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EUROCONTROL Guidelines

EUROCONTROL Guidelines on conformity assessment for the interoperability Regulation of the single European sky

EUROCONTROL

EUROPEAN ORGANISATION
FOR THE SAFETY OF AIR NAVIGATION

EUROCONTROL Guidelines on conformity assessment for the interoperability Regulation of the single European sky

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Abstract			
This document provides guidance relating to Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation) as amended by Regulation (EC) No 1070/2009. Specifically, it provides guidance on the conformity assessment of EATMN constituents and systems.			
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Contact Person (s):		**Tel**	**Unit**
Eivan Cerasi		+32 2 729 3791	DSS/REG/SES

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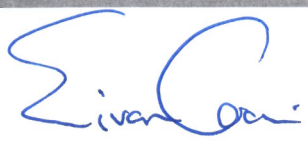
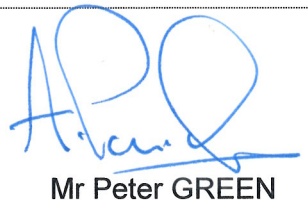
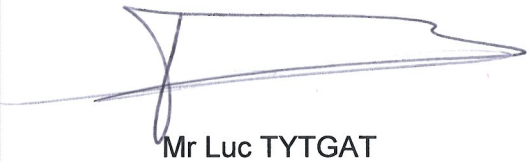
AUTHORITY		NAME AND SIGNATURE	DATE
DSS/REG/SES	Editor	 Mr Eivan CERASI	16/02/2012
Head of SES Unit		 Mr Peter GREEN	17/02/2012
Head of Regulatory Support Division		 Mr. Ian MIDDLETON	17 Feb 12
Director Single European Sky		 Mr Luc TYTGAT	17/02/2012
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DOCUMENT CHANGE RECORD

The following table records the complete history of the successive editions of the present document.

EDITION NUMBER	EDITION DATE	REASON FOR CHANGE	PAGES AFFECTED
1.0	18/05/2010	First Edition	-
2.0	02/03/2011	Second Edition - Changes on subjects of MET information and standby/fallback/contingency (sections 2.2.3, Table 1, 2.5.2, 2.5.5, 2.5.6) - Update to Annex E - Addition of new Annex F 'Verification of compliance' based on 'initial guidelines' (sections 1.2, 6.1, 6.3.1 and Annex F) - Update of 'alternative verification of compliance' - Enhanced 'presumption of conformity' (sections 2.1.2 and 2.2.2) - Enhanced role of notified bodies (Section 2.3.2.4) - Replace 'Community market' by 'EU market' - Figure 3	 12,13,19,20 54-55 9,32,34,57 17 11 17 10-18,32 15
3.0	20/02/2012	Third Edition - Document template update - Update the regulatory references for 'common requirements' and 'safety oversight' - Clarification on the use of contingency systems provided by military organisations - Clarify required DoVs (align with CATF FAQ) - Inclusion of 'EASA material' as MoC - Insertion of two footnotes in section 8.1 - Remove the notion of EATMN object in Section 3.2 (affects Section 1.2, Annex C.8 & Annex D) - Update the guidelines to reflect DLS & A-SMGCS constituents defined in Community specifications - Weblink for compliance template in Annex C - Editorial improvements to Annex D.3 and D.4	 1-7 14, 35, 45, 47 20 25 29 39 10, 23, 24, 47-54 24, 48, 54 47, 59 50, 52

Publications
EUROCONTROL Headquarters
96 Rue de la Fusée
B-1130 BRUSSELS

Tel: +32 (0)2 729 4715
Fax: +32 (0)2 729 5149
E-mail: publications@eurocontrol.int

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1 INTRODUCTION

1.1. Objective of this document

The objective of this document is to guide air navigation service providers (ANSPs) and manufacturers on the demonstration of their compliance with the single European sky interoperability Regulation [1] (as amended by [2]). It provides guidance on the need for and how to achieve conformity assessment (CA) of systems and constituents of the European air traffic management network (EATMN) as required by Article 5 and Article 6 of the interoperability Regulation.

Although these guidelines are not intended to support national supervisory authorities (NSA) in their oversight tasks, it may provide them with useful information on the understanding of conformity assessment of the interoperability Regulation.

The guidelines have been developed by the EUROCONTROL Conformity Assessment Task Force (CATF).

1.2. How to use this document

This document is split into 8 sections, supported by 7 annexes. Acronyms are listed in Annex A and numbers within square brackets are used to identify reference documents listed in Annex B e.g. [1] identifies the first reference document of Annex B.

Section 2 provides an introduction to the legislative requirements for conformity assessment describing the key requirements, roles and responsibilities and special cases. It includes why conformity assessment, is necessary and how, at a high level, it applies to systems within the European air traffic management network. All readers are advised to read Section 2 and refer to the document map below (Figure 1) to identify the relevance of the remaining sections of these guidelines.

Figure 1: Document Map

Sections 3 to 8 provide the core guidance material for conformity assessment. Figure 1 provides an overview of these sections by illustrating a sequential conformity assessment process in line with the principles described in Section 2.

In general terms, conformity assessment is a demonstration of compliance with the essential requirements (ERs) and relevant implementing rules (IRs) for interoperability. In order to do so, an air navigation service provider must establish a representation of how their real world systems map to the EATMN systems defined in the interoperability Regulation.

Section 3 provides guidance on how to create this EATMN representation. This representation facilitates a common understanding between the national supervisory authority (NSA) and the air navigation service provider upon the systems that are being assessed. Section 3 is also applicable to manufacturers of ATM products as they may also use the EATMN representation as a method to identify the scope of their conformity assessment tasks.

For each identified system that is being put into service, the air navigation service provider will need to identify the applicable regulations (regulatory baseline) and relevant means of compliance (MoC baseline) which establishes the baseline for conformity assessment. Equally, the manufacturer will also need to establish the baseline for the conformity assessment of constituents. Guidance on establishing this baseline is provided in Section 4.

The manufacturer is responsible for verifying a constituent's compliance with the established baseline for conformity assessment. This leads to the completion of an EC declaration of conformity (DoC) or an EC declaration of suitability for use (DSU) through self-assessment, a notified body or both. Section 5 describes the role of the manufacturer in completing the DoC/DSU.

The air navigation service provider is responsible for verifying compliance of each instance of a system being put into service with the established baseline for conformity assessment. This leads to the completion of a technical file (collating relevant technical information) and an EC declaration of verification (DoV) for inspection by the national supervisory authority. Guidance is provided in Sections 6 and 7.

The air navigation service provider remains responsible for maintaining the system verification when systems are upgraded or the regulatory baseline changes. Section 8 provides guidance on how to evaluate system changes to determine whether the DoV should be updated. Section 8 also addresses the maintenance of the DoC and DSU by manufacturers.

The Annexes of these guidelines provide access to detailed resources designed to support air navigation service providers and manufacturers in fulfilling their obligations, in particular:

- Annex C provides links to web based resources, including:
  - SES legislation;
  - Latest status of IR and CS;
  - Templates for DoC, DSU and DoV;
  - An example list of constituents and related standards for the CNS domains;
  - A FAQ (Frequently Asked Questions).
- Annex D provides examples of EATMN representation and identifies typical EATMN systems and constituents.
- Annex E provides material on the common interpretation of the essential requirements.
- Annex F provides guidance for manufacturers and ANSPs on the verification of compliance tasks required for the preparation of EC declarations, extending Sections 5.5.3 and 6.3.1 of these guidelines.
- Annex G provides guidance to determine if a system's operational characteristics have changed i.e. if the system has been upgraded.

1.3. Document maintenance

This document will be maintained by EUROCONTROL. Occasional updates will be provided when a significant change is required.

Additional clarifications will be included in the conformity assessment FAQ which is available on the EUROCONTROL website http://www.eurocontrol.int/conformity.

2 CONFORMITY ASSESSMENT PRINCIPLES

2.1. Purpose

This section provides a brief introduction to conformity assessment principles for products being placed on the EU market as a whole (in Section 2.1.1) and goes on to consider the specific extension of these principles to the air traffic management sector in the remainder of the section.

2.1.1 The New Legislative Framework for the marketing of products

In order to facilitate the free movement of goods within the European market technical harmonisation, standards and mutual recognition procedures were deemed necessary.

The New Approach adopted by the Council in 1985 [3], established the following principles for directives applicable to products to be placed on the Community market (now termed EU market):

- Directives - contrary to earlier practice - should no longer contain all technical details but be limited to **essential requirements**.
- Technical specifications of products meeting the essential requirements are laid down in **voluntary harmonised standards** which are referenced in the Official Journal of the European Union.
- Manufacturers may make use of the harmonised standards or other technical specifications to meet the essential requirements.
- Products manufactured in compliance with harmonised standards benefit from a **presumption of conformity** with the corresponding essential requirements.

The New Approach was supplemented by measures for conformity assessment, namely, the Global Approach [4]. The objective of the Global Approach is to define a European policy on conformity assessment. It introduces the notion of modules for the various phases of conformity assessment procedures, the setting-up of accreditation systems, notified bodies and mutual recognition arrangements.

These letter-labelled modules A to H differ according to:

- The phase of product lifecycle (e.g. design, prototype, full production).
- The type of assessment involved (e.g. documentary checks, type approval, quality assurance).
- The person carrying out the assessment (e.g. the manufacturer or a third party).

For example, module A is based on internal production control whereas module H is based on the use of a recognised quality assurance system covering design, manufacturing and final product inspection.

The Global Approach was brought up to date by Decision No 768/2008/EC [5] of the European Parliament and of the Council. This decision updates the principles of conformity assessment thereby modernising the New Approach for the marketing of products and is termed the ‘New Legislative Framework’.

2.1.2 Application to the SES interoperability Regulation

2.1.2.1 Regulatory model

The interoperability Regulation [1] of the single European sky has adopted the principles of the New Legislative Framework as it:

- Defines essential requirements applicable to EATMN systems, constituents and associated procedures in Annex II of the interoperability Regulation.
- Foresees the development of voluntary technical specifications in the form of Community specifications that provide a presumption of conformity.

2.1.2.2 Placed on the EU market

The New Legislative Approach associates conformity assessment procedures with products that are intended to be placed on the EU market. For the purpose of these guidelines, 'placed on the EU market' means an EATMN constituent or EATMN system that is made available for procurement or use by air navigation service providers. This includes constituents and systems that are procured by air navigation service providers as part of a specific binding contract with manufacturer(s). By extension, this also includes ANSP in-house developments that are to be put into service or made available to other parties.

2.1.2.3 Product compliance and CE marking

The interoperability Regulation [1] requires manufacturers to accompany their ATM products (i.e. those that have an interoperability function) with an EC declaration of conformity or suitability for use. It is to be noted that recital (13) indicates that the modules of the Global Approach [4] should be used as far as necessary and that recital (14) recognises that it would be excessive to affix the CE mark to EATMN constituents solely for the purpose of the interoperability Regulation.

2.1.2.4 Verification of systems

The interoperability Regulation [1] requires air navigation service providers to verify compliance of EATMN systems with the essential requirements and relevant implementing rules for interoperability before an EATMN system is 'put into service' - which is defined in Article 2 of the framework Regulation [6] as being *"the first operational use after the initial installation or an upgrade of a system"*. This verification is documented in the form of an EC declaration of verification of systems with an associated technical file. Both are submitted to the national supervisory authority (NSA) as described in Section 7.

2.1.2.5 Presumption of conformity

Community specifications are a voluntary means of compliance with the essential requirements and/or relevant implementing rules for interoperability. They specify requirements defining a solution that can be implemented by a subset of the 8 systems, their constituents and associated procedures. When the relevant requirements of Community specifications published in the Official Journal of the European Union are followed, conformity with the essential requirements and/or relevant implementing rules for interoperability shall be presumed. In line with Article R8 of Decision No 768/2008/EC [5], this is termed "presumption of conformity".

2.2. The European Air Traffic Management network (EATMN)

2.2.1 Introduction

The framework Regulation [6] Article 2 (17) (as amended by [2]) defines the European air traffic management network as "*(EATMN) means the collection of systems listed in Annex I to Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European air traffic management network (the interoperability Regulation) enabling air navigation services in the Community to be provided, including the interfaces at boundaries with third countries*".

Section 2.2 is developed upon the above definition to reach a common understanding of EATMN and pave the way towards harmonised conformity assessment practices.

2.2.2 EATMN and the interoperability Regulation

EATMN is a concept created for the purpose of regulating the interoperability of systems, constituents and associated procedures supporting air navigation services. From the regulatory perspective, the interoperability of EATMN relies upon the following principles:

- EATMN is subdivided into 8 systems which must comply with the essential requirements and relevant implementing rules for interoperability throughout their lifecycle.

- Each implementing rule prescribes:
  - Requirements to ensure interoperability between functions supported by a subset of the 8 systems as a complement or refinement of the essential requirements (e.g. interoperability between airborne and ground components of a data link communication service);
  - Requirements to deploy these functions over EATMN (e.g. geographic coverage, timescale, exemptions, transitional arrangements);
  - Requirements to verify compliance of systems and constituents with interoperability requirements (e.g. specific verification methods, calibration parameters, test coverage)
- Community specifications are voluntary means of compliance published in the Official Journal of the European Union. Other standards and specifications can be used as means of compliance.

2.2.3 Which systems and constituents are part of EATMN?

2.2.3.1 Air navigation service provider systems

Air navigation service providers operate different systems for various objectives:

- Systems used for the provision of air navigation services in a given operational area of responsibility.
- Systems used for monitoring of air traffic (e.g. RVSM compliance).
- Systems used for training purposes.
- Systems used for test purposes and simulation.
- Systems used for local technical functions (e.g. technical supervision, network management) that are not covered by any ICAO Standards and Recommended Practices (SARPs).

From the above, **only systems in the first bullet are considered part of EATMN**. That is, operational, standby, fallback and contingency systems directly supporting the provision of air navigation services are part of EATMN as further discussed in Section 2.5.2.

As a result, only constituents that are manufactured to support such systems are subject to conformity assessment procedures.

2.2.3.2 Systems used by military organisations

Military organisations operate different systems for various objectives:

- Systems used for military operations and training.
- Systems used by military organisations for controlling general air traffic (GAT).
- Systems supporting civil-military coordination functions e.g. COTR (Regulation (EC) No 1032/2006 [11]).

From the above, **only systems in the second and third bullets are considered part of EATMN.** However, the specific applicability of conformity assessment to these systems is further discussed in Section 2.5.3.

2.2.3.3 Pan-European systems

Air navigation services rely upon three major pan-European services and functions, namely:

- The ETFMS supporting all functions dealing with ATFM planning, coordination and execution.
- The IFPS distributing Repetitive Flight Plan (RPL) and Filed Flight Plan (FPL) data.
- The European AIS Database (EAD) providing access to Aeronautical Information from ECAC states and the rest of the world.

All systems supporting these pan-European services and functions are considered part of EATMN. However, the specific applicability of conformity assessment to these systems is further discussed in Section 2.5.5.

2.2.3.4 Systems for the use of meteorological information

Meteorological information is defined by ICAO Annex 3 as meteorological reports, analysis, forecasts, and any other statements relating to existing or expected meteorological conditions.

Systems and constituents that use meteorological information in support of ATS operations are subject to conformity assessment procedures. The approach to the conformity assessment of these systems is further discussed in Section 2.5.6.

Meteorological systems that issue meteorological information are not part of EATMN system No. 8; this includes sensors, acquisition instruments, observation and forecasting equipment.

It is to be noted that the provision of meteorological information, and in particular the quality of such data and certification of services are regulated through other SES regulations including Regulation (EU) No 1034/2011 [12] and Regulation (EU) No 1035/2011 [13].

2.2.3.5 Summary

Table 1 summarizes the scope of EATMN.

Characteristics	Definition
What is an EATMN system?	A system derived from one of the 8 types of interoperability systems (Annex I / 552/2004). A system is described as an assembly or aggregation of **constituents** that have an **interoperability function**. For each EATMN system, the ANSP delivers an EC declaration of verification and a technical file.
Systems included within EATMN	Operational systems directly supporting the provision of air navigation services (including standby, fallback and contingency systems)
	Systems used by military organisations providing services to GAT
	Systems used by military organisations supporting civil-military coordination functions
	Systems that use meteorological information (meteorological reports, analysis, forecasts, and any other statements relating to existing or expected meteorological conditions such as warnings)
	Pan-European systems (e.g. CFMU EATMN systems)
Systems excluded from EATMN	Separate systems supporting technical functions (e.g. technical supervision, recording, replay, archiving)
	Systems that issue meteorological information
	Systems when involved in transversal monitoring processes (e.g. RVSM, Mode S monitoring operations)
	Systems used for military operations and training

Table 1: Scope of EATMN

2.3. Demonstration of compliance

2.3.1 Scope of verification of EATMN systems and constituents

2.3.1.1 EATMN constituents

The framework Regulation [6] Article 2 (19) (as amended by [2]) defines constituents as *"tangible objects such as hardware and intangible objects such as software upon which the interoperability of EATMN depends*". Objects that do not have an interoperability function are not to be considered as constituents. An EATMN constituent can be a product or part of a product that is placed on the EU market by the manufacturer or its authorised representative established in the Community that is intended to have a direct effect on the interoperability of the system it supports.

Compliance is required before the constituent is placed on the EU market or put into service[1]. As indicated in Section 2.2.3 only constituents that support the provision of air navigation services are part of EATMN and subject of a verification of compliance as outlined in Article 5 of the interoperability Regulation [1].

As described in a European Commission position paper to the Single Sky Committee (SSC) on the conformity of constituents [8], air navigation service providers may also consider part of their EATMN system as an EATMN constituent if it is relevant to interoperability. In such cases, the air navigation service provider may request the manufacturer to deliver an EC declaration of suitability for use of the constituent within its ATM environment. Generally, this would be a result of an ANSP procurement project that includes constituents that have not been previously placed on the EU market.

In cases where the constituent is no longer supported by the manufacturer or the constituent is not primarily intended for ATM applications, the EC declaration of suitability for use may be provided by the air navigation service provider.

From the above, an EATMN constituent can be identified by:

- definition within implementing rules or Community specifications,
- manufacturers in reference to a product with an interoperability function suitable for use within an ATM environment, or
- air navigation service providers in reference to a part of their bespoke implementation(s),

and will need to be supported by an EC declaration of conformity or suitability for use.

2.3.1.2 EATMN systems

The framework Regulation [6] Article 2 (39) (as amended by [2]) defines systems as 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*".

As described in Section 2.2.3 only those categories of systems of the interoperability Regulation [1] (Annex I) that support the provision of air navigation services, are part of EATMN and are subject to verification of compliance as outlined in Article 6.

