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## **CONFORMITY ASSESSMENT OF THE**

### **EUROPEAN AIR TRAFFIC MANAGEMENT NETWORK (EATMN)**

#### **1. OBJECTIVE**

The objective of this document is to present in a comprehensive way the conformity assessment provisions of Regulation (EC) N° 552/2005 and some clarifications concerning their application from 20 October 2005.

#### **2. BACKGROUND**

Article 10(1) lays down that “*Starting from 20 October 2005, the essential requirements shall apply to the putting into service of systems and constituents of the EATMN...*”.

Article 6(2) lays down that “*Before a system is put into service, the relevant air navigation service provider shall establish an EC declaration of verification, conforming compliance, and shall submit it to the national supervisory authority...*”.

Since in accordance with Article 3(3)d), the specific conformity assessment procedures shall be described in the interoperability implementing rules (IOP IR), the Commission considers that a general implementing rule on conformity assessment should allow to define more detailed conformity assessment procedures for all the systems that are not under the scope of a specific IOP IR.

The conformity assessments aspects are discussed in the on-going Conformity Assessment Task Force (CATF). The CATF is managed by Eurocontrol (Regulatory Unit – RU and Safety Regulatory Unit – SRU), with the participation of Air Navigation Service Providers (ANSP), National Authorities (NSA) and the European Commission.

The CATF will draw the first general conclusions before the end of 2005 (next meeting foreseen on 29 September 2005). These conclusions seem to be not yet mature enough as to form the basis of an implementing rule but may be considered as guidelines that may be useful for ANSP and NSA.

### 3. CONSTITUENTS AND SYSTEMS

Constituents and systems are the key elements of the EATMN.

A constituent means tangible objects such as hardware and intangible objects such as software upon which the interoperability of the EATMN depends.

Since the definition of constituent is related with the interoperability of the EATMN, it is useful to recall that interoperability means a set of functional, technical and operational properties required of the systems and constituents of the EATMN (...), in order to enable its safe, seamless and efficient operation (...).

A system means the aggregation of airborne and ground-based constituents, as well as space-based equipment that provides support for air navigation services for all phases of flight.

A system is an assembly of constituents. The identification of EATMN systems given in Annex I of the interoperability Regulation has to be considered as an identification of all different types or groups of systems and not always as an identification of the individual systems that will require a specific conformity assessment procedure.

Article 3(3)c) lays down that implementing rules for interoperability shall “*determine the constituents when dealing with systems*”. In the 2 first draft IOp IR concerning systems, Co-ordination and Transfer (COTR) and the Flight Message Transfer Protocol (FMTP) that will be presented to the Single Sky Committee (SSC) of 22 September 2005, no constituents have been identified in the IOP IR. Considering the difficulty of such identification, it may happen for further IOp IR. The situation may be different if the essential requirements on “*the logical architecture of systems*” and “*the construction of systems*” will be complemented or refined by IOp IR and/or by Community specifications (CS).

### 4. PUTTING INTO SERVICE

The requirement to do a conformity assessment of a system from 20 October 2005 and in accordance with the interoperability Regulation is related with the concept of “*putting into service*”.

Putting into service of a system means the first operational use after the initial installation or an upgrade of a system.

The concept of upgrade of a system is not defined but we may reasonably consider that an upgrade is a significant increase of the performance or the capabilities of a system due to important modifications or new features. A periodic update of a system without significant changes should not be considered as an upgrade of a system. On this subject it is useful to recall that compliance with the essential requirements shall be required for all systems of the EATMN currently in operation by 20 April 2011, if not otherwise specified in the relevant IOp IR.

## **5. NOTIFIED BODY**

A notified body is an organisation that fulfils the requirements of Annex V and that is notified by a Member State to the Commission, indicating the area of responsibility for the conformity assessment of constituents and systems.

In accordance with Article 3(3)d), the obligation to use a notified body for the conformity assessment of constituents and systems shall be laid down in an IOP IR.

Organisations recognised in conformity with Article 3 of the service provision Regulation may be appointed as notified bodies by a Member State.

## **6. EC DECLARATION OF VERIFICATION OF SYSTEMS**

Before a system is put into service and in order to confirm compliance with the requirements of the interoperability Regulation, the relevant ANSP shall establish an “*EC declaration of verification of systems*”.

The elements of this declaration and of the technical file that shall be submitted to the NSA, are set out in Annex IV. The NSA may require any additional information to supervise such compliance.

Where a notified body is involved in the verification of a system, he has to draw up a “*certificate of conformity*” in relation to the tasks it carried out.

A notified body is involved if it is required by the relevant IOP IR or if a ANSP decides to delegate part of the verification tasks. In both cases, the ANSP chooses the notified body amongst the bodies notified by any Member State.

Finally, it is useful to recall, that in accordance with Article 6(4), the EC declaration of verification shall be without prejudice to any assessments that the NSA may need to carry out on grounds other than interoperability.

## **7. EC DECLARATION OF CONFORMITY OR SUITABILITY FOR USE OF CONSTITUENTS**

Constituents shall be accompanied by an EC declaration of conformity or suitability for use issued by the manufacturer in conformity and with the elements set out in Annex III.

