in Regulation (EU) No 376/2014 of the European Parliament and of the Council (¹) and the requirements of point IS.D.OR.200 (a) (13), the organisation may be granted approval by the competent authority not to implement the requirements referred to in points (a) to (d)) and the related requirements contained in points IS.D.OR.205 through IS.D.OR.260, if it demonstrates to the satisfaction of that authority that its activities, facilities and resources, as well as the services it operates, provides, receives and maintains, do not pose any information security risks with a potential impact on aviation safety neither to itself nor to other organisations. The approval shall be based on a documented information security risk assessment carried out by the organisation or a third party in accordance with point IS.D.OR.205 and reviewed and approved by its competent authority.

The continued validity of that approval will be reviewed by the competent authority following the applicable oversight audit cycle and whenever changes are implemented in the scope of work of the organisation.

IS.D.OR.205 Information security risk assessment

- (a) The organisation shall identify all of its elements, which could be exposed to information security risks. That shall include:
 - (1) the organisation's activities, facilities and resources, as well as the services the organisation operates, provides, receives or maintains;
 - (2) the equipment, systems, data and information that contribute to the functioning of the elements listed in point (1).
- (b) The organisation shall identify the interfaces that it has with other organisations, and which could result in the mutual exposure to information security risks.
- (c) With regard to the elements and interfaces referred to in points (a) and (b), the organisation shall identify the information security risks which may have a potential impact on aviation safety. For each identified risk, the organisation shall:
 - (1) assign a risk level according to a predefined classification established by the organisation;

⁽¹) Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).

(2) associate each risk and its level with the corresponding element or interface identified in accordance with points (a) and (b).

The predefined classification referred to in point (1) shall take into account the potential of occurrence of the threat scenario and the severity of its safety consequences. Based on that classification, and taking into account whether the organisation has a structured and repeatable risk management process for operations, the organisation shall be able to establish whether the risk is acceptable or needs to be treated in accordance with point IS.D.OR.210.

In order to facilitate the mutual comparability of risks assessments, the assignment of the risk level pursuant to point (1) shall take into account relevant information acquired in coordination with the organisations referred to in point (b).

- (d) The organisation shall review and update the risk assessment carried out in accordance with points (a), (b) and (c) in any of the following situations:
 - (1) there is a change in the elements subject to information security risks;
 - (2) there is a change in the interfaces between the organisation and other organisations, or in the risks communicated by the other organisations;
 - (3) there is a change in the information or knowledge used for the identification, analysis and classification of risks;
 - (4) there are lessons learnt from the analysis of information security incidents.

IS.D.OR.210 Information security risk treatment

- (a) The organisation shall develop measures to address unacceptable risks identified in accordance with point IS.D. OR.205, implement them in a timely manner and check their continued effectiveness. Those measures shall enable the organisation to:
 - (1) control the circumstances that contribute to the effective occurrence of the threat scenario;
 - (2) reduce the consequences on aviation safety associated with the materialisation of the threat scenario;
 - (3) avoid the risks.

Those measures shall not introduce any new potential unacceptable risks to aviation safety.

(b) The person referred to in point IS.D.OR.240 (a) and (b) and other affected personnel of the organisation shall be informed of the outcome of the risk assessment carried out in accordance with point IS.D.OR.205, the corresponding threat scenarios and the measures to be implemented.

The organisation shall also inform organisations with which it has an interface in accordance with point IS.D.OR.205 (b) of any risk shared between both organisations.

IS.D.OR.215 Information security internal reporting scheme

- (a) The organisation shall establish an internal reporting scheme to enable the collection and evaluation of information security events, including those to be reported pursuant to point IS.D.OR.230.
- (b) That scheme and the process referred to in point IS.D.OR.220 shall enable the organisation to:
 - (1) identify which of the events reported pursuant to point (a) are considered information security incidents or vulnerabilities with a potential impact on aviation safety;
 - (2) identify the causes of, and contributing factors to, the information security incidents and vulnerabilities identified in accordance with point (1), and address them as part of the information security risk management process in accordance with points IS.D.OR.205 and IS.D.OR.220;
 - (3) ensure an evaluation of all known, relevant information relating to the information security incidents and vulnerabilities identified in accordance with point (1);

- (4) ensure the implementation of a method to distribute internally the information as necessary.
- (c) Any contracted organisation which may expose the organisation to information security risks with a potential impact on aviation safety shall be required to report information security events to the organisation. Those reports shall be submitted using the procedures established in the specific contractual arrangements and shall be evaluated in accordance with point (b).
- (d) The organisation shall cooperate on investigations with any other organisation that has a significant contribution to the information security of its own activities.
- (e) The organisation may integrate that reporting scheme with other reporting schemes it has already implemented.