Due to the absence of a harmonised logical/technical architecture there is no common mapping between EATMN systems and the technical and operational resources of air navigation service providers. This jeopardises a harmonised approach to conformity assessment, namely, the verification of compliance with the essential requirements and relevant implementing rules for interoperability.

To facilitate a mapping, air navigation service providers should establish an EATMN representation of its resources as outlined in Section 3. In addition, each air navigation service provider should

[1] This covers cases where the constituent is developed in-house by the ANSP or the re-manufacturing of legacy constituents (see Section 2.4)

establish the scope of verification of an EATMN system with its regulatory baseline and associated Means of Compliance (MoC) baseline as explained in Section 4.

Compliance is required, by means of declaration of verification, before the system is put into service by the air navigation service provider.

2.3.2 Roles

2.3.2.1 Manufacturers

The role of the manufacturer, or its authorised representative established in the Community, is to ensure and declare compliance of its EATMN constituent with the essential requirements, specific requirements contained within the relevant implementing rules for interoperability and other relevant technical specifications (e.g. Community specifications, standards). Figure 2 illustrates the steps to be followed by manufacturers to support this obligation:

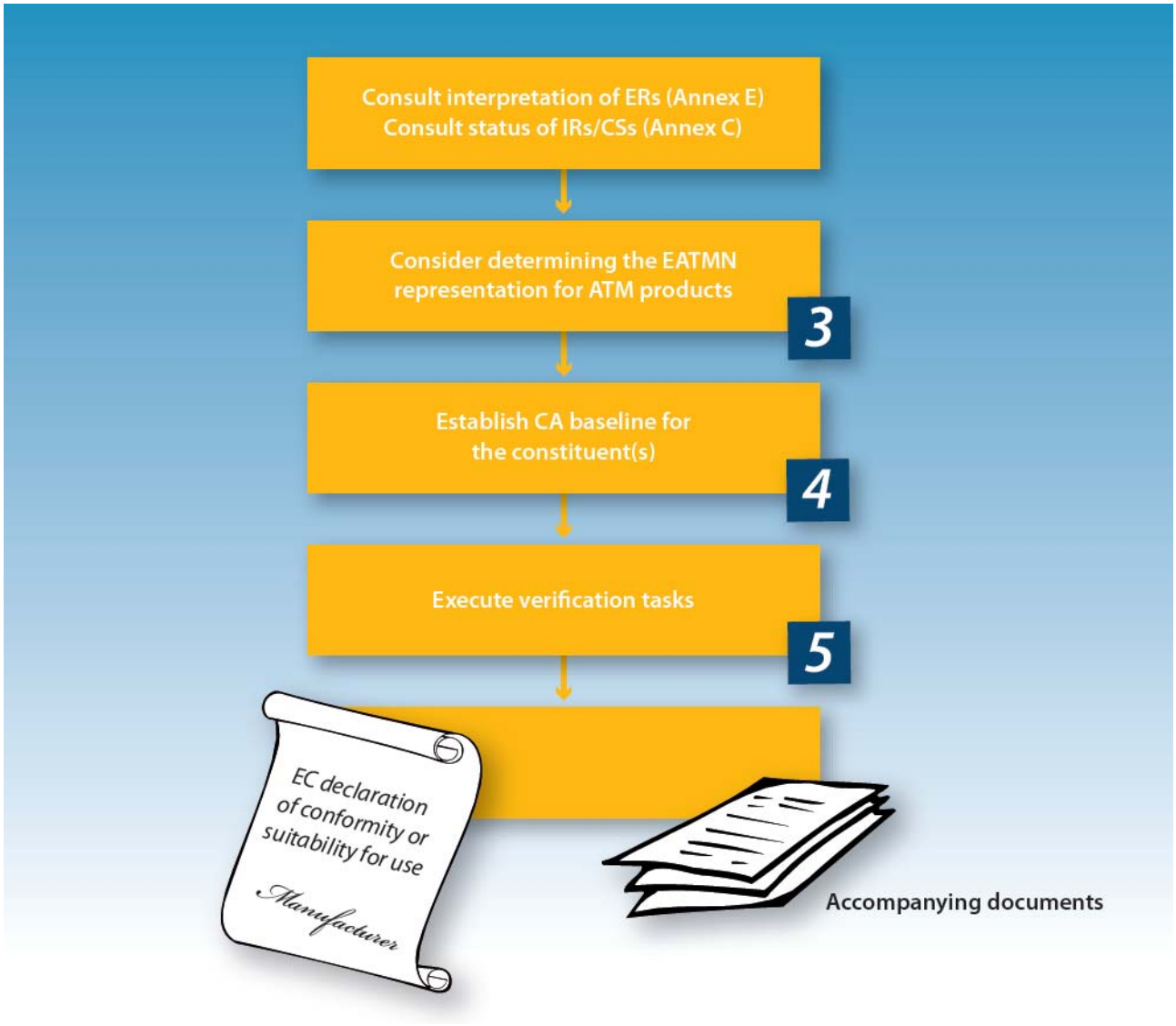

Figure 2: Steps to be followed by manufacturers

The contents of the EC declaration are listed in Annex III of the interoperability Regulation [1] and are further addressed in Section 5 and Annex F of these guidelines.

Links to templates are provided in Annex C.

2.3.2.2 Air navigation service providers

The role of the air navigation service provider is to ensure and declare compliance of its EATMN system with the interoperability Regulation [1] to the national supervisory authority[2] before it is put into service. Figure 3 illustrates the steps to be followed by air navigation service providers to support this obligation:

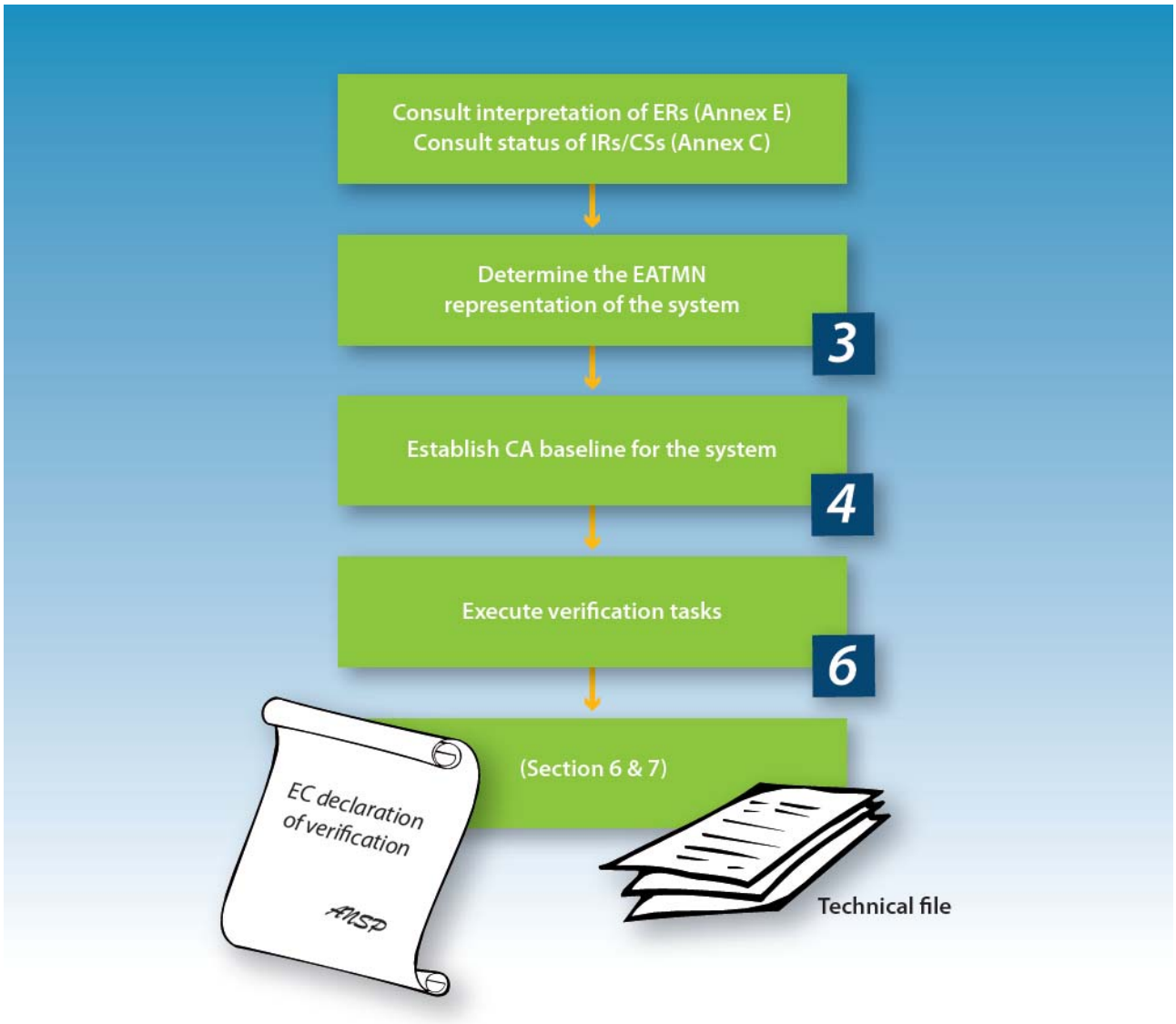

Figure 3: Steps to be followed by air navigation service providers (ANSPs)

The contents of the EC declaration of verification and technical file are listed in Annex IV of the interoperability Regulation [1] and are further addressed in Section 6, Section 7 and Annex F of these guidelines.

Links to templates are provided in Annex C.

2.3.2.3 National supervisory authority

Within a State and for the purposes of conformity assessment, the national supervisory authority(ies)[3] ensure(s) the supervision of compliance of EATMN systems, constituents and procedures with the interoperability Regulation [1]. To fulfil this responsibility, the national supervisory authority will assess the EC declarations, technical files and accompanying documents

[2] Some air navigation service providers may have more than one national supervisory authority.

[3] A list of NSAs is available at: http://ec.europa.eu/transport/air/single_european_sky/national_supervisory_en.htm

prepared by the air navigation service provider and the manufacturer(s). Where necessary for the supervision of compliance, the national supervisory authority may request:

- the air navigation service provider to provide any additional information than the EC declaration of verification of systems and technical file;
- the manufacturer(s) to provide any additional information than the EC declaration of conformity or suitability for use and accompanying documents;
- additional supporting information from other national supervisory authority(ies).

Beyond the interoperability Regulation, the national supervisory authority or other state authorities may also need to ensure compliance with other complementary EC regulations and directives (see Section 2.5 on special cases).

2.3.2.4 Notified bodies

As for the New Legislative Framework, the interoperability Regulation [1] allows Member States to appoint notified bodies that are entitled to provide conformity assessment services, to manufacturers and/or air navigation service providers in relation to their verification of compliance obligations. In addition, implementing rules for interoperability may assign[4] conformity assessment tasks to notified bodies.

Notified bodies perform verification tasks and are competent in assessing whether the verification results are met (as specified in the verification specifications). A notified body is obliged to provide a 'certificate' in relation to the tasks it has performed for the manufacturer or air navigation service provider. The purpose of the certificate is to clearly identify which verification tasks have been accomplished and mentioning reservations, if any. The certificate is not to be confused with the EC declaration to be drawn up by the manufacturer or ANSP. In particular, it is to be noted that the responsibility to assess and declare compliance with the provisions of the interoperability Regulation lies with the ANSP.

The list of notified bodies is maintained by the Commission on the Nando web site[5] and published in the Official Journal of the European Union (See Annex C). At the time of writing, only Germany and Spain have appointed notified bodies for the purpose of the interoperability Regulation.

2.3.3 Safeguards

The national supervisory authority is entitled to restrict or prohibit the use of an EATMN system or constituent accompanied by its EC declaration, if it ascertains that it does not meet the essential requirements and/or relevant implementing rules.

As described in Article 7 of the interoperability Regulation [1], the Commission shall be informed of these measures, shall consult the concerned parties and shall report its findings to the Member State to resolve the issue.

2.3.4 Alternative verification of compliance

Article 6a of the interoperability Regulation [1] (as amended by [2]), recognises certificates issued in compliance with Regulation (EC) No 216/2008 [9]. This is currently applied to airborne constituents and systems of EATMN until the necessary EASA implementation measures are applied to aerodromes, air traffic management and air navigation services (Regulation (EC) No 1108/2009 [14]).

EASA is in the process of preparing new certification specifications that include both interoperability and airworthiness requirements, in particular a certification specification applicable to airborne data link equipment.

[4] At the time of writing, no implementing rules for interoperability specify such requirements.

[5] http://ec.europa.eu/enterprise/newapproach/nando/index.cfm

If the issued certificate supported by its technical file (see recital (33) of Regulation (EC) No 1070/2009 [2]) includes a demonstration of compliance with the essential requirements and relevant implementing rules for interoperability, the certificate is considered as EC declaration of conformity or suitability for use when applicable to a constituent and is considered as EC declaration verification when applicable to a system.

2.4. Legacy systems

The interoperability Regulation [1] entered into force 20 April 2004 and specifies transitional arrangements for EATMN systems and constituents. In particular, Article 10(1) stipulates that starting 20 October 2005, the essential requirements shall apply to the putting into service of all systems and constituents of the EATMN. Furthermore, Article 10(2) requires all EATMN systems and constituents to comply with the essential requirements by 20 April 2011. Legacy systems are understood as being systems and constituents of the EATMN that were put into service before the date of 20 October 2005 and were not modified since that date. When the operational characteristics of the legacy system are changed, an EC declaration of verification and technical file will be required if the changes would have justified a DoV update as described in Section 8.3.2.

European Commission DG/TREN submitted a position paper on legacy systems [10] to the Single Sky Committee. It concludes that EC declarations of conformity or suitability for use cannot be requested from the manufacturer for individual constituents that were placed on the EU market before 20 April 2004 and put into service before 20 October 2005. In this context, 'placed on the EU market' is to be understood as procured as part of a binding contract before 20 April 2004 for a particular installation. The manufacture or re-manufacture of constituents of the same design or the procurement of such individual constituents after 20 April 2004 can no longer be considered as legacy and will need to be accompanied by an EC declaration. Similarly, an EC declaration of verification of systems cannot be requested for systems that were put into service before 20 October 2005.

As required by Article 10(2) and 10(2a) of the interoperability Regulation (as amended by [2]), air navigation service providers and national supervisory authorities will need to agree on the procedures and documents to demonstrate compliance of legacy systems in operation by 20 April 2011. For this purpose, these guidelines recommend that the provisions of Article 6 and Annex IV are used as a basis for this demonstration.

2.5. Special cases for the applicability of conformity assessment

2.5.1 Airworthiness, R&TTE, LVD, EMC, RoHS and WEEE

EATMN systems and constituents may also need to demonstrate their compliance to other EC directives and/or regulations.

Airborne systems and constituents will need to comply with the essential requirements on airworthiness in accordance with Regulation (EC) No 216/2008 [9].

Ground-based ATM equipment is no longer exempt from Directive 1999/5/EC radio and telecommunications terminal equipment (R&TTE). Further guidance is made available by European Commission DG Enterprise and Industry (see Annex C for the relevant web page links).

Furthermore, ATM equipment is not exempt from other directives which require the CE marking, such as:

- Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS).
- Directive 2002/96/EC (as amended) on waste electrical and electronic equipment (WEEE).
- Directive 2004/108/EC on electromagnetic compatibility (EMC).
- Directive 2006/95/EC on electrical equipment designed for use within certain voltage limits (low voltage directive – LVD).

2.5.2 Standby, fallback and contingency systems

Conformity assessment applies to operational systems including the primary system, standby systems, fallback systems and contingency systems.

Standby systems are those systems that meet the same level of service and baseline for conformity assessment (Section 4) as the main primary system. It is recommended that they are considered as a constituent (or set of constituents) of the relevant EATMN system (e.g. all voice switches could be included in a single DoV). Where a standby system is put into service at a different date than the primary system, this can be handled through an update of the initial DoV rather than a new separate DoV.

Fallback systems are those systems that offer a reduced level of service for a defined period when the primary and standby systems are not available. It is necessary to understand their role and interfaces to determine the applicability of conformity assessment:

- If a fallback system was manufactured with the intent of providing an ANS service, then it is recommended that they are considered as constituent (or set of constituents) of the relevant EATMN system.
- If the fallback system was not manufactured to provide an ANS service (e.g. a GSM phone) it will not be accompanied by a DoC or DSU. The technical file should provide evidence that the system is fit for purpose.

Contingency systems provide a service when the primary system is not available for a prolonged period. Contingency plans will be drawn up by the ANSP based on the business continuity requirements and according to the safety requirements of the organisation informed by SES regulations and national requirements which will define the baseline for conformity assessment.

Where an ANSP is responsible for the contingency system, it is required to prepare the relevant DoV and TF before it is put into service. If the contingency plan requires the use of another ANSP's system, these guidelines recommend that the ANSP and NSA take steps to ensure that the other ANSP has satisfactorily completed conformity assessment procedures.

Where the contingency plan requires the use of systems of a military organisation, it is to be noted that conformity assessment material may not be available as described in Section 2.5.3. Nevertheless, ANSPs must still be able to demonstrate that the concerned systems comply with the essential requirements and relevant implementing rules for interoperability. This implies that the ANSP is to obtain evidence of conformity from the military organisation and/or the system manufacturer.

A summary of each type of system is given in the table below:

Type	Functionality	Use	Characteristic
Standby	Same as prime	When prime system fails	Independent system (often a duplicate). A fault-tolerant system can be considered as an integrated prime/standby system.
Fallback	Reduced	To provide protection & safety after prime/standby system failure	May be a subset of prime system or a separate system
Contingency	Similar to prime but may be reduced – depends on business continuity plans	Interim provision of service whilst prime/standby system is being recovered	Separate system and often separately located.

Table 2: Summary of standby, fallback and contingency systems

2.5.3 Military systems

An EU Member State statement on military issues related to single European sky has been published in the Official Journal of the European Union (OJ L 96, 31.03.2004 p. 9). Conformity assessment obligations of the interoperability Regulation [1] do not apply to military operations and training.

Concerning systems used by military organisations providing services to GAT, military organisations primarily[6] providing such services are subject to the same conformity assessment requirements as civil ANSPs. Military organisations that do not primarily provide such services, but operate specific air traffic service units that do, should consider applying of the relevant conformity assessment requirements.

When deploying EATMN systems or implementing rules for interoperability, relevant military organisations shall demonstrate by appropriate means that their systems are in conformity with the essential requirements and relevant implementing rules. For example, Article 3(4) and Article 3(5) of Regulation (EC) No 1032/2006 [11] require such measures of conformity.

