EASA-FS.4/ATM/ANS-TeB/2-2019

Working paper WP06

09-10 December 2019

EASA Guidelines on the issue and use of EC declarations of conformity, suitability for use and verification of systems

Introduction

Regulation (EU) 2018/1139 repealed Regulation (EC) No 552/2004, i.e. the interoperability Regulation. However, in accordance with Article 139(2), Articles 4, 5, 6, 6a and 7, as well Annexes III and IV in the interoperability Regulation remain applicable for a limited time. These Articles address the establishment of Community specifications, and the verification of compliance with the essential requirements and the relevant implementing rules for interoperability[1], including the implementation of safeguarding measures against non-compliance. On their part, Annexes III and IV detail the nature and content of the EC declarations, as well as the accompanying documentation, e.g. the technical file.

In accordance with Article 139(4), any reference made to the interoperability Regulation is a reference to equivalent provisions of the EASA Basic Regulation; in particular, this also applies to

a) references to the essential requirements previously included in Annex II to Regulation (EC) No 552/2004, which should be interpreted as a reference to Annex VIII, and where applicable Annex VII, to the Basic Regulation
b) and the systems and constituents that are expected to meet such essential requirements, which were previously contained in Annex I to Regulation (EC) No 552/2004, and are now described in Point 3.1 of Annex VIII to the Basic Regulation.

A traceability between the essential requirements of the interoperability Regulation and the EASA Basic Regulation is provided in Annex. It should be noted that the revised essential requirements remain similar in terms of nature and granularity. Hence, it is recommended that, for the sake of simplicity, EC declarations not be issued retroactively, i.e. EATMN systems and constituents implemented before the interoperability Regulation was repealed are considered suitable for use.

General Guidelines for Conformity Assessment

No later than 12 September 2023, the European Commission will publish detailed rules for conformity assessment. It should be noted that the transition arrangements defined in Article 139(2) ensure the applicability of the existing EC declaration mechanisms until a new conformity assessment framework is adopted.

Until the publication of new rules on conformity assessment, it should be noted that:

a) Article 5 of the interoperability Regulation remains applicable to manufacturers or its authorised representatives in respect of constituents. Therefore, the issuance of EC declarations of conformity (DoC) or suitability for use (DSU) remains mandatory.
b) Article 6 of the interoperability Regulation remains applicable to ANS providers, i.e. providers of ATS, CNS, AIS or MET in respect of ATM/ANS systems that form part of the EATMN.
c) Article 6a of the interoperability Regulation remains applicable, although the necessary implementing measures that would enable certification of ground systems and constituents have never been adopted[2]. This means that there are not established

[1] Implementing regulations adopted on the basis of Regulation (EC) No 552/2004.

[2] Regulation (EU) 2018/1139 contemplates the development of rules in support of certification processes, but this possibility will not be explored until EASA RMT.0161 commences in 2020/Q1.

procedures and guidance to apply for and grant certificates, which makes certification in accordance with Article 6a not feasible.

It is recommended that the conformity assessment procedures for ATM/ANS constituents be applied as follows:

a) EC declarations of conformity or suitability for use of EATMN constituents issued in accordance with interoperability Regulation before the Basic Regulation became applicable remain valid, i.e. they do not need to be re-issued, as long as those constituents are not upgraded.
b) Since the date of applicability of the Basic Regulation, whenever a new ATM/ANS constituent is placed on the market or an existing ATM/ANS constituent is upgraded:
    i. a new or updated EC declaration of conformity or suitability for use should be issued;
    ii. the declaration should refer to the applicable essential requirements defined in Annex VIII of the EASA Basic Regulation (see Annex), and, if applicable, Annex VII;
    iii. the declaration should refer to the relevant rules for interoperability;
    iv. the declaration should contain the elements detailed in point 3 of Annex III to the interoperability Regulation;
    v. the declaration may be supported by accompanying documents.