IS.D.OR.220 Information security incidents – detection, response and recovery

- (a) Based on the outcome of the risk assessment carried out in accordance with point IS.D.OR.205 and the outcome of the risk treatment performed in accordance with point IS.D.OR.210, the organisation shall implement measures to detect incidents and vulnerabilities that indicate the potential materialisation of unacceptable risks and which may have a potential impact on aviation safety. Those detection measures shall enable the organisation to:
 - (1) identify deviations from predetermined functional performance baselines;
 - (2) trigger warnings to activate proper response measures, in case of any deviation.
- (b) The organisation shall implement measures to respond to any event conditions identified in accordance with point (a) that may develop or have developed into an information security incident. Those response measures shall enable the organisation to:
 - (1) initiate the reaction to the warnings referred to in point (a)(2) by activating predefined resources and course of actions:
 - (2) contain the spread of an attack and avoid the full materialisation of a threat scenario;
 - (3) control the failure mode of the affected elements defined in point IS.D.OR.205(a).
- (c) The organisation shall implement measures aimed at recovering from information security incidents, including emergency measures, if needed. Those recovery measures shall enable the organisation to:
 - (1) remove the condition that caused the incident, or constrain it to a tolerable level;
 - (2) reach a safe state of the affected elements defined in point IS.D.OR.205(a) within a recovery time previously defined by the organisation.

IS.D.OR.225 Response to findings notified by the competent authority

- (a) After receipt of the notification of findings submitted by the competent authority, the organisation shall:
 - (1) identify the root cause or causes of, and contributing factors to, the non-compliance;
 - (2) define a corrective action plan;
 - (3) demonstrate the correction of the non-compliance to the satisfaction of the competent authority.
- (b) The actions referred to in point (a) shall be carried out within the period agreed with the competent authority.

IS.D.OR.230 Information security external reporting scheme

(a) The organisation shall implement an information security reporting system that complies with the requirements laid down in Regulation (EU) No 376/2014 and its delegated and implementing acts if that Regulation is applicable to the organisation.

- (b) Without prejudice to the obligations of Regulation (EU) No 376/2014, the organisation shall ensure that any information security incident or vulnerability, which may represent a significant risk to aviation safety, is reported to their competent authority. Furthermore:
 - (1) where such an incident or vulnerability affects an aircraft or associated system or component, the organisation shall also report it to the design approval holder;
 - (2) where such an incident or vulnerability affects a system or constituent used by the organisation, the organisation shall report it to the organisation responsible for the design of the system or constituent.
- (c) The organisation shall report the conditions referred to in point (b) as follows:
 - a notification shall be submitted to the competent authority and, if applicable, to the design approval holder or to the organisation responsible for the design of the system or constituent, as soon as the condition has been known to the organisation;
 - (2) a report shall be submitted to the competent authority and, if applicable, to the design approval holder or to the organisation responsible for the design of the system or constituent, as soon as possible, but not exceeding 72 hours from the time the condition has been known to the organisation, unless exceptional circumstances prevent this.

The report shall be made in the form defined by the competent authority and shall contain all relevant information about the condition known to the organisation;

(3) a follow-up report shall be submitted to the competent authority and, if applicable, to the design approval holder or to the organisation responsible for the design of the system or constituent, providing details of the actions the organisation has taken or intends to take to recover from the incident and the actions it intends to take to prevent similar information security incidents in the future.

The follow-up report shall be submitted as soon as those actions have been identified, and shall be produced in the form defined by the competent authority.

IS.D.OR.235 Contracting of information security management activities

- (a) The organisation shall ensure that when contracting any part of the activities referred to in point IS.D.OR.200 to other organisations, the contracted activities comply with the requirements of this Regulation and the contracted organisation works under its oversight. The organisation shall ensure that the risks associated with the contracted activities are appropriately managed.
- (b) The organisation shall ensure that the competent authority can have access upon request to the contracted organisation to determine continued compliance with the applicable requirements laid down in this Regulation.