2.5.4 Non-certified service providers

Commercial service providers such as telecommunication service providers, airspace management (ASM) providers, air traffic flow management (ATFM) providers, which are not certified as air navigation service provider in accordance with Article 7 of the service provision Regulation [7], are currently exempted from conformity assessment tasks.

2.5.5 Pan-European services and functions

The framework Regulation [6] makes the distinction between services and functions. In particular, under Article 2 of this Regulation:

- ‘aeronautical information service’ (AIS) is explicitly defined as a service.
- ‘air traffic flow management’ (ATFM) and ‘airspace management’ (ASM) are explicitly defined as functions.

The issue and renewal of certificates for organisations providing pan-European services is foreseen by Regulation (EC) No 1108/2009 [14]. As a result, the relevant conformity assessment procedures for the EATMN systems put into service by these organisations in support of pan-European services will be derived through the EASA certification procedures.

Following Article 2 of the framework Regulation [6], a pan-European provider of the ATFM and ASM functions is not an air navigation service provider. Therefore its EATMN systems, both central and local, are exempted from conformity assessment tasks as foreseen by Article 6 of the interoperability Regulation [1].

Air navigation service providers that put EATMN systems into service that relate to these pan-European services and functions, will need to perform conformity assessment procedures as required by the interoperability Regulation.

2.5.6 Systems for the use of meteorological information

Air traffic service providers shall provide a DoV covering systems that use meteorological information to support ATS operations, in accordance with Article 6 of the interoperability Regulation. The technical file of the DoV should include reference to the arrangements required by the service provision Regulation with the meteorological service provider(s) that specify the required quality of service.

[6] Refer to Article 7(5) of the service Regulation [7].

Manufacturers, of airborne[7] or ground constituents that make use of meteorological information to inform operational decisions or that integrate an EATMN interoperability function (for example a common interface), shall provide an EC declaration of conformity or suitability of use.

Where a meteorological service provider operates a constituent with an EATMN interoperability function, the air traffic service provider may obtain the technical documentation from the meteorological provider in order to complete the technical file.

2.5.7 Relationship to national legislation

National legislation may prescribe further *verification* and approval requirements before a system is put into service. The air navigation service provider should verify additional requirements with the appropriate state authorities.

[7] Airborne constituents may be subject to alternative verification of compliance, as described in Section 2.3.4.

3 DETERMINING EATMN SYSTEMS AND CONSTITUENTS

3.1. Introduction

As described in Section 2.2, the EATMN is a concept developed for the purpose of the interoperability Regulation [1]. As indicated in Figure 4, EATMN is subdivided into **eight systems**. Implementing rules and Community specifications contain requirements to ensure interoperability between these systems and their constituents.

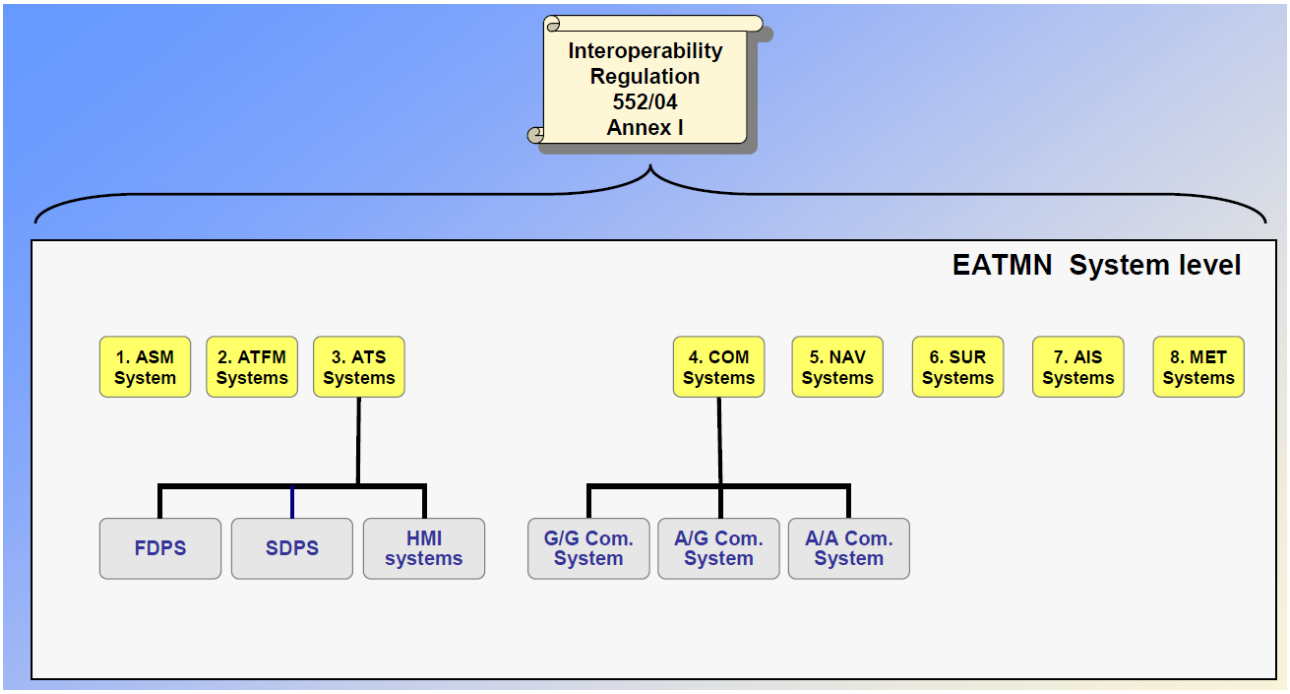

Figure 4: EATMN systems

Air navigation service providers operate systems designed to fit with their local technical, operational and organisational environment. As a result, they must determine which elements of their environment represent EATMN constituents and systems in order to perform their verification of compliance tasks. In other words, they need to map their real-world systems in terms of EATMN constituents and EATMN systems for which they will apply conformity assessment procedures. This mapping is termed the **EATMN representation**.

Manufacturers may also consider this form of representation to relate multiple EATMN constituents of their product to EATMN systems.

3.2. EATMN representation

The EATMN representation illustrates the interoperability relevant air navigation service provider resources in terms of the eight EATMN systems and their constituents. The EATMN representation provides a stable view of these resources as it is primarily subject to change when new systems and constituents are being put into service.

Constituents are *"tangible objects such as hardware and intangible objects such as software upon which the interoperability of EATMN depends*" [6]. Section 2.3.1.1 indicated that constituents could be defined in implementing rules or Community specifications and in certain cases by manufacturers and air navigation service providers.

At present, only a limited number of constituents have been defined within implementing rules and Community specifications. Consequently, manufacturers and air navigation service providers will need to identify their products or ATM equipment in terms of constituents of EATMN systems. This

identification of constituents composing EATMN systems will depend on the ANSP's specific environment or a given manufacturer's product portfolio.

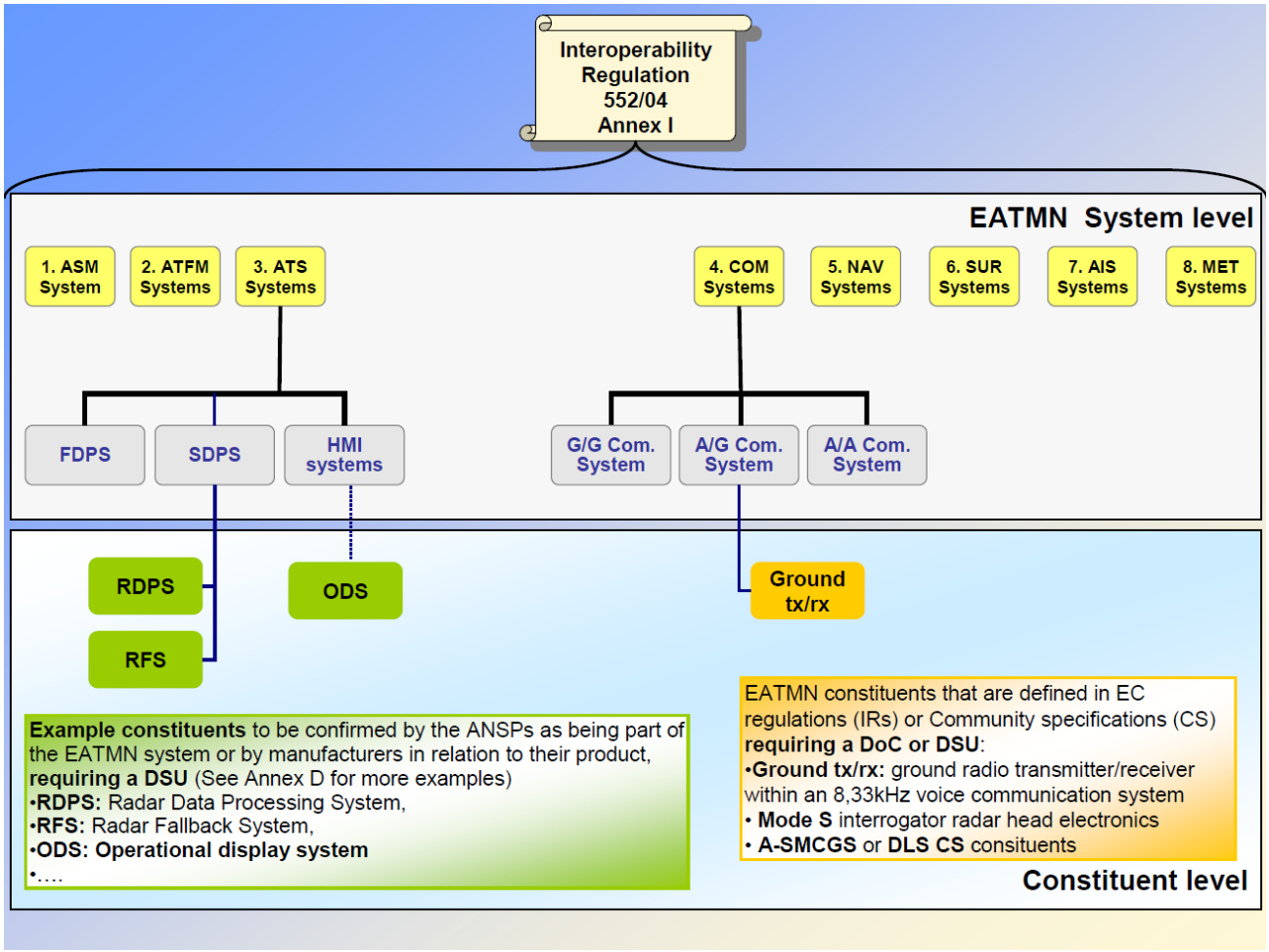

Figure 5: Example EATMN constituents

Air navigation service providers can then map their environment in terms of EATMN systems and constituents, providing a EATMN representation that is compatible with the regulatory framework. Similarly and depending on their nature, manufacturers can also consider mapping their products in terms of EATMN constituents. Example EATMN representations are provided in Annex D which is complemented by the CATF website (see Annex C) for the communications, navigation and surveillance domains.

EATMN systems and products can be complex, distributed and multiple. For the purpose of the EATMN representation there is a need to consider all:

- Operational services (ACC, APP and TWR), sites and technical assets.
- Manufacturer product portfolio or product configurations.

Air navigation service providers should define the EATMN representation[8] most appropriate to their EATMN systems taking into account interface constraints (e.g. coordination and transfer[9] is

[8] This approach may not be suitable for distributed systems such as surveillance.

[9] Regulation (EC) No 1032/2006 [11].

applicable between air traffic service units (ATSU)) and the notion of putting into service. Examples of EATMN representations can be found in Annex D.

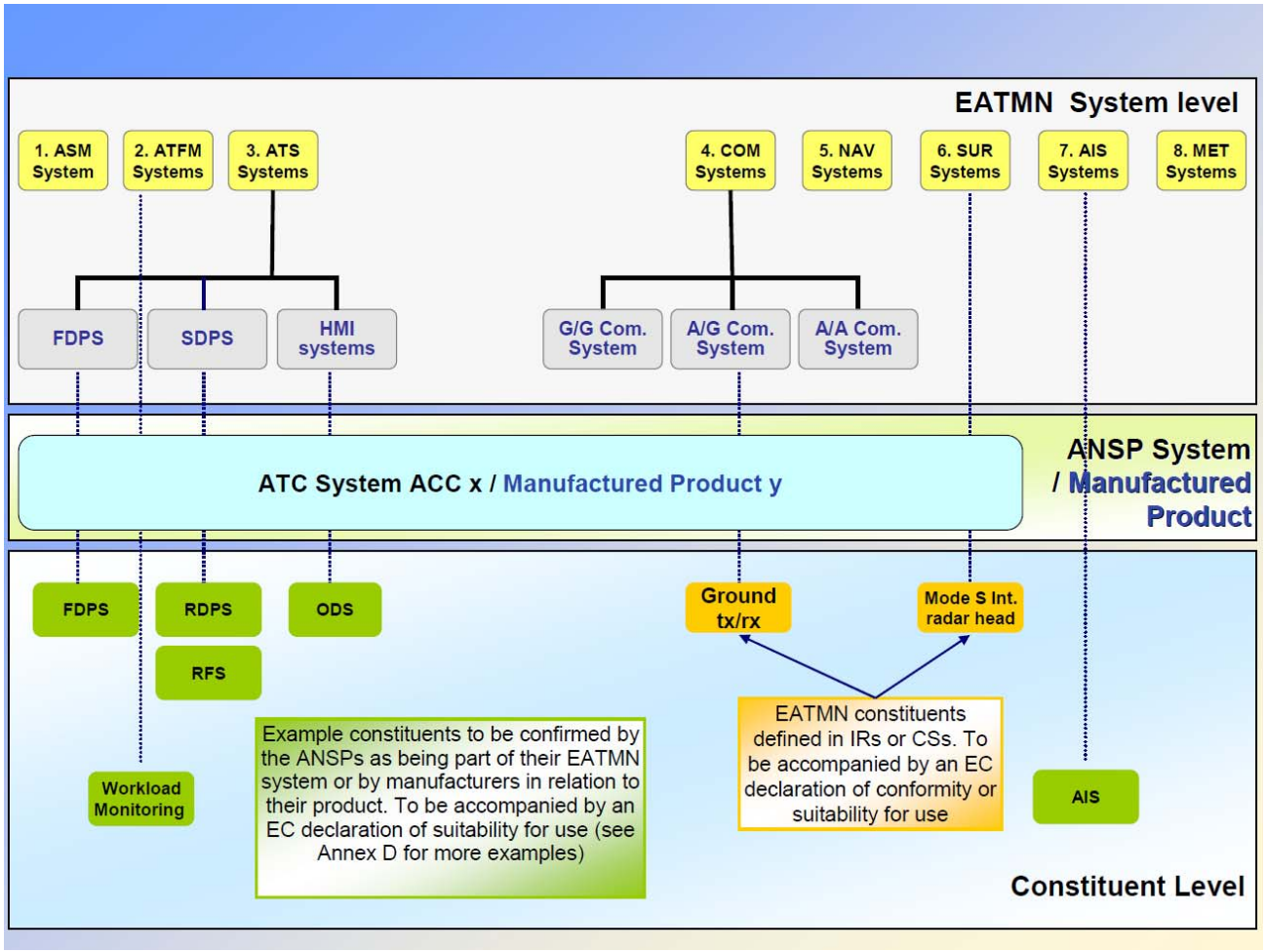

Figure 6: EATMN representation

It is expected that that each manufacturer will provide at least one declaration for a given product irrespective of the number of embedded constituents.

It is also expected that air navigation service providers will deliver a single declaration of verification for each EATMN system that they put into service. However, in preparing the EATMN representation, it is possible that an ANSP's 'real system' covers the functionality of more than one EATMN system. In such event, it may be more practical to prepare a single declaration of verification of systems for the 'real system' being put into service clearly indicating that it covers multiple EATMN systems.

The EATMN representation of ATM systems or manufactured ATM products should contain:

- A list of EATMN systems derived from the 8 types of systems.
- A brief description of each system with:
  - A graphical illustration of the breakdown into constituents as illustrated in Figure 6;
  - A textual explanation of the main functions supported by the system or product.

3.3. Acceptance and documentation

For air navigation service providers, the EATMN representation is the **initial and essential step when performing conformity assessment**. These guidelines recommend using the EATMN representation as a means to facilitate the understanding of which systems are being assessed and that it is to be submitted to the national supervisory authority for agreement prior to the

execution of conformity assessment tasks. It should be included in the technical file accompanying the EC declaration of verification.

4 ESTABLISHING THE BASELINE FOR CONFORMITY ASSESSMENT

4.1. Introduction

The baseline for conformity assessment consists of:

- The regulatory baseline, which defines mandatory requirements specified in relevant EC regulations; and
- The means of compliance (MoC) baseline, which consists of the voluntary standards and specifications that the manufacturer or air navigation service provider uses to ensure compliance with the regulatory baseline.

This section provides guidance for determining both the regulatory and means of compliance baselines. As illustrated by Figure 7, these are essential inputs before verification tasks can be initiated. In particular for air navigation service providers, Figure 7 illustrates the dependency of the EC declaration of verification to the putting into service and its re-assessment in case of change (see Section 8).