It is equally recommended that the conformity assessment procedures for ANS providers are as follows:

a) EC declarations of verification of EATMN systems issued in accordance with the interoperability Regulation before the EASA Basic Regulation became applicable remain valid, i.e. they do not need to be re-issued, as long as those systems are not upgraded.
b) When a new ATM/ANS system is put into service or an existing ATM/ANS system is upgraded:
    i. a new or updated EC declaration of verification of systems should be issued;
    ii. the declaration should refer to the applicable essential requirements in Annex VIII to the EASA Basic Regulation (see Annex) and, if applicable, Annex VII;
    iii. the declaration should refer to the relevant rules for interoperability;
    iv. the declaration should contain the elements detailed in point 1 of Annex IV to the interoperability Regulation;
    v. the declaration should be accompanied by a technical file as detailed in point 3 of Annex IV to the interoperability Regulation;
    vi. the declaration is to be submitted to the competent authority, i.e. the national supervisory authority or EASA, as applicable.

Specific Guidelines for the Conformity Assessment of ATM/ANS Systems and Constituents not previously contemplated in Annex I to the interoperability Regulation

The previous section applies to EATMN systems and constituents that were subject to the interoperability Regulation, i.e. included in the list of Annex I to the interoperability Regulation. As the EASA Basic Regulation extends the referred to list in Point 3.1 of Annex VIII, specific consideration must be given to the systems and constituents that are (planned to be) in service and were not previously subject to the interoperability Regulation, in particular, systems and

constituents that support meteorological services, other than those related to the use of meteorological information. In this regard:

- Systems and constituents that support meteorological services, not subject to the interoperability Regulation, but put into service before the EASA Basic Regulation became applicable do not need to be accompanied by an EC declaration as long as they are not upgraded.
- An EC declaration should be issued for new or upgraded ATM/ANS systems and constituents that support meteorological services that are put into operation after the EASA Basic Regulation became applicable.

Again it is recommended that the issuance of EC declarations not be retroactively extended to ATM/ANS systems implemented before the interoperability Regulation was repealed, as such requirement was not applicable at that time.

ANNEX – Traceability of Essential Requirements

ERs in Annexes VIII and VII to the Basic Regulation	Equivalent ERs in Annex II to the interoperability Regulation	Comparison
Annex VIII **Essential requirements for ATM/ANS systems**	**ANNEX II** **Essential requirements**	
Note: only relevant requirements for ATM/ANS systems and constituents used in support of ATM/ANS services and functions have been taken into account		
2. SERVICES		
2.1. Aeronautical information and data for airspace users for the purpose of air navigation		
2.1.1. The data used as a source for aeronautical information shall be of sufficient quality, complete, current and provided in a timely manner.	Part B, Point 7 Part A, Point 1	Similar in nature and granularity
2.1.2. Aeronautical information shall be accurate, complete, current, unambiguous, from a legitimate source, and of adequate integrity, as well as in a format suitable for users.	Part B, Point 7 Part A, Point 1	Similar in nature and granularity
2.1.3. The dissemination of such aeronautical information to airspace users shall be timely and use sufficiently reliable and expeditious means of communication protected from intentional and unintentional interference and corruption.	Part B, Point 7 Part A, Point 1 Part A, Point 3 (last paragraph)	Similar in nature and granularity
2.2. Meteorological information		
2.2.1. The data used as a source for aeronautical meteorological information shall be of sufficient quality, complete and current.	Part B, Point 8 Part A, Point 1	The interoperability Regulation focuses on systems that are used to display MET info to end users, while the MET requirements in the Basic Regulation are applicable to any MET system used. They are drafted in the same way as the requirements for aeronautical data and info, thus encompassing the entire MET data/info lifecycle (from origination to end use). This is consistent with the fact that the MET-related requirements now apply to any MET systems used in support of the service provision.