For the time being no constituents has been identified in the Regulation or in the 2 first draft IOP IR.

At the same time a constituent is always part of a system.

In this situation we may consider:

- If a constituent is identified in the legislation through an IOP IR, the manufacturer shall issue an EC declaration of conformity or suitability for use of the constituent.
- If a manufacturer wants to put on the market a product which he pretends is covering certain requirements included in the interoperability Regulation or in an IOP IR, or that is in conformity with a CS, then he shall prepare an EC declaration of conformity or suitability for use to substantiate his argument.

- If an ANSP has identified a constituent as part of system and that constituent may be concerned by certain requirements included in the interoperability Regulation or in an IOp IR, then he may request an EC declaration of conformity or suitability for use to the manufacturer.

In the case of an airborne constituent that is concerned by an IOp IR, the manufacturer shall also issue an EC declaration of conformity or suitability for use.

## **8. COMPLEMENTARY ASPECT OF INTEROPERABILITY**

“Whereas 14” foresees that the interoperability Regulation should not affect the obligation on manufacturers to affix the CE mark to certain constituents in order to certify their compliance with other Community legislation relating to them.

This whereas confirms the complementary aspect of the interoperability Regulation in relation with other relevant Community legislation.

If we take the example of ground aeronautical radio equipment, they will be under the scope of Directive 1999/5/EC (R&TTE – Radio and Telecommunication Terminal Equipment Directive) from 20 October 2005 and the interoperability Regulation may be only the basis for complementary provisions.

More precisely, the R&TTE Directive sets essential requirements for health & safety, electromagnetic compatibility and radio spectrum usage. Radio spectrum matters are addressed only to the extent necessary to avoid harmful interference. This directive does not generally deal with functional safety, functionality, fitness for purpose or interoperability.

In practice a ground aeronautical radio equipment has to be certified in conformity with the R&TTE Directive. General information can be found under:

[http://europa.eu.int/comm/enterprise/rtte/index\\_en.htm](http://europa.eu.int/comm/enterprise/rtte/index_en.htm)

Concerning the certification in accordance with the complementary requirements, particularly the essential requirements of the interoperability Regulation, the relevant certificates, previously mentioned, have to be issued. If there is a lack of applicable detailed requirements (Implementing rules) or means of compliance (Community specifications), the technical requirements actually used for certification and that are related with the essential requirements of the interoperability Regulation may continue to be used.

## **9. CONFORMITY ASSESSMENT PROCEDURES**

In the 2 first draft IOp IR concerning systems, COTR and FMTP, provisions on conformity assessment are included.

For example in the IOp on COTR these procedures are in Articles 7 and 8

“Article 7

***Conformity or suitability for use of constituents***

*Before issuing an EC declaration of conformity or suitability for use, manufacturers of constituents of the systems (...) shall assess the conformity or suitability for use of these constituents in compliance with the requirements set out in Annex IV, Part A.*

## *Article 8*

### ***Verification of systems***

*1. Air navigation service providers, which can demonstrate that they fulfil the conditions set out in Annex V, shall conduct a verification of the systems (...) in compliance with the requirements set out in Annex IV, Part B.*

*2. Air navigation service providers, which cannot demonstrate that they fulfil the conditions set out in Annex V, shall subcontract to a notified body a verification of the systems (...). This verification shall be conducted in compliance with the requirements set out in Annex IV, Part C.”*

In the absence of an IOp IR concerning conformity assessment these procedures may also be used for other systems.

The procedures for the conformity or suitability for use of constituents are laid down in Annex IV, Part A of the draft IOp IR.

For the verification of systems, two procedures are foreseen.

If the ANSP has the relevant technical competence and can demonstrate impartiality and independence of judgement in relation to the verification activities, the participation of a notified body is not required. In this case, the verification shall be conducted in compliance with the requirements set out in Annex IV, Part B of the draft IOp IR.

If the ANSP does not fulfil these requirements, the ANSP shall subcontract to a notified body the verification of the system. In this case, the verification shall be conducted in compliance with the requirements set out in Annex IV, Part C of the draft IOp IR.

For information we include Annexes IV and V of the draft IOp IR on COTR.

## **“ANNEX IV**

### ***PART A: REQUIREMENTS FOR THE ASSESSMENT OF THE CONFORMITY OR SUITABILITY FOR USE OF CONSTITUENTS REFERRED TO IN ARTICLE 7***

- 1. The verification activities shall demonstrate the conformity of constituents with the interoperability and performance, quality of service and safety requirements of this Regulation or their suitability for use whilst these constituents are in operation in the test environment.*
- 2. The manufacturer shall manage the conformity assessment activities and shall in particular:*
  - determine the appropriate test environment;*
  - verify that the test plan describes the constituents in the test environment;*
  - verify that the test plan provides full coverage of applicable requirements;*