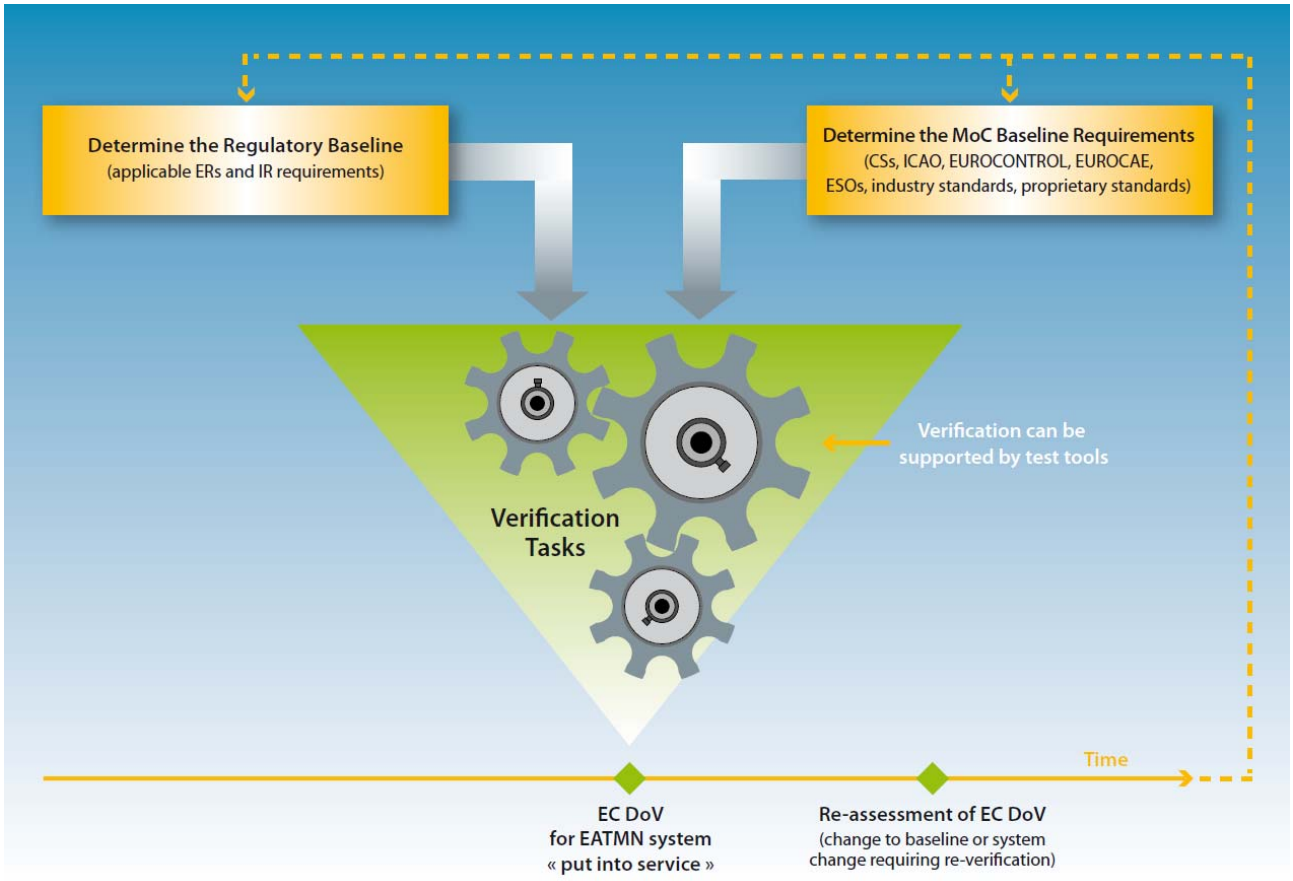

Figure 7: Verification cycle for EATMN systems being put into service

4.2. Definition of the regulatory baseline

The regulatory baseline of an EATMN system or constituent addressed by these guidelines is the set of regulatory requirements applicable to this system or constituent that is relevant to the interoperability Regulation [1]. The requirements will comprise essential requirements (ERs) and those from applicable implementing rules (IRs). IR articles dealing with the scope, dates of application, transient and exemption measures, if any, must be carefully analysed to determine the regulatory baseline applicable to a given EATMN system or constituent.

Note: Other regulations (e.g. R&TTE directive, Section 2.5.1) may also apply to a given EATMN constituent or system and will need to follow the specific conformity assessment procedures defined by those regulations. These are outside the scope of conformity assessment for the interoperability Regulation and thus not further considered.

4.2.1 Determining relevant IRs

Implementing rules (IRs) contain regulatory requirements refining essential requirements. Therefore the manufacturer and air navigation service provider must identify the relevant implementing rules applicable to the constituent or system. This will enable the EC declaration to include exact traceability to the regulatory requirements contained in IRs. It is to be noted that certain implementing rules for interoperability include specific provisions of ICAO standards and/or EUROCAE documents thereby making them an integral part of the regulatory baseline for conformity assessment of the SES interoperability Regulation.

IRs are continually being developed and so the regulatory baseline for a given system or constituent is subject to change and must be maintained all along the system lifetime.

A list of current implementing rules is maintained by the European Commission (see link to web site in Annex C).

4.2.2 Determining applicable ERs

The EATMN, its systems and their constituents must meet ERs. The two forms of ERs are specified in Annex II of the interoperability Regulation [1]:

- General requirements (which apply to all EATMN systems and constituents):
  - seamless operation (ER1)
  - support for new concepts of operation (ER2)
  - safety (ER3)
  - civil/military coordination (ER4)
  - environmental constraints (ER5)
  - principles governing the logical architecture of systems (ER6)
  - principles governing the construction of systems (ER7)
- Specific requirements (which refine the generic requirements for seamless operation and support for new concepts of operation for the following specific EATMN systems):
  - systems and procedures for airspace management
  - systems and procedures for air traffic flow management
  - systems and procedures for air traffic services
    - Flight data processing systems
    - Surveillance data processing
    - Human-machine interface systems
  - communications systems and procedures for ground-to-ground, air-to-ground and air-to-air communications
  - navigation systems and procedures
  - surveillance systems and procedures
  - systems and procedures for aeronautical information services
  - systems and procedures for the use of meteorological information

Essential requirements are not expected to change. They are mandatory and must be taken into account by all stakeholders. In particular, the manufacturer and air navigation service provider must determine the applicability of the essential requirements depending on the product or system undergoing conformity assessment. A constituent or system is unlikely to take into account all aspects of each essential requirement simply because of the high level, all-encompassing nature of the requirements. However, an EATMN constituent or system cannot be in conflict with any applicable essential requirement.

The essential requirements are of a high-level nature, which is insufficient to enable a detailed technical verification as required by conformity assessment.

The essential requirements are considered as general principles that systems must fulfil, rather than true technical requirements which are usually specified by air navigation service providers or manufacturers.

Annex E provides further information on the interpretation of all the essential requirements in view of supporting an assessment or demonstration of compliance. Two of these essential requirements (ER6 and ER7) deal with technical solutions for the logical and physical system architecture but as there is no commonly approved logical and physical reference architecture in Europe, short-term measures are proposed. It is to be noted that the use of Community specifications facilitates this assessment as they contain a traceability matrix to the essential requirements.

4.3. Establishing the MoC baseline

The means of compliance (MoC) baseline is the set of requirements originated from Community specifications, other standards and proprietary technical specifications that are considered as a means of compliance with the regulatory baseline.

In order to perform EC verification against the essential requirements, it is necessary to select relevant reference materials containing the detailed technical and operational requirements and then, to apply suitable verification methods. There is substantial scope for selecting appropriate reference material, so long as the EATMN system or constituent can be shown to meet the requirements in the reference material and that traceability between the reference material and the essential requirements can be made. Recital (10) of the interoperability Regulation also suggests that reference material must be developed by recognised international organisations.

Seven types of MoC reference material are identified herein:

- Community specifications (CS) referenced in the Official Journal of the European Union;
- EASA material;
- ICAO documents;
- European Standards (EN);
- EUROCONTROL documents [EUROCONTROL specifications, concept of operations, etc];
- EUROCAE documents [ED series of technical standards]; and
- ANSP documents [proprietary technical specifications including relevant requirements documents].

The MoC baseline is the set of requirements originating from the identified reference material, applicable to a given EATMN system or constituent:

- **Requirements from a CS**: These requirements are recognised as a means of compliance with the relevant regulatory baseline providing a presumption of conformity with the essential requirements and relevant implementing rules for interoperability. However, they may be insufficient to manufacture a product or put a system into service as they may only cover part of the functional requirements.
- **Requirements from other reference material**: These requirements, e.g. from EASA, EUROCONTROL, ICAO, EUROCAE or proprietary ANSP references, must be accompanied

with a justification showing how they demonstrate compliance with the regulatory baseline and thus ensure interoperability.

Where a Community specification exists it should be used as the preferred means of compliance; however, the manufacturer and air navigation service provider are free to choose alternate MoC specifications provided they are able to demonstrate compliance to the regulatory baseline.

The extent of the MoC baseline determines the scope of the verification tasks to be undertaken to assess conformity. Three scenarios are considered:

- A CS covering the full scope of the system undergoing conformity assessment: the MoC baseline is populated with the minimum set of requirements originating from applicable CS(s).
- A CS partially covering the scope of the system undergoing conformity assessment: the MoC baseline is populated with the minimum set of requirements originated from applicable CS(s) and additional requirements as explained above, in other words, the full scope is covered by a combination of requirements from the Community specification(s) and other reference material.
- No CS covers the scope of the system undergoing conformity assessment: the MoC baseline is populated with the minimum set of requirements originating from other reference material.

4.4. Compliance with the baseline for conformity assessment

The verification of compliance with the baseline for conformity assessment involves the verification of compliance of the regulatory and MoC baselines. The verification of compliance with the regulatory baseline consists of:

- An assessment of compliance of the system or constituent with the essential requirements.
- An assessment of compliance of the system or constituent with relevant implementing rules.

The assessment of compliance of the system or constituent with the essential requirements is a rationale showing that the system or constituent has been designed to ensure interoperability in its technical and operational environment (Annex E gives an acceptable approach for such an assessment). Manufacturers are to document this rationale in their accompanying documents and trace the applicable essential requirements in the DoC/DSU (Section 5). Air navigation service providers are to document this rationale in the technical file (Section 6) and trace the applicable essential requirements in the DoV (Section 7). This rationale can be presented in the form of a compliance matrix.

The verification of compliance of the system or constituent with the MoC baseline leads to inspection and/or testing methods in accordance with conformance-related requirements of MoC reference materials.

5 COMPLETING A DECLARATION OF CONFORMITY OR SUITABILITY FOR USE (DOC/DSU)

5.1. Purpose

This section describes the manufacturer's role of completing a DoC or DSU:

- For constituents that comply with a referenced Community specification, manufacturers are required to accompany the constituent with an EC declaration of conformity (DoC).
- For all other cases, manufacturers are required to provide the EC declaration of suitability for use (DSU).

The DoC and DSU are formal documents that should be completed and submitted as evidence that a defined constituent (see Section 3) meets the applicable baseline (see Section 4). **They must contain traceability to the requirements that were used for conformity assessment as determined by the regulatory baseline and references to any used Community specifications. The accompanying documents of the DoC or DSU must contain traceability to the requirements that were used for conformity assessment as determined by the MoC baseline. The traceability to the requirements can be documented in the form of a compliance matrix.**

5.2. Overview of completing a DoC/DSU

The manufacturer of an EATMN constituent, or its authorised representative established in the Community, is required by Article 5(2) of the interoperability Regulation [1] to verify and declare compliance of its constituent with applicable regulatory requirements (i.e. the essential requirements and relevant implementing rules). For this purpose, the manufacturer responsible for the design and development of the constituent must therefore determine the applicable conformity assessment baseline (see Section 4) applicable to its constituent and then provide suitable evidence that the regulatory baseline has been complied with. The evidence should consist of the DoC/DSU and accompanying documents and must be dated and signed by the manufacturer.

The following sections provide guidance on:

- The contents of a DoC/DSU.
- The procedure for achieving the verification of compliance of constituents.
- Considerations on manufacturers and subcontractors.
- Update of DoC/DSU.

5.3. Contents of a DoC/DSU

In accordance with Annex III of the interoperability Regulation [1] a DoC or DSU must be written in the same language as the instructions given in accompanying documents and must contain the following:

- **References**, including title and number, to the applicable regulations (e.g. regulatory baseline).
- **Name and full address of the manufacturer** or its authorised representative established within the Community (in the case of the authorised representative, also the trade name of the manufacturer).
- **Description of the constituent** that is adequate to understand the core functions of the device in its technical environment and its external interfaces. This will include a meaningful name for the constituent.

- **Description of the procedure followed** in order to declare conformity or suitability for use including whether notified bodies were involved in verification tasks or which recognised quality processes were applied.
- All of the **relevant provisions** met by the constituent (e.g. relevant provisions derived from the reference material of the MoC baseline as described in section 4.3) and in particular, its **conditions of use**. Performance indicators of the constituent should appear under this item.
- If applicable, **name and address of notified body** or bodies involved in the procedure followed in respect of conformity or suitability for use and date of examination **certificate** together, where appropriate, with the duration and conditions of validity of the certificate (some implementing rules may assign conformity assessment tasks to notified bodies).
- References to **Community specifications** complied with by the constituent (e.g. MoC baseline), if any.
- **Date and signature** along with identification (including position and title) of signatory empowered to enter into commitments on behalf of the manufacturer or of the manufacturer's authorised representative established in the Community.

Links to DoC and DSU templates are provided in Annex C.

5.4. Accompanying documents

The interoperability Regulation does not oblige the manufacturer to deliver the accompanying documents of the DoC or DSU to the air navigation service provider. However, it is expected that the manufacturer will deliver or reference part of these documents such as: instructions, manuals, implementation conformance statements, performance specifications.

In any event, the manufacturer must be prepared to provide all accompanying documents upon request of the national supervisory authority.

5.5. Procedure for achieving the verification of compliance of constituents

5.5.1 Determine whether to develop a DoC or DSU

Depending on the existence or application of Community specifications, the following cases are to be distinguished with regard to verifying compliance of constituents.

Criteria to develop a DoC or DSU	Type of declaration
Community specifications are applied	DoC
Community specifications are not applied	DSU

Table 3: Cases considered for verifying compliance of constituents

It is to be understood that the DoC can only be declared when the constituent has applied all relevant requirements of the Community specifications. For example, if the scope of a Community specification covers both ground and airborne constituents, ground constituents will need to apply the ground-related requirements in order to declare conformity. As a result, by applying Community specifications, constituents shall be presumed to be in conformity with the essential requirements and relevant implementing rules for interoperability.

5.5.2 Define the baseline for conformity assessment

Having defined the constituent, and whether to produce a DoC or DSU, the manufacturer must then determine the applicable conformity assessment baseline. This involves consulting the

interpretation of the essential requirements provided in Annex E along with the list of implementing rules and supporting Community specifications referred by Annex C and other relevant specifications.

Details on establishing the baseline for conformity assessment are given in Section 4. For constituents (as opposed to systems) it may be the air navigation service provider *or* the manufacturer who is responsible for the determination of the regulatory and MoC baselines. As with systems, there is substantial scope for selecting appropriate reference material as a MoC, so long as the constituent can be shown to meet the requirements in the reference material and that traceability between the reference material and the essential requirements can be made.

5.5.3 Constituent verification process

The interoperability Regulation [1] does not specify the method and procedure for achieving verification of compliance. However as described in Section 2, it recommends the use of the modules of Council Decision 93/465/EEC (now repealed by [5]) which can be applied during the design, production and final inspection of constituents. The manufacturer is free to choose which module is applied unless otherwise specified in the relevant implementing rule(s). To date, no implementing rule requires the use of a specific module for conformity assessment; therefore it is expected that manufacturers are likely to make use of Module A (internal product control).

For the production process, the manufacturer may choose from internally assembled and documented procedures and verifications, type or end-product acceptances through a notified body (e.g. in line with Module B of [5]), or even use of a certified quality management system as approved by a notified body (e.g. in line with Module H of [5]).

The manufacturer can delegate verification tasks to a notified body even if there is no obligation to do so in the regulatory baseline.

When verification tasks are achieved by an in-house entity, the manufacturer should ensure that this entity is fully trained and organised to implement conformity assessment activities, giving credit to its EC declarations.

According to Article 5(4) of the interoperability Regulation [1], where an implementing rule is identified as part of the constituent's applicable regulatory baseline, it shall identify appropriate tasks pertaining to the assessment of conformity or suitability for use of the constituent to be carried out by notified bodies.

No CE label is required to designate interoperability compliance of systems and constituents that are used exclusively for air traffic management purposes (see Section 2.1.2.3).

Further guidance on the verification process of constituents is developed in Annex F.

5.5.4 Considerations on manufacturers and subcontractors

The manufacturer has the ownership and the intellectual property rights of the constituent. The manufacturer is fully responsible for the design and performance of the constituent. The manufacturer places the constituent on the EU market and can provide value added services for the constituent when it is part of an EATMN system being put into service e.g. system integration and maintenance.

A subcontractor may deliver a constituent under the terms of reference of a bilateral contract with the air navigation service provider. The air navigation service provider has the full ownership of the constituent unless there are some background assets provided by the subcontractor. The decision of requesting an EC declaration signed by the subcontractor is left to the air navigation service provider and should be clarified in the contract agreed by both parties.

5.5.5 Update of EC declarations issued by manufacturers

The manufacturer of a constituent must consider the revision of the EC declaration when the baseline for conformity assessment applicable to this constituent changes prior to any new installation (see Section 8).

6 COMPLETING A TECHNICAL FILE (TF)

6.1. Purpose

Having determined the EATMN representation (see Section 3) and established the baseline for conformity assessment (see Section 4), the air navigation service provider must then execute the verification processes that will provide evidence of conformity. This evidence should be captured in the technical file (TF) which will accompany the EC declaration of verification of systems (DoV) (see Section 7) as proof that the defined system meets the applicable regulatory baseline. The following sections provide guidance on:

- The contents of a TF.
- The procedure for developing a TF (derived from Annex IV of the interoperability Regulation [1]).

The technical file must contain traceability to the requirements that were used for conformity assessment as determined by the regulatory and MoC baselines and the EATMN representation. The traceability to the requirements can be documented in the form of a compliance matrix.

6.2. Contents of a TF

The TF must be separate to the DoV but must be written in the same language. The TF must:

- Make **reference to the DoV**.
- Accompany the DoV and be retained and maintained by the air navigation service provider throughout the service life of the system.
- **Reference to test case documents and results** with a view of ensuring compliance with essential requirements and any particular requirements contained in the relevant implementing rules for interoperability.
- Contain a **list of constituents** and copies of their DoCs or DSUs (i.e. an EATMN representation of the system).
- Contain all the necessary documents relating to the characteristics of the system (hardware and/or software), including:
  - Conditions and **limits of use** of the system;
  - A description of **configurations** of the system;
- Indicate the relevant parts of the **technical specifications** and Community specifications that form the MoC baseline with the applicable implementing rules for interoperability.
- Where a notified body has been involved in the verification of the system(s), contain **certificate(s) countersigned** by this body stating that the system complies with the interoperability Regulation and mentioning any reservations.

For this purpose and where appropriate, these guidelines recommend that the TF:

- references publicly available regulations, standards and technical specifications that constitute the baseline for conformity assessment;
- contains the rationale showing the compliance to the regulatory and MoC baseline requirements (the baseline for conformity assessment) as described in Section 4.4. This rationale can be presented in the form of a compliance matrix; and

- clearly indicates any relevant safety objectives, safety requirements and other safety-related conditions met by the system to facilitate NSA safety oversight tasks specified in Articles 6 and 10 of Regulation (EU) No 1034/2011 [12].

6.3. Procedure for achieving the verification of compliance of systems

6.3.1 System verification process

According to Annex IV of the interoperability Regulation, verification of systems is the procedure whereby an air navigation service provider checks and certifies that a system complies with the interoperability Regulation and may be put into operation. The air navigation service provider is required to check the following aspects:

- Overall design.
- Development and integration of the system, including in particular constituent assembly and overall adjustments.
- Operational system integration.
- Specific system maintenance provisions if applicable.