2.2.2. To the extent possible, aeronautical meteorological information shall be precise, complete, current, of adequate integrity and unambiguous in order to meet the needs of airspace users. Aeronautical meteorological information shall be from a legitimate source.	Part B, Point 8 Part A, Point 1	See comment in 2.2.1
2.2.3. The dissemination of such aeronautical meteorological information to airspace users shall be timely and use sufficiently reliable and expeditious means of communication protected from interference and corruption.	Part B, Point 8 Part A, Point 1 Part A, Point 3 (last paragraph)	See comment in 2.2.1
2.3. Air traffic services		
2.3.1. The data used as a source for the provision of air traffic services shall be correct, complete and current.	Part B, Point 3 Part A, Point 1	ERs are similar in nature and with regard to the global objectives. ATS ERs in the Basic Regulation clearly consider the use of technology and automation, which is explicitly or implicitly reflected in this Point. ERs in Part B of Annex II contemplate the division of requirements per FDPS, SDP and HMI, while Part A provides general requirements to be taken into account.
2.3.2. The provision of air traffic services shall be sufficiently precise, complete, current, and unambiguous to meet the safety needs of users.	Part B, Point 3 Part A, Point 3 (first 4 paragraphs)	See comment in 2.3.1
2.3.3. Automated tools providing information or advice to users shall be properly designed, produced and maintained to ensure that they are fit for their intended purpose.	Part B, Point 3 Part A, Point 3 (second and fourth paragraph)	See comment in 2.3.1
2.3.4. Air traffic control services and related processes shall provide for adequate separation between aircraft and, on the aerodrome manoeuvring area, prevent collisions between aircraft and obstructions and, where appropriate, assist in protection from other airborne hazards and shall ensure prompt and timely coordination with all relevant users and adjacent volumes of airspace.	Part B, Point 3 Part A, Point 2 Part A, Point 3 (first 4 paragraphs)	See comment in 2.3.1
2.3.5. Communication between air traffic services and aircraft and between relevant air traffic services units shall be timely, clear, correct and unambiguous, protected from interference and commonly understood and, if applicable, acknowledged by all actors involved.	Part B, Point 3 Part A, Point 1 Part A, Point 3 (last paragraph) Part A, Point 4 (second paragraph)	See comment in 2.3.1
2.3.6. Means shall be in place to detect possible emergencies and, when appropriate, to initiate effective search and rescue action. Such means shall, as a minimum, comprise appropriate alerting mechanisms, coordination measures and procedures, means and personnel to cover the area of responsibility efficiently.	-	Not explicitly addressed, although with little relevance from system point of view.

2.4. Communication services Communication services shall achieve and maintain sufficient performance with regard to their availability, integrity, continuity and timeliness. They shall be expeditious and protected from corruption and interference.	Part B, Point 4 Part A, Point 3 (last paragraph)	Similar in nature and granularity
2.5. Navigation services Navigation services shall achieve and maintain a sufficient level of performance with regard to guidance, positioning and, when provided, timing information. The performance criteria include accuracy, integrity, legitimacy of the source, availability, and continuity of the service.	Part B, Point 5	Similar in nature and granularity
2.6. Surveillance services Surveillance services shall determine the respective position of aircraft in the air and of other aircraft and ground vehicles on the aerodrome surface, with sufficient performance with regard to their accuracy, integrity, legitimacy of the source, continuity and probability of detection.	Part B, Point 5 Part A, Point 4 (second paragraph)	Similar in nature and granularity

2.7. Air traffic flow management The tactical management of air traffic flows at Union level shall use and provide sufficiently precise and current information of the volume and nature of the planned air traffic affecting service provision and shall coordinate and negotiate re-routing or delaying traffic flows in order to reduce the risk of overloading situations occurring in the air or at the aerodromes. Flow management shall be performed with a view to optimising available capacity in the use of airspace and enhancing air traffic flow management processes. It shall be based on safety, transparency and efficiency, ensuring that capacity is provided in a flexible and timely manner, consistent with the European Air Navigation Plan. The measures referred to in Article 43, concerning flow management shall support operational decisions by air navigation service providers, aerodrome operators and airspace users and shall cover the following areas: (a) flight planning; (b) use of available airspace capacity during all phases of flight, including en-route slot assignment; (c) use of routings by general air traffic, including: — the creation of a single publication for route and traffic orientation, — options for diversion of general air traffic from congested areas, and — priority rules regarding access to airspace for general air traffic, particularly during periods of congestion and crisis; and (d) the consistency between flight plans and airport slots and the necessary coordination with adjacent regions, as appropriate.	Part B, Point 2 Part A, Point 4	In this case, the ERs in the Basic Regulation provide more guidance on what is expected to be achieved. More details are provided with regard to the importance of an adequate data sharing, the actors involved, and the relevant considerations; thus resulting in a more explicit requirement, though perfectly compatible with the corresponding requirements in Annex II to the interoperability Regulation.
2.8. Airspace management The designation of specific volumes of airspace for a certain use shall be monitored, coordinated and promulgated in a timely manner in order to reduce the risk of loss of separation between aircraft in all circumstances. Taking into account the organisation of military activities and related aspects under the responsibility of the Member States, airspace management shall also support the uniform application of the concept of the flexible use of airspace as described by the ICAO and as implemented under Regulation (EC) No 551/2004, in order to facilitate airspace management and air traffic management in the context of the common transport policy.	Part B, Point 1 Part A, Point 4	Similar in nature and granularity