IS.D.OR.240 Personnel requirements

- (a) The accountable manager of the organisation or, in the case of design organisations, the head of the design organisation, designated in accordance with Regulation (EU) No 748/2012 and Regulation (EU) No 139/2014 as referred to in points 1(a) and (b) of Article 2 of this Regulation, shall have corporate authority to ensure that all activities required by this Regulation can be financed and carried out. That person shall:
 - (1) ensure that all necessary resources are available to comply with the requirements of this Regulation;
 - (2) establish and promote the information security policy referred to in point IS.D.OR.200(a)(1);
 - (3) demonstrate a basic understanding of this Regulation.
- (b) The accountable manager or, in the case of design organisations, the head of the design organisation, shall appoint a person or group of persons to ensure that the organisation is in compliance with the requirements of this Regulation, and shall define the extent of their authority. That person or group of persons shall report directly to the accountable manager or, in the case of design organisations, to the head of the design organisation, and shall have the appropriate knowledge, background and experience to discharge their responsibilities. It shall be determined in the procedures who deputises for a particular person in the case of lengthy absence of that person.

- (c) The accountable manager or, in the case of design organisations, the head of the design organisation shall appoint a person or group of persons with the responsibility to manage the compliance monitoring function referred to in point IS.D.OR.200(a)(12).
- (d) Where the organisation shares information security organisational structures, policies, processes and procedures, with other organisations or with areas of their own organisation which are not part of the approval or declaration, the accountable manager or, in the case of design organisations, the head of the design organisation, may delegate its activities to a common responsible person.
 - In such a case, coordination measures shall be established between the accountable manager of the organisation or, in the case of design organisations, the head of the design organisation, and the common responsible person to ensure adequate integration of the information security management within the organisation.
- (e) The accountable manager or the head of the design organisation, or the common responsible person referred to in point (d), shall have corporate authority to establish and maintain the organisational structures, policies, processes and procedures necessary to implement point IS.D.OR.200.
- (f) The organisation shall have a process in place to ensure that they have sufficient personnel on duty to carry out the activities covered by this Annex.
- (g) The organisation shall have a process in place to ensure that the personnel referred to in point (f) have the necessary competence to perform their tasks.
- (h) The organisation shall have a process in place to ensure that personnel acknowledge the responsibilities associated with the assigned roles and tasks.
- (i) The organisation shall ensure that the identity and trustworthiness of the personnel who have access to information systems and data subject to the requirements of this Regulation are appropriately established.

IS.D.OR.245 Record-keeping

- (a) The organisation shall keep records of its information security management activities
 - (1) The organisation shall ensure that the following records are archived and traceable:
 - (i) any approval received and any associated information security risk assessment in accordance with point IS.D. OR.200(e);
 - (ii) contracts for activities referred to in point IS.D.OR.200(a)(9);
 - (iii) records of the key processes referred to in point IS.D.OR.200(d);
 - (iv) records of the risks identified in the risk assessment referred to in point IS.D.OR.205 along with the associated risk treatment measures referred to in point IS.D.OR.210;
 - (v) records of information security incidents and vulnerabilities reported in accordance with the reporting schemes referred to in points IS.D.OR.215 and IS.D.OR.230;
 - (vi) records of those information security events which may need to be reassessed to reveal undetected information security incidents or vulnerabilities.
 - (2) The records referred to in point (1)(i) shall be retained at least until 5 years after the approval has lost its validity.
 - (3) The records referred to in point (1)(ii) shall be retained at least until 5 years after the contract has been amended or terminated.
 - (4) The records referred to in point (1)(iii), (iv) and (v) shall be retained at least for a period of 5 years.
 - (5) The records referred to in point (1)(vi) shall be retained until those information security events have been reassessed in accordance with a periodicity defined in a procedure established by the organisation.