To meet this requirement, the air navigation service provider can make use of or develop its own internal procedures to verify system compliance. Typically engineering departments would already have suitable processes in place to enable the system to be verified against the MoC (see Section 4) considering the above aspects. It must be noted that before the verification process begins, these guidelines recommend that the EATMN representation (see Section 3) is prepared and submitted to the national supervisory authority for agreement (see Annex D for an example of an EATMN representation). In the absence of a standard process to organise and perform the necessary verification tasks, an approach is developed in Annex F.

The consolidated results and evidence obtained in these steps should be captured in the technical file and declared in the DoV (see Section 7).

6.3.2 Use of a notified body

Notified bodies will be requested to intervene in the verification of systems when it is explicitly required by implementing rules. On their initiative, manufacturers and air navigation service providers may also involve a notified body to perform verification tasks.

In general, implementing rules for interoperability require air navigation service providers to subcontract system verification tasks to notified bodies when they do not fulfil certain conditions specified in those implementing rules (e.g. Article 8(2) of Regulation (EC) 1032/2006 [11]).

6.4. Documents supporting a TF

Once the verification activities described above have been carried out, the material and evidence will be consolidated in a technical file in accordance with Annex IV of the interoperability Regulation.

The TF should be supported by the following documents:

- The verification results, typically including test plan, test specification and test results.
- The technical specifications and Community specifications used as the MoC.
- The certificate(s) of conformity of the notified bodies (if used).
- The EC declaration of conformity (DoC) or of suitability for use (DSU) of constituents.

Technical specifications and Community specifications do not need to be included in the technical file and may instead be referenced. The verification results, certificate of conformity and DoC/DSU must all be included as part of the technical file that is submitted to the national supervisory authority (NSA).

This file will be produced under the authority of the air navigation service provider and will provide proof of compliance with the applicable requirements and will be attached to the EC declaration of verification for the concerned EATMN system.

7 COMPLETING A DECLARATION OF VERIFICATION (DOV)

Having executed the verification procedure (see Section 6.3) and consolidated the results and evidence into the technical file (see Section 6) the EC declaration of verification (DoV) shall be established thereby confirming that the defined EATMN system (see Section 3) being put into service has been verified to meet the applicable regulatory baseline and MoC baseline (see Section 4). The EC declaration of verification (DoV) is a formal document that must be submitted to the national supervisory authority. The following sections provide guidance on:

- The contents of a DoV.
- The procedure for developing a DoV.

7.1. Contents of a DoV

The DoV must be separate to the technical file and must, according to Annex IV of the interoperability Regulation [1] contain the following:

- **References**, including title and number, to the applicable regulations (e.g. regulatory baseline).
- **Name and full registered address of the air navigation service provider** and the location address of the system if different.
- **Brief description of the system** based on the EATMN representation including the identification of any pre-existing system parts that will be connected to the new installation such as antenna or display.
- **Description of the procedure followed** in order to declare conformity of the system. This self-declaration should describe the process followed, from design requirement, to constituent testing, installation design and integration testing to confirm that the system and constituents meet the applicable regulatory baseline.
- If applicable, the name and address of the **notified body** that carried out verification tasks.
- **Reference to the TF** and the references of the documents contained in the TF.
- Where appropriate, **reference to relevant Community Specifications** or where none exist, reference to any relevant **recognised compliance documentation** such as ICAO, EUROCONTROL or EUROCAE documents that support the declaration.
- All of the **relevant temporary or definitive provisions** to be complied with by the systems and in particular, any operating restrictions or conditions of use.
- If temporary, the **duration of validity of the EC declaration** or a statement that it is unlimited, as determined by the air navigation service provider.
- **Date and signature** along with identification (including position and title) of signatory empowered to enter into commitments on behalf of the air navigation service provider.

Links to a DoV template are provided in Annex C.

7.2. Procedure for developing a DoV

7.2.1 Development of the EC declaration of verification of system

Once the technical file is drawn up, the EC declaration of verification of system will be produced under the authority of the air navigation service provider, and in principle in compliance with the template referred by Annex C of these guidelines.

The DoV relies on the following inputs from the TF:

- The brief description of the system (as developed under Section 3).
- A description of the conformity assessment baseline including references to EC regulations.
- The description of the procedure followed in order to declare conformity of the system (as carried out when compiling the TF).
- Certificates of notified bodies.
- The references of the documents contained in the technical file.
- The relevant temporary or definitive provisions to be complied with by the systems.

7.2.2 Submission to the national supervisory authority (NSA)

At the end of the process, the air navigation service provider must have produced under its authority an EC declaration of verification of systems with the corresponding technical file, which will be sent to the national supervisory authority before putting the system into service. It is to be noted that some air navigation service providers may have more than one national supervisory authority. Any additional national requirements such as ‘operational approvals’ can be combined with the EC declaration of verification of system.

These guidelines recommend that air navigation service providers submit their EC DoV to their national supervisory authority 1 month (30 days) prior to the planned date for putting the system into service. The submission period can be shortened for time-critical procedures that are agreed with the national supervisory authority.

For major systems that are developed over a long period, early contact should be established between the air navigation service provider and their national supervisory authority and regular communication should be maintained throughout the entire system development phase. To facilitate this interaction, intermediate document parts such as the EATMN representation (see Section 3) can be submitted to the national supervisory authority.

7.2.3 Period of validity

The period of validity of the EC declaration of verification of systems will be linked to the life cycle of the concerned system. Therefore it will be case specific.

8 CONFORMITY ASSESSMENT MAINTENANCE

8.1. Introduction

In line with Annex IV (4) of the interoperability Regulation [1], these guidelines recommend that the air navigation service provider keeps all conformity assessment material (EC declarations, technical files, accompanying files, certificates) throughout the full service life of the EATMN system. Concerning EATMN constituents, these guidelines recommend that the manufacturer keeps all conformity assessment material (EC declarations, accompanying documents, certificates and any other supporting technical documentation) for a period ending at least 10 years after the last manufactured constituent has been put into service. It is to be noted that the period, for which manufacturers and/or notified bodies are to keep any kind of documentation, can be a regulatory requirement of relevant implementing rules for interoperability (e.g. Regulation (EC) No 1265/2007 Annex III.B.2), the modules used for conformity assessment or other relevant EU Regulations.

Within that period, maintenance of conformity assessment material will be necessary as a result of cases such as:

- Expiration of certificates issued by notified bodies[10] or temporary declarations[11].
- Modification of the conditions of use as detailed in a DoC/DSU.
- System upgrade.
- Corrective actions, triggered by national supervisory authorities, relating to measures of safeguard (Article 7 (5) and (6) of the interoperability Regulation).

Guidance on the case of system upgrade is presented in this section, complemented by Annex G.

8.2. Maintaining the EC declaration of conformity or suitability for use

Under normal circumstances, once the EC declaration of conformity or suitability for use is completed for a constituent that is placed on the market, there is no reason for the manufacturer to update the declaration unless it depends on time-limited certificates or if the conditions of use of the constituent are modified.

However, in view of the duration of procurement projects, it is good practice that the manufacturer re-assesses the baseline for conformity assessment applicable to its constituent at the beginning of each new procurement project and/or before the constituent is 'put into service' which is defined in Article 2 (33) of the framework Regulation [6] as *"the first operational use after the initial installation or an upgrade of a system"*. When changes are identified, the EC declaration of conformity or suitability of use must be updated.

8.3. Maintaining the EC declaration of verification of system following a system upgrade

8.3.1 Purpose

The process described in the Sections 3 to 7 assumes that the system is undergoing initial installation. For an existing system that is being 'upgraded', maintenance of the conformity assessment material will be necessary.

The framework Regulation [6] Article 2 (40) defines an upgrade as *"any modification that changes the operational characteristics of a system"*.

So to determine whether or not a system has been 'upgraded' requires the air navigation service provider to establish whether or not the operational characteristics of the system have changed. If

[10] Annex III (3) of the interoperability Regulation [1]

[11] Annex IV (1) of the interoperability Regulation [1]

it is deemed that operational characteristics have changed, then the air navigation service provider is responsible for re-submitting the EC declaration of verification and the updated technical file to the national supervisory authority before putting the upgraded system into service.

A process for determining changes to a system's operational characteristics along with the subsequent impact of those changes is described in the following sections.

8.3.2 Identifying changes to a system's operational characteristics

If the 'operational characteristics' of the system change then the air navigation service provider is required to update the EC declaration of verification (DoV) and the technical file, other changes will at least require an update of the technical file (TF).

Determining whether or not a system's operational characteristics have changed can be achieved by undertaking a cascaded analysis of the system characteristics from the following three perspectives:

- Regulatory perspective
- Engineering perspective
- End-user perspective

These three perspectives are illustrated below in Figure 8.

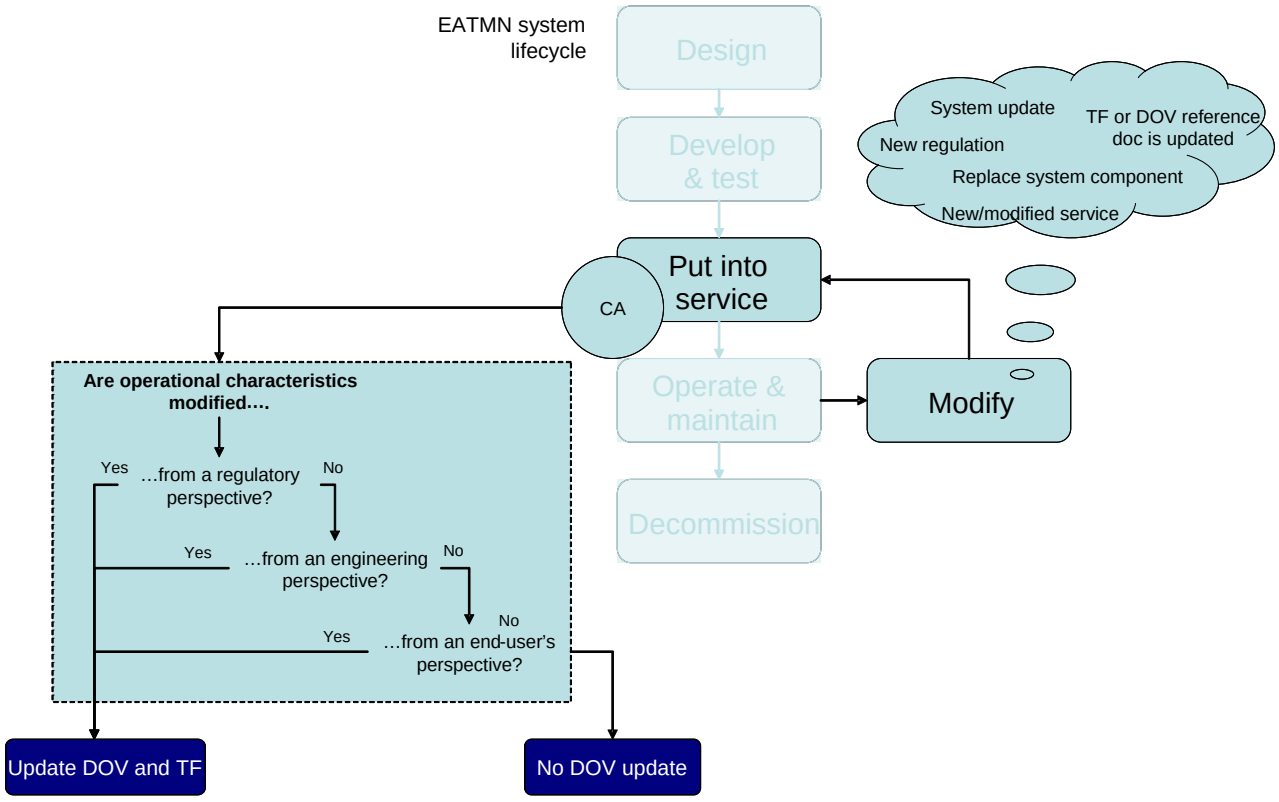

Figure 8: Determining operational characteristics

In the first perspective, changes are considered in terms of how they affect the baseline for conformity assessment that was established when the system was initially put into service (see Section 4); for example changes that introduce new regulatory elements or functionality that requires an extension of the existing regulatory baseline.

All changes that introduce a new statement of compliance against the baseline for conformity assessment or that modify an existing statement of compliance against that baseline, will affect the system's operational characteristics and thus necessitate a DoV update. In general, if the means of

compliance (MoC) to the regulatory baseline (as described in Section 4.3) is changed without affecting the regulatory baseline itself (for example by implementing a new or extended version of a technical specification) then the operational characteristics of the system will not have changed. This would mean that only the technical file (in which the MoC is identified) will need to be updated and not the DoV.

If the system change does not affect the baseline for conformity assessment then the engineering perspective is considered.

The second and third perspectives, the engineering and end-user perspectives, consider situations where air navigation service providers introduce change to EATMN systems without a change to the regulatory baseline, for example:

- replacement of an obsolete asset;
- move an existing service to a new location;
- change the means of compliance (MoC) e.g. implement the latest revision of a technical specification;
- upgrade of an existing system (hardware and/or software) to improve the service offered;
- upgrade of system management capabilities;
- extend a service, for example by extending radar coverage;
- increase of the maximum number of sectors to be handled by the system.

It may also be a change to the EATMN representation, for example to add or remove a constituent. In either case, the impact on operational characteristics should be considered firstly from an engineering and then from an end-user perspective.

The engineering perspective is only analysed if there is no change to the regulatory baseline. From the engineering perspective, operational characteristics are defined by the functionality, performance, user interaction and composition of the system such that:

- A system change that modifies system requirements, i.e. *what* the system must do, infers a change to operational characteristics. For example the addition of a constituent that increases the system functionality.
- A system change that modifies only design requirements, i.e. *how* the system must meet the system requirements; or test requirements, i.e. *whether* the system meets its requirements; does not infer a change to operational characteristics. For example replacing a constituent with another constituent of equivalent functionality.

The end-user perspective is only analysed if there are no significant changes from the engineering perspective. In this way the end-user perspective becomes a final check before determining if operational characteristics have not changed and thus a DoV update is unnecessary.

From an end-user (controller/airspace user) perspective, operational characteristics are defined solely by the services offered by systems. The system's operational characteristics are thus changed if it results in a change to the service perceived at the controller/airspace user level.

The air navigation service provider must therefore review the impact of a change on all elements of the DoV and update the relevant elements of the TF. Further details of how to apply each perspective are provided in Annex G.

8.4. Maintaining the technical file

Following any system change described in Section 8.3.2, a decision to not update the DoV must still result in an update of the TF to maintain consistency with the actual implementation. The air navigation service provider must therefore review the impact of a change on all elements of the TF and determine the extent to which each must be updated.

For example, a change to a test specification in the technical file might increase the test coverage of the system without affecting any of the reference documents or the declaration itself. For this purpose, it would be good practice to capture TF changes that do not require a DoV update by means of a file sub-version number, to ensure that the TF content is always consistent with the actual implementation.

ANNEX A: ACRONYMS

ACC	Area Control Centre
AIS	Aeronautical Information Service
AMAN	Arrival Manager
APP	Approach Unit
APW	Area Proximity Warning
ASM	Airspace Management
ATFM	Air Traffic Flow Management
ATM	Air Traffic Management
ATS	Air Traffic Services
CA	Conformity Assessment
CFMU	Central Flow Management Unit
COM	Communications
CS	Community Specification
DG	Directorate General
DMEAN	Dynamic Management of the European Airspace Network
DoC	Declaration of Conformity
DoV	Declaration of Verification
DSU	Declaration of Suitability of Use
EAD	European AIS Database
EASA	European Aviation Safety Authority
EC	European Commission
ECAC	European Civil Aviation Conference
ED	EUROCAE Document
EMC	Electromagnetic Compatibility
EN	European Standard
ER	Essential Requirement
FAQ	Frequently Asked Questions
FDPS	Flight Data Processing System
FPL	Filed Flight Plan
GAT	General Air Traffic
ICAO	International Civil Aviation Organization
IFPS	Integrated Initial Flight Plan Processing System
IOP	Interoperability
IR	Implementing Rule
LVD	Low Voltage Directive

MET	Meteorological
MSAW	Minimum Safe Altitude Warning
NAV	Navigation
NSA	National Supervisory Authority
OJ	Official Journal
R&TTE	Radio & Telecommunications Terminal Equipment
RDPS	Radar Data Processing System
RFS	Radar Fallback System
ROHS	Restriction of Hazardous Substances
RPL	Repetitive Flight Plan
RVSM	Reduced Vertical Separations Minima
SARP	Standard and Recommended Practice
SDPS	Surveillance Data Processing System
STCA	Short Term Conflict Alert
SUR	Surveillance
TF	Technical File
TREN	Transport and Energy
TWR	Tower Unit
WEEE	Waste Electrical and Electronic Equipment

ANNEX B: REFERENCES

1. Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation)
2. Regulation (EC) No 1070/2009 of 21 October 2009 amending Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004 and (EC) No 552/2004 in order to improve the performance and sustainability of the European aviation system
3. Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards (85/C 136/01)
4. Council Resolution of 21 December 1989 on a global approach to conformity assessment (90/C 10/01)
5. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC
6. Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation)
7. Regulation (EC) No 550/2004 of the European Parliament and of the Council of 10 March 2004 on the provision of air navigation services in the single European sky (the service Regulation)
8. DG/TREN position paper - Conformity assessment of Constituents – SSC/08/28/5
9. Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC
10. DG/TREN “Application of the interoperability Regulation (EC) N° 552/2004 to legacy system of European ATM network from 20 April 2011 (amended version of 4 September 2008)”
11. Regulation (EC) No 1032/2006 of 6 July 2006 laying down requirements for automatic systems for the exchange of flight data for the purpose of notification, coordination and transfer of flights between air traffic control units
12. Regulation (EU) No 1034/2011 of 17 October 2011 on safety oversight in air traffic management and air navigation services and amending Regulation (EU) No 691/2010
13. Regulation (EU) No 1035/2011 of 17 October 2011 laying down common requirements for the provision of air navigation services and amending Regulations (EC) No 482/2008 and (EU) No 691/2010
14. Regulation (EC) No 1108/2009 of the European Parliament and of the Council of 21 October 2009 amending Regulation (EC) No 216/2008 in the field of aerodromes, air traffic management and air navigation services and repealing Directive 2006/23/EC
15. European Air Traffic Management Master Plan, Edition 1 - 30 March 2009
16. Regulation (EC) No 633/2007 of 7 June 2007 laying down requirements for the application of a flight message transfer protocol used for the purpose of notification, coordination and transfer of flights between air traffic control units

ANNEX C: WEB RESOURCES

This Annex provides access to CA related resources on the EUROCONTROL and European Commission Web sites. The main web resources are maintained by the European Commission (http://ec.europa.eu/transport/air/single_european_sky/single_european_sky_en.htm) and EUROCONTROL (http://www.eurocontrol.int/conformity).