2.9. Flight procedure design Flight procedures shall be properly designed, surveyed and validated before they can be deployed and used by aircraft.	-	Not explicitly covered. Specific software and tools can be used for flight procedure design purposes, although these are not expressly included in the list of systems included in Point 3.1 of Annex VIII, nor were they included in Annex I to the interoperability Regulation.
3. SYSTEMS AND CONSTITUENTS		
3.1. General ATM/ANS systems and ATM/ANS constituents providing related information to and from the aircraft and on the ground shall be properly designed, produced, installed, maintained, protected against unauthorised interference and operated to ensure that they are fit for their intended purpose. The systems and procedures shall include in particular those required to support the following functions and services: (a) Airspace management; (b) Air traffic flow management; (c) Air traffic services, in particular flight data processing systems, surveillance data processing systems and human-machine interface systems; (d) Communications including ground-to-ground/space, air-to-ground and air-to-air/space communications; (e) Navigation; (f) Surveillance; (g) Aeronautical information services; and (h) Meteorological services.	Annex II, globally.	Very high level requirement that could be met by meeting the relevant requirements in Annex II. As regards the affected systems, it should be noted that the list of systems that should meet the Basic Regulation ERs is not exhaustive. The systems expressly mentioned are the same to those included in Annex I to the interoperability Regulation, except that the Basic Regulation broadly considers any systems in support of MET, as well as space-based COM services.

3.2. System and constituent integrity, performance and reliability The integrity and safety-related performance of systems and constituents whether on aircraft, on the ground or in space, shall be fit for their intended purpose. They shall meet the required level of operational performance for all their foreseeable operating conditions and for their whole operational life. ATM/ANS systems and ATM/ANS constituents shall be designed, built, maintained and operated using the appropriate and validated procedures, in such a way as to ensure the seamless operation of the European air traffic management network (EATMN) at all times and for all phases of flight. Seamless operation can be expressed, in particular, in terms of information-sharing, including the relevant operational status information, common understanding of information, comparable processing performances and the associated procedures enabling common operational performances agreed for the whole or parts of the EATMN. The EATMN, its systems and their constituents shall support, on a coordinated basis, new agreed and validated concepts of operation that improve the quality, sustainability and effectiveness of air navigation services, in particular in terms of safety and capacity. The EATMN, its systems and their constituents shall support the progressive implementation of civil/military coordination, to the extent necessary for effective airspace and air traffic flow management, and the safe and efficient use of airspace by all users, through the application of the concept of the flexible use of airspace. To achieve those objectives, the EATMN, its systems and their constituents shall support the timely sharing of correct and consistent information covering all phases of flight, between civil and military parties, without prejudice to security or defence policy interests, including requirements on confidentiality.	Part A, Point 1 Part A, Point 2 Part A, Point 3, paragraphs 2, 3, 4 Part A, Point 4 Part B, globally	Except for the first paragraph of 3.2, which is a very generic requirement, these Basic Regulation essential requirements are almost a literal copy of the requirements in Annex II. The first paragraph is a very generic requirement that seeks to ensure system suitability for use, therefore, it is met by conforming to the specific requirements for the different EATMN systems in Part B.
3.3. Design of systems and constituents		