- *ensure the consistency and quality of the technical documentation and the test plan;*
  - *plan the test organisation, staff, installation and configuration of test platform;*
  - *perform the inspections and tests as specified in the test plan;*
  - *write the report presenting the results of inspections and tests.*
3. *The manufacturer shall ensure that the constituents (...), integrated in the test environment meet the interoperability and performance, quality of service and safety requirements of this Regulation.*
4. *Upon satisfying completion of verification of conformity or suitability for use, the manufacturer shall under its responsibility draw up the EC declaration of conformity or suitability for use, specifying notably the requirements of this Regulation met by the constituent and its associated conditions of use in accordance with Annex III (3) of the interoperability Regulation.*

**PART B: REQUIREMENTS FOR THE VERIFICATION OF SYSTEMS REFERRED TO  
IN ARTICLE 8(1)**

1. *The verification of systems shall demonstrate the conformity of these systems with the interoperability and performance, quality of service and safety requirements of this Regulation in a simulated environment that reflects the operational context of these systems.*
2. *The verification of systems (...) shall be conducted in accordance with appropriate and recognised testing practices.*
3. *Test tools used for the verification of systems (...) shall have appropriate functionalities.*
4. *The verification of systems (...) shall produce the elements of the technical file required by Annex IV (3) of the interoperability Regulation and the following elements:*
  - *description of the implementation;*
  - *the report of inspections and tests achieved before putting the system into service.*
5. *The air navigation service provider shall manage the verification activities and shall in particular:*
  - *determine the appropriate simulated operational and technical environment reflecting the operational environment;*
  - *verify that the test plan describes the integration (...) in the system tested in a simulated operational and technical environment;*
  - *verify that the test plan provides full coverage of the interoperability and performance, quality of service and safety requirements of this Regulation;*
  - *ensure the consistency and quality of the technical documentation and the test plan;*
  - *plan the test organisation, staff, installation and configuration of the test platform;*
  - *perform the inspections and tests as specified in the test plan;*
  - *write the report presenting the results of inspections and tests.*
6. *The air navigation service provider shall ensure that the implementation (...), integrated in systems operated in a simulated operational environment meets the interoperability and performance, quality of service and safety requirements of this Regulation.*
7. *Upon satisfying completion of verification of compliance, air navigation service providers shall draw up the EC declaration of verification of system and submit it to the national supervisory authority together with the technical file as requested by Article 6 of the interoperability Regulation.*

**PART C: REQUIREMENTS FOR THE VERIFICATION OF SYSTEMS REFERRED TO  
IN ARTICLE 8(2)**

1. *The verification of systems shall demonstrate the conformity of these systems with the interoperability and performance, quality of service and safety requirements of this Regulation in a simulated environment that reflects the operational context of these systems.*
2. *The verification of system (...) shall be conducted in accordance with appropriate and recognised testing practices.*
3. *Test tools used for the verification of systems (...) shall have appropriate functionalities.*
4. *The verification of systems (...) shall produce the elements of the technical file required by Annex IV (3) of the interoperability Regulation and the following elements:*
  - *description of the implementation*
  - *the report of inspections and tests achieved before putting the system into service.*
5. *The air navigation service provider shall determine the appropriate simulated operational and technical environment reflecting the operational environment and shall have verification activities performed by a notified body.*
6. *The notified body shall manage the verification activities and shall in particular:*
  - *verify that the test plan describes the integration (...) in the system tested in a simulated operational and technical environment;*
  - *verify that the test plan provides full coverage of the interoperability and performance, quality of service and safety requirements of this Regulation;*
  - *ensure the consistency and quality of the technical documentation and the test plan;*
  - *plan the test organisation, staff, installation and configuration of the test platform;*
  - *perform the inspections and tests as specified in the test plan;*
  - *write the report presenting the results of inspections and tests.*
7. *The notified body shall ensure that the implementation (...), integrated in systems operated in a simulated operational environment meets the interoperability and performance, quality of service and safety requirements of this Regulation*
8. *Upon satisfying completion of verification tasks, the notified body shall draw up a certificate of conformity in relation to the tasks it carried out.*
9. *Then, the air navigation service provider shall draw up the EC declaration of verification of system and submit it to the national supervisory authority together with the technical file as requested by Article 6 of the interoperability Regulation.*

## ANNEX V

### **Conditions referred to in Article 8**

1. *The air navigation service provider must have in place reporting methods within the organization which ensure and demonstrate impartiality and independence of judgement in relation to the verification activities.*
2. *The air navigation service provider must ensure that the personnel involved in verification processes, carry out the checks with the greatest possible professional integrity and the greatest possible technical competence and are free of any pressure and incentive, in particular of a financial type, which could affect their judgment or the results of their checks, in particular from persons or groups of persons affected by the results of the checks.*
3. *The air navigation service provider must ensure that the personnel involved in verification processes, have access to the equipment that enables them to properly perform the required checks.*
4. *The air navigation service provider must ensure that the personnel involved in verification processes, have sound technical and vocational training, satisfactory knowledge of the requirements of the verifications they have to carry out, adequate experience of such operations, and the ability required to draw up the declarations, records and reports to demonstrate that the verifications have been carried out.*
5. *The air navigation service provider must ensure that the personnel involved in verification processes, are able to perform their checks with impartiality. Their remuneration shall not depend on the number of checks carried out, or on the results of such checks.*