C.1 Frequently Asked Questions

http://www.eurocontrol.int/ses/public/faq/catf_faq.html

Provides a FAQ on Conformity Assessment which is updated regularly by EUROCONTROL is response to questions from stakeholders.

C.2 SES Framework Regulation

Regulation (EC) No 549/2004 of the European Parliament and Council laying down the framework for the creation of the single European sky

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0549:EN:NOT

The framework Regulation, supported by three other Regulations (service provision, airspace and interoperability) is designed to create a European Airspace conceived and managed as a single continuum (the Single European Sky - SES) to optimise the safety and efficiency of the European Air Traffic Management Network (EATMN).

Regulation (EC) No 550/2004 of the European Parliament and Council on the provision of air navigation services in the single European sky

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0550:EN:NOT

This Regulation sets out an authorisation system, compliance review mechanism and revised payment arrangements for the provision of air navigation services within the community.

Regulation (EC) No 551/2004 of the European Parliament and Council on the organisation and use of airspace in the single European sky

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0551:EN:NOT

This Regulation sets out a mechanism to establish a single coherent Community airspace with common design, planning and management procedures.

Regulation (EC) No 552/2004 of the European Parliament and Council on the interoperability of the European Air Traffic Management network

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0552:EN:NOT

This Regulation is designed to achieve interoperability between the Community's air navigation service providers and the creation of an internal market in equipment, systems and associated services.

Regulation (EC) No 1070/2009 of the European Parliament and Council amending Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004 and (EC) No 552/2004 in order to improve the performance and sustainability of the European aviation system

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R1070:EN:NOT

This Regulation amends Regulations (EC) No 549/2004 (the framework Regulation), (EC) No 550/2004 (the service provision Regulation), (EC) No 551/2004 (the airspace Regulation) and (EC) No 552/2004 (the interoperability Regulation).

Regulation (EU) No 1035/2011 laying down common requirements for the provision of air navigation services and amending Regulations (EC) No 482/2008 and (EU) No 691/2010

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R1035:EN:NOT

This Regulation lays down in detail the Common Requirements for air navigation service provision (includes ATS, Met Services, AIS and CNS/ATM provision).

C.3 Latest status of implementing rules

http://ec.europa.eu/transport/air/single_european_sky/implementing_rules_en.htm

Provides an up to date list of current IRs along with the status of those under development.

C.4 Latest status of Community specifications

http://ec.europa.eu/transport/air/single_european_sky/community_specifications_en.htm

Provides an up to date list of current CSs along with the status of those under development.

C.5 List of notified bodies

http://ec.europa.eu/enterprise/newapproach/nando/index.cfm

Provides an up to date list of notified bodies under the interoperability Regulation

C.6 ATM Guidance on the R&TTE Directive

http://ec.europa.eu/enterprise/sectors/rtte/documents/guidance/aeronautical/index_en.htm

Provides a short document containing advice to the application of the R&TTE directive within ATM.

C.7 Conformity Assessment Templates

http://www.eurocontrol.int/ses/public/standard_page/ca_guidance.html

Provides templates for: DoC, DSU and DoV.

C.8 Template matrix for documenting evidence of compliance

http://www.eurocontrol.int/ses/public/standard_page/ca_guidance.html

Provides a compliance matrix, in the form of a template, on the type of evidence to support a demonstration of compliance to the essential requirements of the interoperability Regulation.

C.9 Example constituents for the CNS domain

http://www.eurocontrol.int/ses/public/standard_page/ca_list_example_constituents.html

Provides an example list of CNS equipment that could be considered as an EATMN constituent along with a list of applicable standards that could form part of the MoC.

ANNEX D: EXAMPLES OF EATMN REPRESENTATIONS

D.1 Introduction

Section 3 presented the need to develop an EATMN representation to map air navigation service provider resources in terms of EATMN systems and constituents. This representation may also be adopted by manufacturers as their products may be composed of several constituents.

When establishing such representations, air navigation service providers must consider constraints in terms of interoperability interfaces identified by EC regulations (e.g. COTR [11] is applicable between air traffic service units) and the notion of putting into service. Furthermore, it has been recognised that this approach may not be suitable for distributed systems such as surveillance.

To provide examples of EATMN representations, an example list of constituents complementing the four[12] EATMN constituents is required. Manufacturers and air navigation service providers are entitled to consider such objects as formal constituents of their system or product [8].

D.2 Example list of constituents

This section presents a non-exhaustive example list of constituents that are not defined in implementing rules or Community specifications, complemented by a brief functional description. The level of granularity should be meaningful for both manufacturers and air navigation service providers to support the preparation of their EATMN representations and the required EC declarations. Some of these example constituents may be considered by the ANSP as an EATMN system when developing their EATMN representation.

Example Constituent	Description	Main Functions
AIS	*Aeronautical Information System*	The Aeronautical Information System collects and manages both static and dynamic Aeronautical Information in support of the activities of the NOTAM Office (NOF) of a country and the Briefing Offices (BOF) at airports, in full compliance with ICAO rules.
AIP	*Aeronautical Information Publication*	The Aeronautical Information Publication system manages static Aeronautical Information (Static AIP information and amendments). The AIP supports the production of Aeronautical Publication at country scale (AIP, Amendments, AIP Supplements and AIC) including the related Aeronautical maps, in full compliance with ICAO rules.
AMAN	*Arrival Manager*	Arrival manager (AMAN) is a helping tool which role is to provide sequencing and metering capability for the optimal use of airport runway(s). AMAN computes optimised arrival flight sequences for a managed TMA according to a selected TMA configuration and delivers the appropriate action apportionments to flights (TTL/TTG) to the relevant ACC.
APW	*Area Proximity Warning*	APW provides a warning to the Air Traffic Controllers whenever a violation of a permanent or temporary restricted area is predicted within a parameter time or is already taking place.
A-SMGCS	*Advanced Surface Movement Guidance and Control System*	A-SMGCS is responsible for elaboration and distribution of ground movements' surveillance information at airports. A-SMGCS monitors all ground movements of vehicles and aircraft in order to prevent conflict and congestion situations. A-SMGCS is an example ATM product that can be represented in terms of as multiple constituents; two of which are defined in Community specifications.
CDT	*Conflict Detection Tools*	Conflict Detection Tools are automated decision support tools supporting conflict detection between flights in a number of look-ahead horizons

[12] At the time of writing two constituents are defined in implementing rules: Voice Channel Spacing (EC Regulation No 1265/2007) and the Mode S interrogator codes (EC Regulation No 262/2009). Other constituents are defined in the A-SMGCS Level 1 Community specification (EN 303 213-1) and the Data Link Services (DLS) System Community specification (EN 303 214).

Example Constituent	Description	Main Functions
		encompassing planning and tactical horizons.
AGDPS	*Air/Ground Data Processing Server*	The Air/Ground Data Processing Server (AGDPS) hosts the Data-Link applications and support the interface with the ground ATM system (association with Flight Plan data and connexion with the CWPs).
DMAN	*Departure Manager*	Departure Manager (DMAN) is a helping tool which role is to compute departure sequence matching ATFCM, CDM and TMA constraints, as well as minimising the aircraft delays, by providing the controllers with suggestions (Runway, Holding Point and SID) and alerts (ATFCM or CDM time schedule adherence) to manage the departure streams according to the dynamic airport configuration.
FDPS	*Flight Data Processing System*	The Flight Data Processing System is responsible of the core flight data processing. • Initial flight plan processing, • Flight data management and distribution, • SSR codes management, • Trajectory prediction, • Coordination and transfer and the flight message transfer protocol
Monitoring Aids	*Monitoring Aids*	The Monitoring Aids are responsible for flight plan conformance monitoring which detects deviations from the system trajectory and generates warnings whenever a flight is deviating from its system trajectory (laterally, vertically or longitudinally).
MSAW	*Minimum Safety Altitude Warning*	MSAW provides an alert to the Air Traffic Controllers whenever a system track is predicted to infringe the relief or to infringe the Minimum Safe Altitude Warning above a relief or obstacle.
ODS	*Operational Display System*	The Operational Display System provides advanced HMI functions to the following operator roles: • Air Traffic Controllers (ACC/APP/TWR), • Operational Supervisor, • Flight Data Operator. ODS supports the following main capabilities: • Input facility, • Air Situation Display facilities, • Graphic facilities, • Electronic strip facilities, • Flight plan management facilities, • Alarm and warning facilities, • Operational Data management that enables the operational supervisor to perform specific functions.
Operational Supervision	*Operational Supervision*	The Operational Supervision provides support to manage the Operational configuration of a Centre. It associates roles with responsibilities and provides dynamic mapping of the Controllers workstations. It manages and distributes frequency plans used by an ATC centre, and the holding areas of an ATC centre. It allows the Operational Supervisor to manage the various sectorisation plans that can exist in the system and provides the facility to change them on-line according to the traffic. It performs collapse, de-collapse and transfer of functional sectors according to the sectorisation plan and distributes flight data accordingly.
RDPS	*Radar Data Processing System*	The Radar Data Processing System is the main resource for processing and display of air situation information to the CWPs. The RDPS receives and merges surveillance information from different sources and performs co-ordinate conversion, plot processing (including filtration) and multi-radar tracking to generate positional data for aircraft. The

Example Constituent	Description	Main Functions
		RDP enables monitoring and control of the system (configuration and registration management). The RDPS distributes system tracks to Controllers Work Positions.
RFS	*Radar Fallback System*	The Radar Fallback System is the fallback resource for processing and display of air situation information to the CWPs in emergency system mode via a separate LAN in case of failure of the RDPS and/or in case of failure of the operational main LAN. The RFS processes radar sensors data for track elaboration and track update: the RFS receives plots, combined plots and tracked plots from primary and secondary radars and processes these data to create and maintain mono-radar tracks and multi-radar tracks corresponding to real aircraft. The RFS distributes multi-radar tracks.
STCA	*Short Term Conflict Alert*	STCA provides an alert to the Air Traffic Controllers whenever, at the same time, the safe vertical and horizontal separation between aircraft are predicted to be violated within a parameter time.
Workload Monitoring	*Workload Monitoring*	The Workload Monitoring function provides the operational supervisor with information about the current and predicted workload in the centre. It enables decisions about task distribution to sectors and the management of sectorisation.

A complementary listing of example constituents for communications, navigation and surveillance can be found at Annex C.

D.3 Association of constituents to EATMN systems

This section illustrates the association between the above listed constituents and three EATMN systems specified in the interoperability Regulation [1]. It is to be noted that none of the above refine the EATMN system for airspace management or EATMN systems for the use of meteorological information. Concerning communications, navigation and surveillance, refer to Annex C.

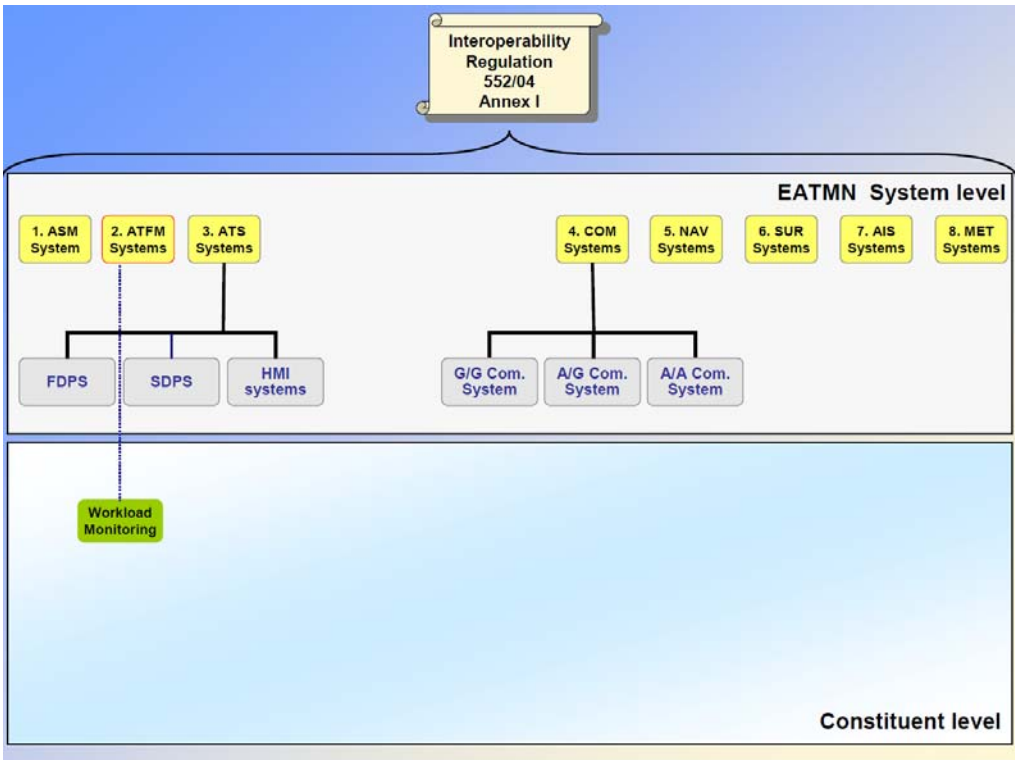

Figure 9: EATMN system for air traffic flow management

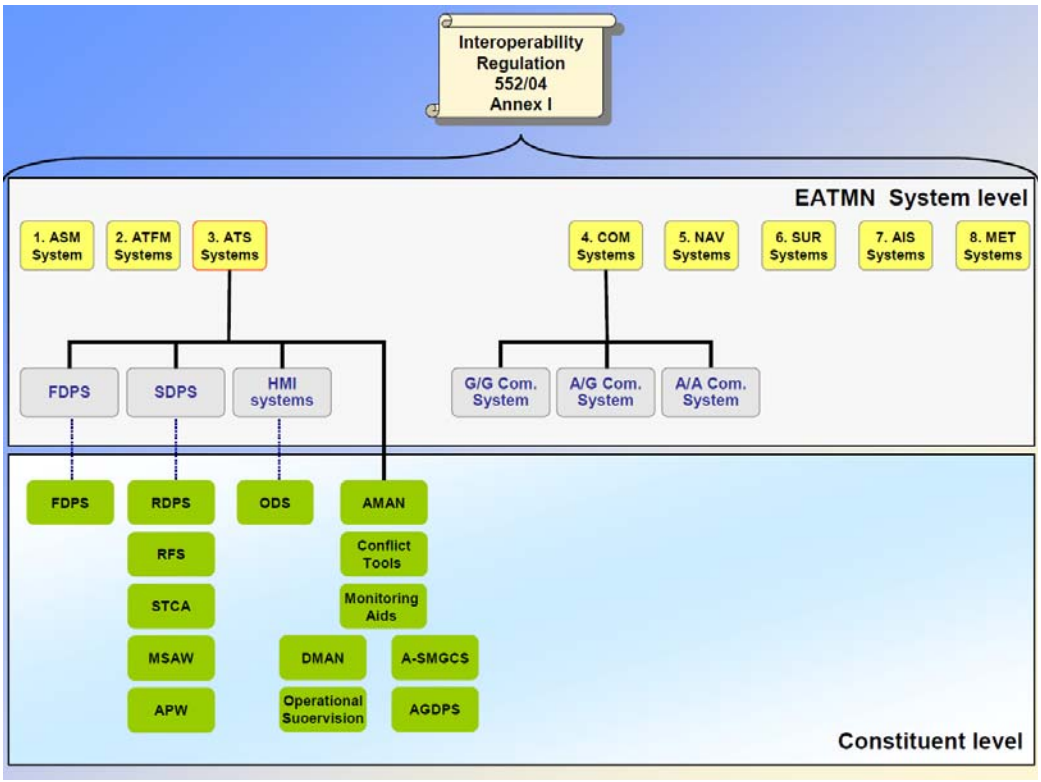

Figure 10: EATMN system for air traffic services

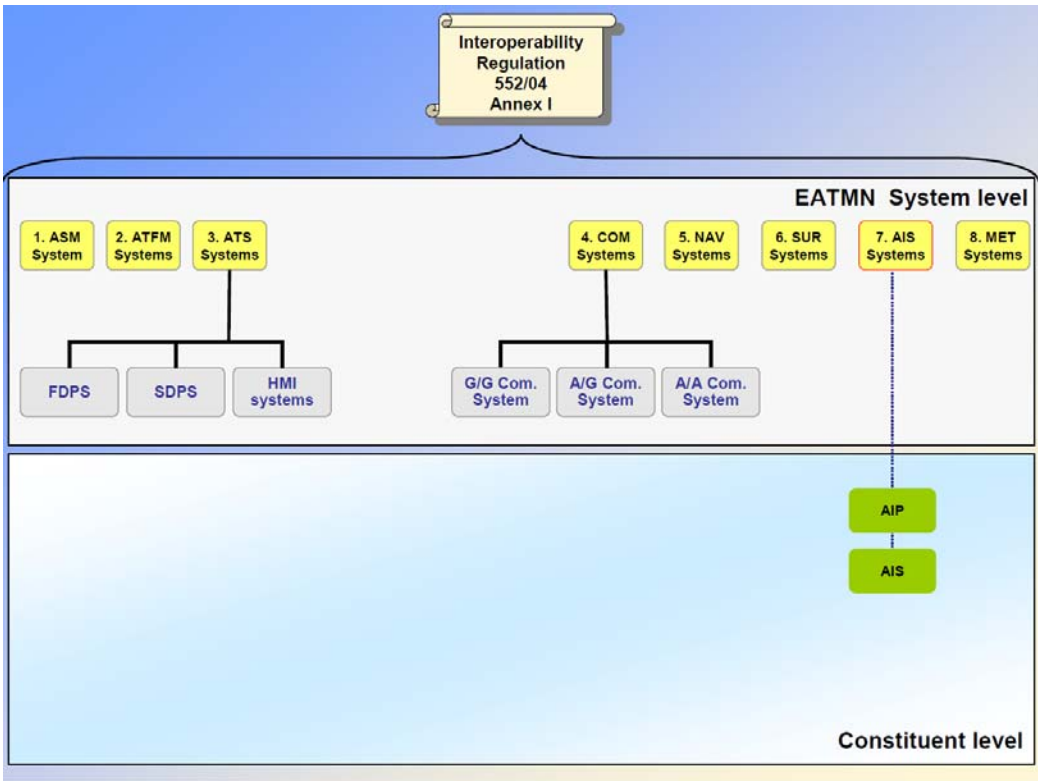

Figure 11: EATMN system for aeronautical information services

D.4 Examples of EATMN representations

This section presents three examples of EATMN representations combining EATMN systems and constituents. The first, illustrates the representation of an air traffic control en-route area control centre (ACC), the second illustrates the representation of an air traffic control tower system and the third illustrates the representation of two ATM products.