3.3.1. Systems and constituents shall be designed to meet applicable safety and security requirements.	Part A, Point 3, especially paragraph 3 Part A, Point 4 Part B, Point 1	Only national security requirements are considered in the interoperability Regulation when taking about civil-military coordination and airspace management. In this regard, this does not represent an issue, since there are no common EU security requirements for ground systems and constituents for the time being.
3.3.2. Systems and constituents, considered collectively, separately and in relation to each other, shall be designed in such a way that an inverse relationship exists between the probability that any failure can result in a total system failure and the severity of its effect on the safety of services.	Part A, Point 3, especially paragraph 3	The equivalent requirements in the interoperability Regulation are not that explicit, but it is assumed that the noted 'inverse relationship' is widely applied as best practice.
3.3.3. Systems and constituents, considered individually and in combination with each other, shall be designed taking into account limitations related to human capabilities and performance.	Part A, Point 3, paragraph 4 Part B, Point 3.3	Similar in nature and granularity
3.3.4. Systems and constituents shall be designed in a manner that protects them and the data they convey from harmful interactions with internal and external elements.	Part A, Point 3, last paragraph Part A, Point 5	
3.3.5. Information needed for production, installation, operation and maintenance of the systems and constituents as well as information concerning unsafe conditions shall be provided to personnel in a clear, consistent and unambiguous manner.	-	Not explicitly addressed in Annex II to the interoperability Regulation. However, it should be noted that this information requirement is implicitly addressed during the verification of compliance activities described in Annexes III and IV to said Regulation, so it has no impact during the transitional period.
3.4. Continuing level of service Safety levels of systems and constituents shall be maintained during service and any modifications to service.	Part A, Point 3, especially the first 3 paragraphs	The validity of the requirements in Annex during the system lifecycle is somehow implicit.
ANNEX VII **Essential requirements for aerodromes**		

1. PHYSICAL CHARACTERISTICS, INFRASTRUCTURE AND EQUIPMENT		
1.3. Safety-related aerodrome equipment, including visual and non-visual aids		
1.3.1. Aids shall be fit for purpose, recognisable and provide unambiguous information to users under all intended operational conditions.	Part B, Point 4 Part B, Point 5 Part B, Point 6 Part B, Point 7 Part B, Point 8	Very generic requirement that could be satisfied by meeting the relevant requirements for relevant systems used in support of ATM/ANS
1.3.2. Safety-related aerodrome equipment shall function as intended under the foreseen operating conditions. Under operating conditions or in case of failure, safety-related aerodrome equipment shall not cause an unacceptable risk to aviation safety.	Part A, Point 3, except paragraph 4	
1.3.3. The aids and their electrical power supply system shall be so designed that failures do not result in inappropriate, misleading or insufficient information being given to users or in interruption of an essential service.	Part B, Point 4 Part B, Point 5 Part B, Point 6 Part A, Point 3, paragraph 3	Issues related to power supply can be considered to be addressed by means of specific safety requirements that deal with degraded modes of operation. Requirement also addressed indirectly by the performance requirements stipulated in relevant Part B requirements.
1.3.4. Suitable means of protection shall be provided to avoid damage or disturbance to such aids.	Part A, Point 3, last paragraph Part B, Point 4 Part B, Point 5 Part B, Point 6 Part B, Point 8	Protection measures are not explicitly addressed in the ERs of the interoperability Regulation, although the different requirements to deliver the necessary performance at all times should indirectly deal with these kind of measures.
1.3.5. Sources of radiation or the presence of moving or fixed objects shall not interfere with or adversely affect the performance of aeronautical communications, navigation and surveillance systems.	Part A, Point 3, last paragraph Part B, Point 4 Part B, Point 5 Part B, Point 6	The different requirements to deliver the necessary performance that the interoperability Regulation prescribes should indirectly address the issues highlighted in the requirement.
1.3.6. Information on operation and use of safety-related aerodrome equipment shall be made available to relevant staff, including clear indications of the conditions which may create unacceptable risks to aviation safety.	-	Not explicitly addressed in Annex II to the interoperability Regulation. However, it should be noted that this information requirement is implicitly addressed during the verification of compliance activities described in Annexes III and IV to said Regulation, so it has no impact during the transitional period.