- (b) The organisation shall keep records of qualification and experience of its own staff involved in information security management activities
 - (1) The personnel's qualification and experience records be retained for as long as the person works for the organisation, and for at least 3 years after the person has left the organisation.
 - (2) Members of the staff shall, upon their request, be given access to their individual records. In addition, upon their request, the organisation shall provide them with a copy of their individual records on leaving the organisation.
- (c) The format of the records shall be specified in the organisation's procedures.
- (d) Records shall be stored in a manner that ensures protection from damage, alteration and theft, with information being identified, when required, according to its security classification level. The organisation shall ensure that the records are stored using means to ensure integrity, authenticity and authorised access.

IS.D.OR.250 Information security management manual (ISMM)

- (a) The organisation shall make available to the competent authority an information security management manual (ISMM) and, where applicable, any referenced associated manuals and procedures, containing:
 - (1) a statement signed by the accountable manager or, in the case of design organisations, by the head of the design organisation, confirming that the organisation will at all times work in accordance with this Annex and with the ISMM. If the accountable manager or, in the case of design organisations, the head of the design organisation, is not the chief executive officer (CEO) of the organisation, then such CEO shall countersign the statement;
 - (2) the title(s), name(s), duties, accountabilities, responsibilities and authorities of the person or persons referred to in point IS.D.OR.240(b) and (c);
 - (3) the title, name, duties, accountabilities, responsibilities and authorities of the common responsible person referred to in point IS.D.OR.240(d), if applicable;
 - (4) the information security policy of the organisation as referred to in point IS.D.OR.200(a)(1);
 - (5) a general description of the number and categories of staff and of the system in place to plan the availability of staff as required by point IS.D.OR.240;
 - (6) the title(s), name(s), duties, accountabilities, responsibilities and authorities of the key persons responsible for the implementation of point IS.D.OR.200, including the person or persons responsible for the compliance monitoring function referred to in point IS.D.OR.200(a)(12);
 - (7) an organisation chart showing the associated chains of accountability and responsibility for the persons referred to in points (2) and (6);
 - (8) the description of the internal reporting scheme referred to in point IS.D.OR.215;
 - (9) the procedures that specify how the organisation ensures compliance with this Part, and in particular:
 - (i) the documentation point IS.D.OR.200(c);
 - (ii) the procedures that define how the organisation controls any contracted activities referred to in point IS.D. OR.200(a)(9);
 - (iii) the ISMM amendment procedure defined in point (c);
 - (10) the details of currently approved alternative means of compliance.
- (b) The initial issue of the ISMM shall be approved and a copy shall be retained by the competent authority. The ISMM shall be amended as necessary to remain an up-to-date description of the ISMS of the organisation. A copy of any amendments to the ISMM shall be provided to the competent authority.
- (c) Amendments to the ISMM shall be managed in a procedure established by the organisation. Any amendments that are not included within the scope of this procedure and any amendments related to the changes referred to in point IS.D. OR.255(b), shall be approved by the competent authority.

(d) The organisation may integrate the ISMM with other management expositions or manuals it holds, provided there is a clear cross reference that indicates which portions of the management exposition or manual correspond to the different requirements contained in this Annex.

IS.D.OR.255 Changes to the information security management system

- (a) Changes to the ISMS may be managed and notified to the competent authority in a procedure developed by the organisation. This procedure shall be approved by the competent authority.
- (b) With regard to changes to the ISMS not covered by the procedure referred to in point (a), the organisation shall apply for and obtain an approval issued by the competent authority.

With regard to these changes:

- (1) the application shall be submitted before any such change takes place, in order to enable the competent authority to determine continued compliance with this Regulation and to amend, if necessary, the organisation certificate and related terms of approval attached to it;
- (2) the organisation shall make available to the competent authority any information it requests to evaluate the change;
- (3) the change shall be implemented only upon receipt of a formal approval by the competent authority;
- (4) the organisation shall operate under the conditions prescribed by the competent authority during the implementation of such changes.

IS.D.OR.260 Continuous improvement

- (a) The organisation shall assess, using adequate performance indicators, the effectiveness and maturity of the ISMS. That assessment shall be carried out on a calendar basis predefined by the organisation or following an information security incident.
- (b) If deficiencies are found following the assessment carried out in accordance with point (a), the organisation shall take the necessary improvement measures to ensure that the ISMS continues to comply with the applicable requirements and maintains the information security risks at an acceptable level. In addition, the organisation shall reassess those elements of the ISMS affected by the adopted measures.