In the second and third examples, different colours are used providing visibility of EATMN constituents defined in implementing rules and/or Community specifications (orange) versus those that are identified by the manufacturers and air navigation service providers (green).

In all examples, an intermediate layer is inserted to name the product or operational system that is being put into service.

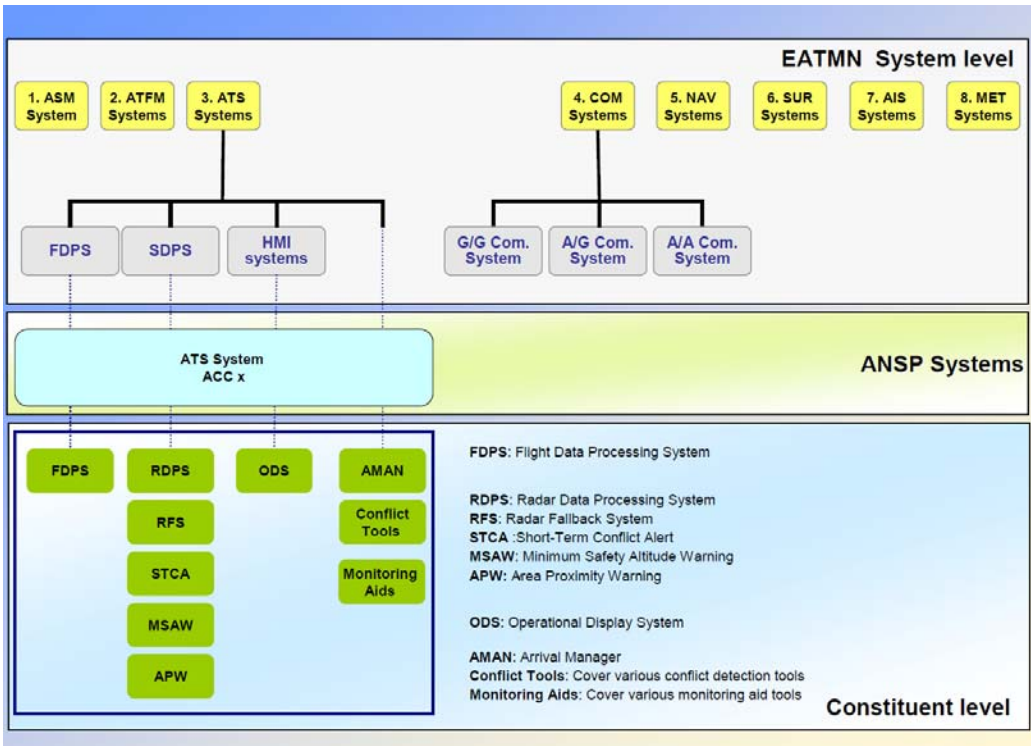

Figure 12: EATMN representation of an area control centre (ACC)

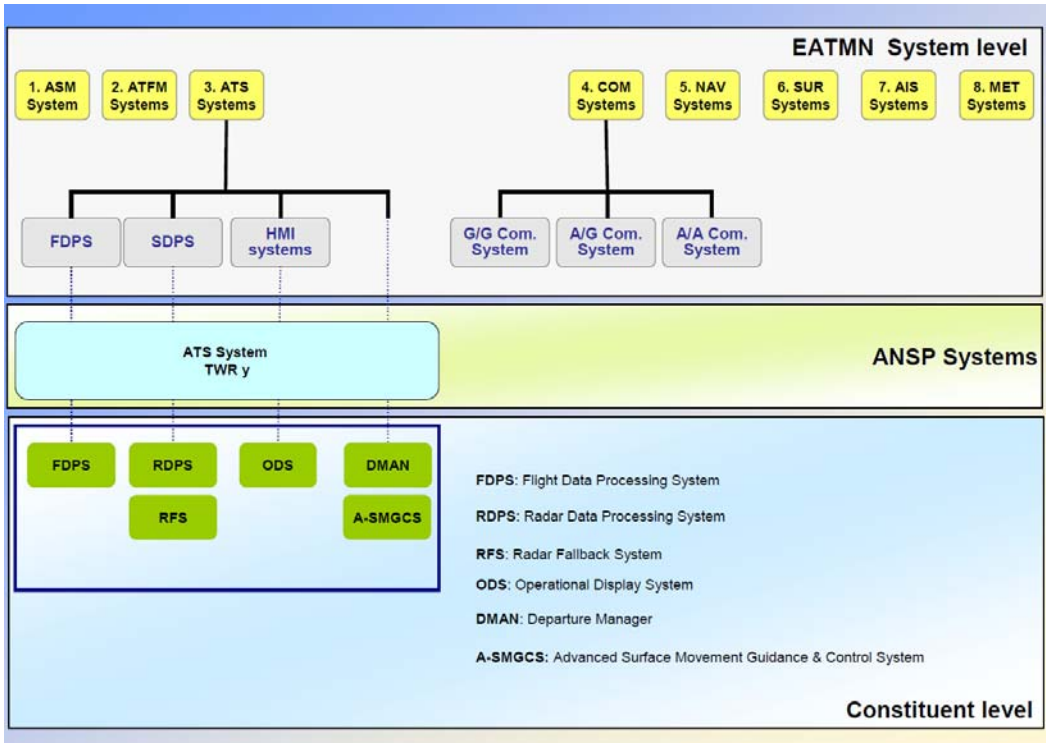

Figure 13: EATMN representation of a tower (TWR)

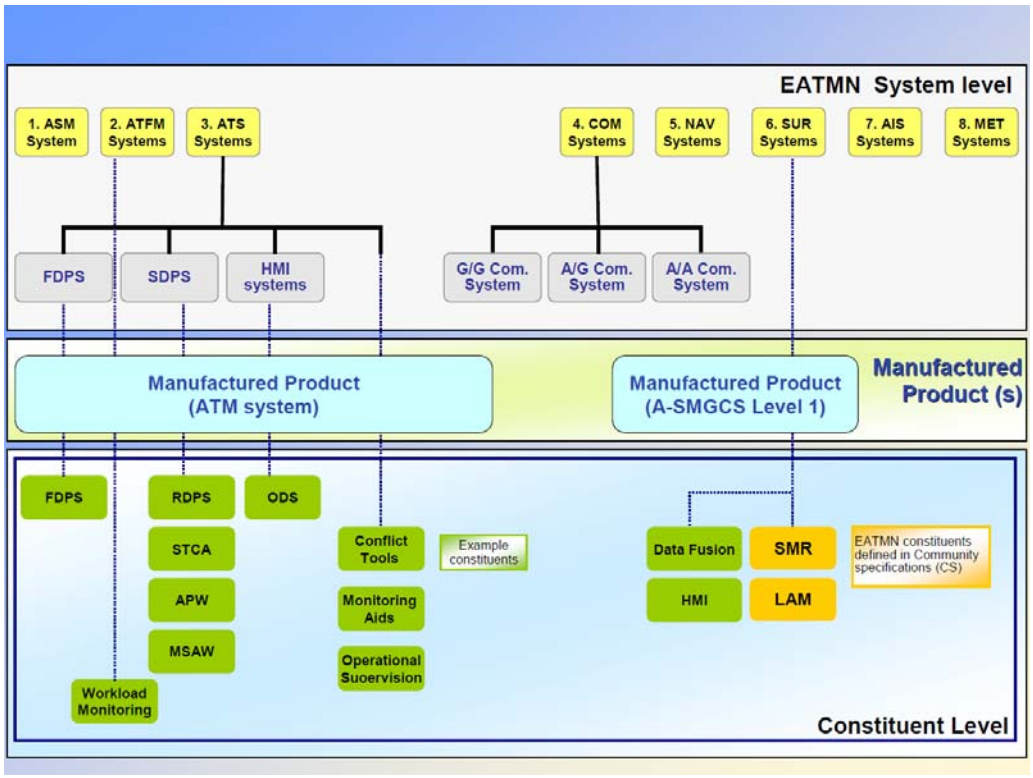

Figure 14: EATMN representation of an ATM product

D.5 Documenting the EATMN representation

The air navigation service providers (and manufacturer) can list their own resources (and product parts) in a similar tabular format as presented above. This is to be complemented by a graphical representation in which these resources are mapped to EATMN systems and constituents for a given operational system, product portfolio or product configuration.

This representation can be appended to the technical file of the EC declaration of verification (DoV).

ANNEX E: INTERPRETATIONS OF ESSENTIAL REQUIREMENTS

Seven essential requirements are described in Annex II of the interoperability Regulation [1]: seamless operation, support for new concepts of operation, safety, civil-military coordination, environmental constraints, principles governing the logical architecture of systems and principles governing the construction of systems. This Annex provides further explanations about these high level essential requirements to clarify the verification of compliance of systems and constituents with these requirements.

As implementing rules can complement and refine essential requirements, in particular in terms of safety, seamless operation and performance, they contribute to their interpretation. Equally, by defining the technical and operational conditions to meet essential requirements, Community specifications contribute to their interpretation. In addition, certificates issued in accordance with Regulation (EC) No 216/2008 applicable to EATMN constituents or systems can include a demonstration of compliance with the essential requirements thereby contributing to their interpretation (see Section 2.3.4).

Below the essential requirements are labelled 'ER' and numbered according to Annex II, Part A of the interoperability Regulation.

ER1: Seamless operation

ER1 is a general requirement applicable to all EATMN systems and constituents. It is likely that all implementing rules and Community specifications for interoperability support this essential requirement. The framework Regulation [6] defines seamless operation as "*the operation of the EATMN in such a manner that from the user's perspective it functions as if it were a single entity*".

Seamless operation of the EATMN, at all times and for all phases of flight, is expressed in terms of: information-sharing, operational status information, common understanding of information and comparable operational performances. More specifically for the flight data processing system, the essential requirement explicitly makes reference to an "agreed and validated operational concept" to ensure safe, smooth and expeditious processing throughout EATMN. It is to be noted that seamless operation clearly encompasses airborne and ground systems and constituents and is not limited to interoperability between ground systems; in this context the data link services implementing rule is good example of the scope of this essential requirement.

ER2: Support for new concepts of operation

ER2 is a general requirement applicable to EATMN systems and constituents which support new concepts of operation such as collaborative decision-making, increased automation and alternative methods of delegation of separation responsibility. It is to be noted that WP-B of the SESAR Joint Undertaking will define a target concept of operation that will further assist in the development of new concepts of operation.

Since the adoption of SES II, the essential requirement is also required to support improved sustainability of ATM; ANSPs should demonstrate how their systems integrate new concepts of operation that reduce their environmental impact and promote sustained development.

As described in the interoperability Regulation, Annex II, Part B as amended by Regulation (EC) No 1070/2009 [2], the application of new concepts of operation envisaged by the ATM Master Plan [14] for FDPS, SDPS and communication systems can also be considered as a contribution to the achievement of this essential requirement.

In the short-term, the Dynamic Management of the European Airspace Network (DMEAN) implements the cornerstone functions of network management concept and can be considered as a contribution to the achievement of ER2. In addition, the coordinated deployment of data link services involving ANSPs, airline operators, manufacturers and communication service providers is another example contributing to the achievement of this essential requirement.

ER3: Safety

ER3 is a general requirement applicable to all EATMN constituents and systems. Implementing rules for interoperability do not really refine ER3. In general, they restate the obligation of developing a safety assessment prior to the initial installation and the implementation of system changes, however, it is to be noted that some implementing rules contain safety-related requirements. The development of a safety assessment for an EATMN constituent or system can be considered as a contribution to the achievement of compliance with ER3. Furthermore, as ER3 requires systems to be designed, built, maintained and operated to be free from harmful interference, compliance with the R&TTE and EMC directives can also be considered as a contribution to the achievement of this essential requirement.

ER4: Civil-military coordination

ER4 is a general requirement applicable to those EATMN systems and constituents that provide interoperability between civil and military systems. The implementing rules on coordination and transfer [11] supported by the flight message transfer protocol [16] already refine this essential requirement in terms of automatic exchanges of flight data for the purpose of civil-military coordination between EATMN flight data processing systems. The Dynamic Management of the European Airspace Network (DMEAN) stakeholder actions plan (issued in April 2008) defines an incremental implementation plan involving civil-military coordination. An upgrade of EATMN systems which contributes to implement the DMEAN stakeholder action plan can also be considered as a contribution to the achievement of compliance with ER4.

ER5: Environmental constraints

ER5 is a general requirement applicable to all EATMN constituents or systems. Until now, ER5 has not been “refined” by further requirements in terms of implementing rules. ESSIP implementation objectives ENV01 and ENV02 are accepted by the EATMN community in respect of environmental matters. Both objectives refer to Directive 2003/30/EC on “the establishment of rules and procedures with regard to the introduction of noise-related operating restrictions at Community airports” and Directive 2008/50/EC on ambient air quality. An upgrade of EATMN systems which contributes to implement ESSIP objectives related to environment can be considered as a contribution to the achievement of ER5. Furthermore, as ER5 requires systems to minimise their environmental impact, compliance with the RoHS and WEEE directives can also be considered as a contribution to the achievement of this essential requirement.

ER6: Principles governing the logical architecture of systems

ER6 is a general requirement applicable to all EATMN systems. The ER is applicable to the logical architecture of systems and not of constituents. Until now, there is no common validated logical architecture of ATM systems. SWIM/ Flight object will be the cornerstones for new generation of ATM systems and integral elements of the future SESAR architecture developed within WP-B of the SESAR Joint Undertaking.

The verification of compliance with ER6 should focus on the capability of the EATMN system to accept evolution and in particular to meet performance requirements. ANSPs should provide performance characteristics achieved by the EATMN system and demonstrate that those performances are appropriate for the target operational environment with the traffic evolution forecast. In the short-term, the ANSP’s proprietary architecture and performance indicators can be referenced (e.g. number of aircraft, number of controller stations, number of messages) can be considered as evidence of compliance with ER6.

ER7: Principles governing the construction of systems

ER7 is a general requirement applicable to, all EATMN systems. The ER is applicable to the construction of systems and not of constituents. Until now, there is no common validated technical architecture of ATM systems relating to system/constituent modularity, redundancy, high availability and fault-tolerance. However, manufacturers of constituents that would integrate such features contribute to a system’s compliance with this essential requirement.

The verification of compliance with ER7 should focus on the capability of the EATMN system to provide high availability without interruption of service. ANSPs should provide a rationale or reference to technical documents showing that the EATMN system can achieve the required level of availability. This rationale can be considered as an evidence of compliance with ER7.

ANNEX F: VERIFICATION OF COMPLIANCE

F.1 Introduction

This annex provides guidance for manufacturers and ANSPs on the verification of compliance tasks required for the preparation of EC declarations, extending Sections 5.5.3 and 6.3.1 of the guidelines. Before initiating verification tasks, there must be a clear understanding of which constituent or system is being verified against which set of requirements. For this purpose, these guidelines recommend that the EATMN representation (see Section 3) and the baseline of conformity assessment (see Section 4) are established before undertaking verification activities. The figure below presents a conformity assessment flow diagram to introduce the verification of compliance tasks.

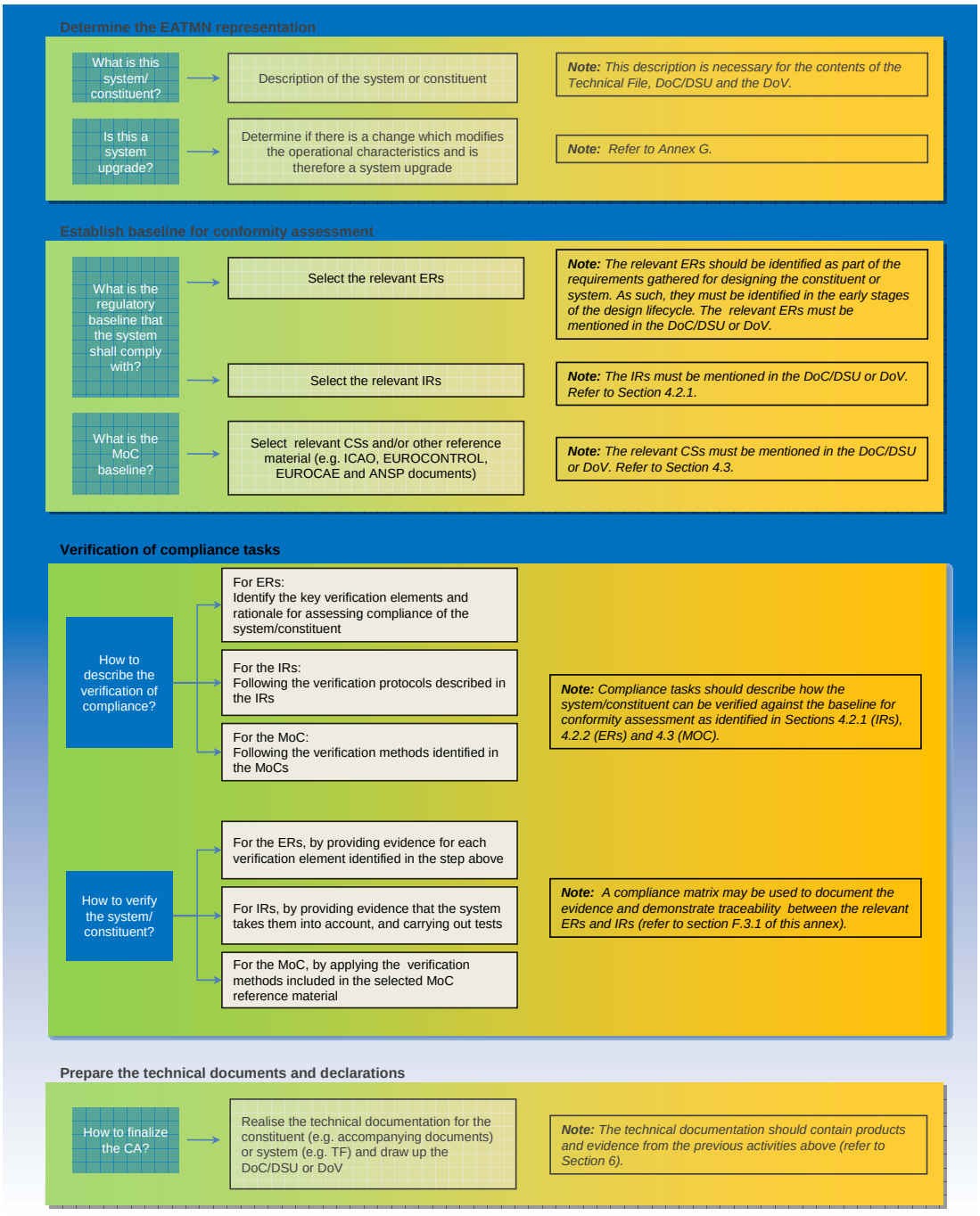

Figure 15: The role of verification tasks within conformity assessment

F.2 Approach to verification of compliance

The model of the interoperability Regulation is one in which ANSPs procure and integrate constituents that are put onto the market by manufacturers. Irrespective of who manufactures the constituents, it is ultimately the ANSP that has the responsibility of verification before the system (an aggregation of constituents) is put into service. As manufacturers are required to verify their constituents and ANSPs are required to verify their systems, verification of compliance is to be performed by both parties.

Implementing rules for interoperability may specify detailed measures in relation to conformity assessment. They usually require ANSPs to demonstrate impartiality, independence of judgement and technical competence by those responsible for executing the verification activities. Otherwise the ANSP is obliged to subcontract a notified body as described in Section 6.3.2.

Any involvement of a notified body in the verification of compliance of constituents or systems involves the hand-over of results; reports and a certificate (see Section 2.3.2.4).

Alternatively, verification of compliance can be achieved through the application of Article 6a of the interoperability Regulation [1] as described in Section 2.3.4.

F.3 Verification of compliance against ERs and relevant IRs

Verification of compliance against the ERs is necessary for all constituents and systems and is to be documented by means of an EC declaration. Additional requirements from specific IRs may also form part of the regulatory baseline (see Section 4.2) and need to be verified. The MoC (Means of Compliance) baseline consists of the voluntary standards and specifications that the manufacturer or air navigation service provider uses to ensure compliance with the regulatory baseline.

Typically, the technical verification activities will focus on the implementation of the voluntary standards which often include tests or other means of verifying their successful implementation.

F.3.1 Verification of compliance against ERs

For each of the 8 EATMN systems identified in Annex I of the interoperability Regulation, Annex II, contains the general and specific essential requirements. For each ER, the table below provides a breakdown of the key aspects (verification elements) that form the essence of the requirement and the basis on which the rationale for compliance should be focussed.

A detailed compliance matrix can document the evidence supporting the necessary declaration. A template including suggested examples of evidence is made available on the EUROCONTROL website (see Annex C) which can be part of a constituent’s accompanying documents or a system’s technical file.

ER	Verification elements
ER1: Seamless operation	Design and build (to ensure seamless operation)
	Maintenance
	Operation
	Information sharing (importing and exporting of information/data)
ER2: Support for new concepts of operation	New and validated concepts of operation
	Improved quality
	Improved sustainability
	Improved effectiveness
	Improved safety
	Improved capacity
	New concepts examined
ER3: Safety	Agreed safety management methodologies
	Agreed reporting methodologies
	Safety nets (not duplicate or standby systems)
	Safety requirements
	Normal and degraded modes (HMI and safety aspects)
	Agreed safety levels for all phases of flight
	Compatible with human capabilities
	Free from harmful [electromagnetic] interference
ER4: Civil-military coordination	Support civil/military coordination
	Effective airspace management
	Safe and efficient use of airspace
	Sharing of timely and correct information between civil and military parties
	National security
ER5: Environmental constraints	Minimise environmental impact
ER6: Principles governing the logical architecture of systems	Standard or local logical architecture
ER7: Principles governing the construction of systems	Sound engineering principles
	Modularity of the system and interchangeability of constituents
	System availability (without interruption of service)
	Redundancy and fault tolerance

For each of the 8 EATMN systems specified in Annex I of the interoperability Regulation, there are further specific refinements that apply to the two essential requirements: ‘seamless operation’ and ‘support for new concepts of operation’. These are identified in Part B of Annex II and summarised in the following table.

EATMN System	Modifies/ supplements	Verification elements
Systems and procedures for airspace management	ER1: Seamless operation	Pre-tactical and tactical information about airspace availability
		Correct and timely information provision
		National security requirements
Systems and procedures for air traffic flow management	ER1: Seamless operation	Sharing flight information
		Joint use of correct and coherent flight information
		Relevant, strategic, pre-tactical and tactical flight information
		Dialogue capabilities with regard to optimised use of airspace
Systems and procedures for air traffic services		
• Flight data processing systems	ER1: Seamless operation	Timely sharing of accurate and consistent information
		Common operational understanding of information
		Ensure coherent and consistent planning
		Resource efficient tactical coordination
		Design for equivalent and appropriate flight data processing for a given environment
		Agreed and validated operational concept
		Accuracy and error tolerance of processing results
	ER2: New concepts of operation	Introduction of advanced concepts of operation
		Coherent and efficient processing of flight information
		Validation of design, build, installation, maintenance and operation for new concepts of operation
		Timely sharing of correct and consistent information
		Common understanding of the current and forecasted operating situation
• Surveillance data processing systems	ER1: Seamless operation	Design, build, maintenance and operation to provide the required performance and quality of service
		Integrity, availability, continuity and timeliness of relevant, accurate, reliable, consistent and coherent information
	ER2: New concepts of operation	Availability of new sources of surveillance information
• Human-machine interface systems	ER1: Seamless operation	Design, build, maintenance and operation to offer a progressively harmonised working environment (including functions and ergonomics)
	ER2: New concepts of operation	Introduction of new operational concepts; increased automation
		Human capabilities in normal and degraded modes of operation

EATMN System	Modifies/ supplements	Verification elements
Communications systems and procedures for ground-to-ground, air-to-ground and air-to-air communications	ER1: Seamless operation	Design, build, maintenance and operation to achieve the required performance, quality of service, coverage and redundancy
	ER2: New concepts of operation	Support the implementation of advanced concepts of operation
Navigation systems and procedures	ER1: Seamless operation	Design, build, maintenance and operation to achieve the required horizontal and vertical navigation performance
		Accuracy and functional capability
		Agreed and validated operational concept
Surveillance systems and procedures	ER1: Seamless operation	Design, build, maintenance and operation to provide the required performance
		Surveillance systems accuracy, coverage and range; quality of service
		Surveillance network accuracy, timeliness, coverage and redundancy
		Enabled sharing of surveillance data
Systems and procedures for aeronautical information services	ER1: Seamless operation	Precise, timely and consistent availability of aeronautical information in electronic form
		Commonly agreed and standardised data set
	ER2: New concepts of operation	Timely information
		Improvement of the efficiency of airspace and airport use
Systems and procedures for the use of meteorological information	ER1: Seamless operation	Consistence and timeliness improvement
		Quality of presentation
	ER2: New concepts of operation	Consistence, timeliness and presentation quality of meteorological information
		Improvement of the speed of availability and usability of meteorological information

F.3.2 Verification against implementing rules

In addition to satisfying the relevant essential requirements of the interoperability Regulation, manufacturers and ANSPs need to identify the relevant implementing rules (IRs) applicable to a constituent or system and to demonstrate compliance with these requirements. Unless, specific conformity assessment procedures are specified in the IRs, the ANSP or manufacturer is free to choose an appropriate procedure.

It is to be noted that implementing rules do not contain explicit traceability to the essential requirements and the scope may not cover the entire functionality of the system. Hence the ANSP or manufacturer must verify that the system or constituent complies with both the ERs and any applicable IRs.

F.3.3 Verification against MoC

Section 4.3 of these guidelines provides examples of the types of MoC reference material and the procedure for establishing the MoC baseline. SES Community specifications usually contain traceability to the essential requirements and relevant implementing rules for interoperability, which means that their application provides a proven satisfaction of compliance against the identified regulatory baseline.

Verification methods vary from constituent to constituent but typically include flight trials, testing methods, simulations, pre-operational trials, etc. These verification methods can be specified or referenced within the Community specifications or the other standards that were implemented. Otherwise the manufacturer and ANSP will need to provide evidence of the verification procedure (such as conformity assessment modules, site acceptance test reports, flight trial results, calibration details, etc.).

F.4 Documenting the verification results

It is necessary to provide evidence that the relevant regulatory requirements have been met. This can be demonstrated by means of a compliance matrix showing traceability between the relevant ERs and IRs and the verification activities that have been performed (e.g. through application of the means of compliance) to demonstrate satisfaction of the ERs and IRs.

The results of the verification tasks should be referred to as part of the supporting evidence in the accompanying documents of constituents or the TF of a system.

ANNEX G: DETERMINATION OF SYSTEM UPGRADE

G.1 Overview

This annex provides a process for determining if a proposed system change includes modification of the operational characteristics and therefore constitutes an 'upgrade' of the system which requires the ANSP to update and resubmit the DoV to their national supervisory authority (NSA).

The process includes 3 steps as illustrated below:

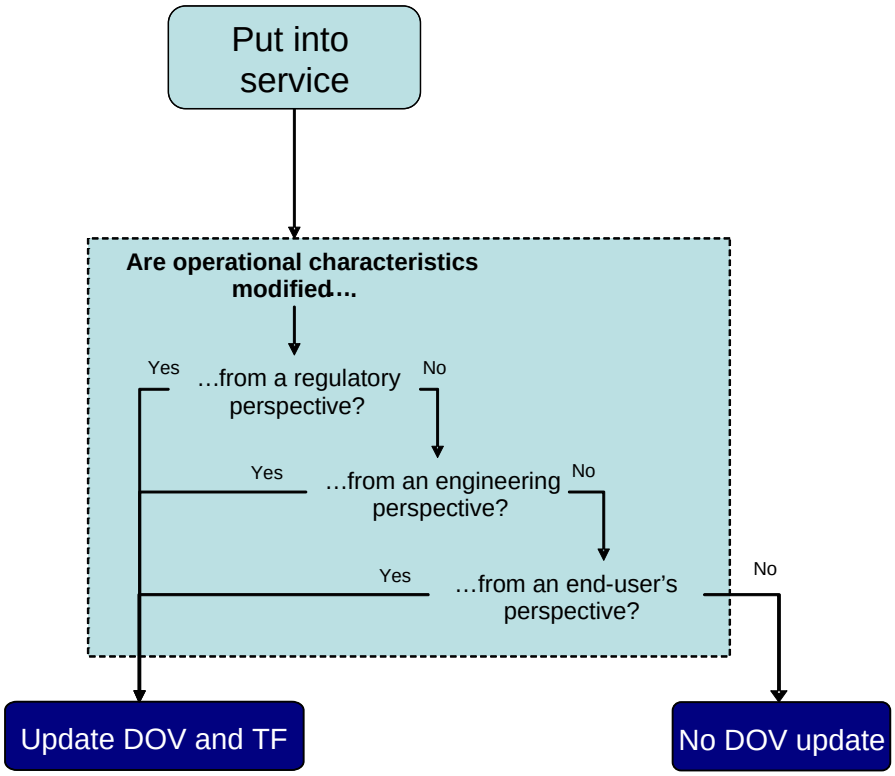

Figure 16: Determination of a system upgrade

G.2 The regulatory perspective

G.2.1 Overview

In achieving the initial CA, the ANSP will have established the baseline for conformity assessment and will have demonstrated to the NSA how the system complies with this baseline. The baseline for conformity assessment consists of:

- The regulatory baseline (see Section 4.2); and
- The means of compliance (MoC) baseline (see Section 4.3).

The baseline for conformity assessment may change in one of two ways:

- **The baseline is modified by the introduction of new regulation or a change to the means of compliance.** For example an IR or CS is published, which the ANSP is directly responding to in introducing the change.
- **The baseline is modified by the introduction of additional functionality or a changed EATMN representation to which the baseline must now extend.** For example, implementing a new constituent may require the ANSP to demonstrate compliance to an extended regulatory baseline that includes the additional regulatory requirements that apply to the new constituent and that were previously not applicable.

In both cases the ANSP will need to demonstrate compliance to the modified baseline for conformity assessment to the NSA by updating the DoV. Hence:

All changes that introduce new statements of compliance against the baseline for conformity assessment or that modify existing statements affect the system operational characteristics and thus necessitate a DoV update.

G.2.2 Method for determining a change to operational characteristics from the regulatory perspective

The figure and accompanying table below highlight the key considerations to take into account to determine whether operational characteristics have changed from a regulatory perspective.

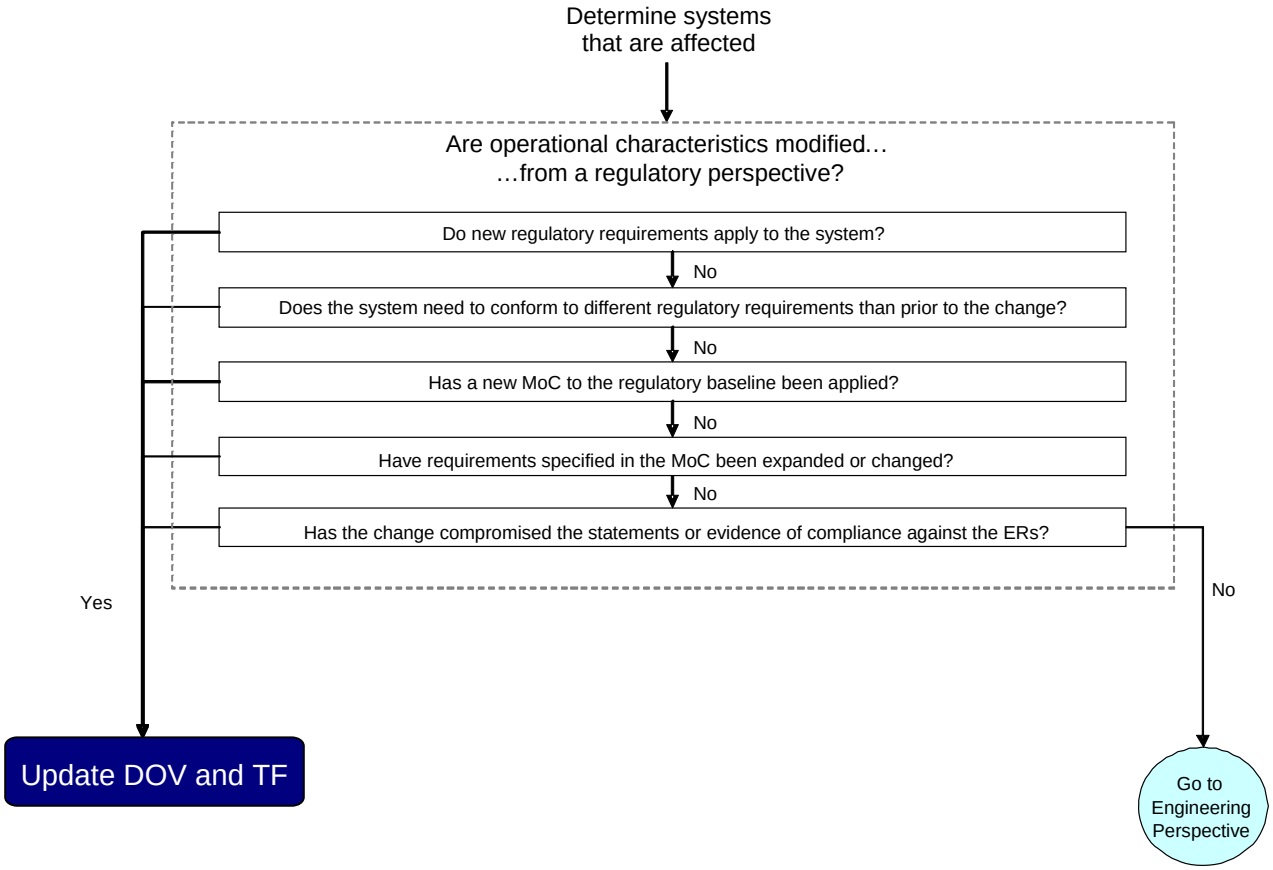

Figure 17: Determining operational characteristics from a regulatory perspective

Consideration	Affect on operational characteristics
Is the change to the regulation or to the system?	A change to the regulation must be assessed against all systems to which it applies A change to the system must be assessed against the full regulatory baseline applicable to that system
Do new regulatory requirements apply to the system?	The application of new IR requirements changes the operational characteristics of the system. *Note that regulatory requirements may apply to both new systems and retrospectively to legacy systems.*
Does the system need to conform to different IR requirements than prior to the change?	Extending the capability of a system such that more IR requirements apply, alters compliance with the regulatory baseline and thus changes the operational characteristics of the system.
Has a new MoC to the baseline for conformity assessment been introduced?	Adopting a new MoC will alter the compliance with the baseline for conformity assessment and thus change the operational characteristics of the system.
Have requirements specified in the MoC been expanded or changed?	Increasing or decreasing the system's coverage/application of the MoC changes the operational characteristics of the system.
Has the change compromised the statements or evidence of compliance against the ERs?	A change that modifies the established traceability between the system and ERs alters the operational characteristics of the system.

G.3 The engineering perspective

G.3.1 Overview

From the engineering perspective, operational characteristics are defined by the functionality, performance, user interaction and composition of the system. The nature of the change is therefore considered in terms of:

- Functionality: Are new functions added?
- Performance: Is there an increase in the level of performance?
- Interface: Does the composition or interfaces of the system alter?
- User Interaction: Are external interfaces impacted?

The four system aspects listed above will be captured in the accompanying system lifecycle documentation. This documentation should therefore be used to identify changes to operational characteristics as part of the change management processes in place with the ANSP.

ANSPs may apply numerous different system or software engineering (SE) lifecycle processes (for example: ISO/IEC 12207, European Space Agency (ESA) Software Engineering Standards PSS-05 and ECSS-ST-E-40 and Military Standard (MIL-STD) 498).

Legacy systems may have less documentation than for newer systems, for which more mature methodologies and standards were available during the development lifecycle. The ANSP may work with the NSA to establish the minimum set of evidence necessary to show that the system meets the interoperability Regulation.

A system change that modifies system requirements, i.e. *what* the system must do, infers a change to operational characteristics. This includes requirements that infer training the operator (a clear indicator of changing operational characteristics). System requirements (including functional, performance, interface and user requirements) will be identified in the system requirements specification and will be traced throughout design and test documents too.

A further indicator of an 'upgrade' from the engineering perspective is to determine the impact of the change on the EATMN representation, which is established as part of the initial CA process (see chapter 3). If this representation requires change, for example to accommodate the addition or removal of a constituent, then it is likely that there is change to the operational characteristics and that a DoV update will thus be required.

In general, if the means of compliance (MoC) to the regulatory baseline (as described in Section 4.3) is changed without affecting the regulatory baseline itself (for example by implementing a new or extended version of a technical specification) then the operational characteristics of the system will not have changed.

A system change that modifies only design requirements, i.e. *how* the system must meet the system requirements; or test requirements, i.e. *whether* the system meets its requirements; does not infer a change to operational characteristics. Such requirements will be specified in design and test specifications.

G.3.2 Method for determining a change to operational characteristics from the engineering perspective

Having concluded that the change does not affect the compliance with the baseline for conformity assessment, the figure and accompanying table below highlight the key considerations to take into account to determine whether operational characteristics have changed from an engineering perspective.

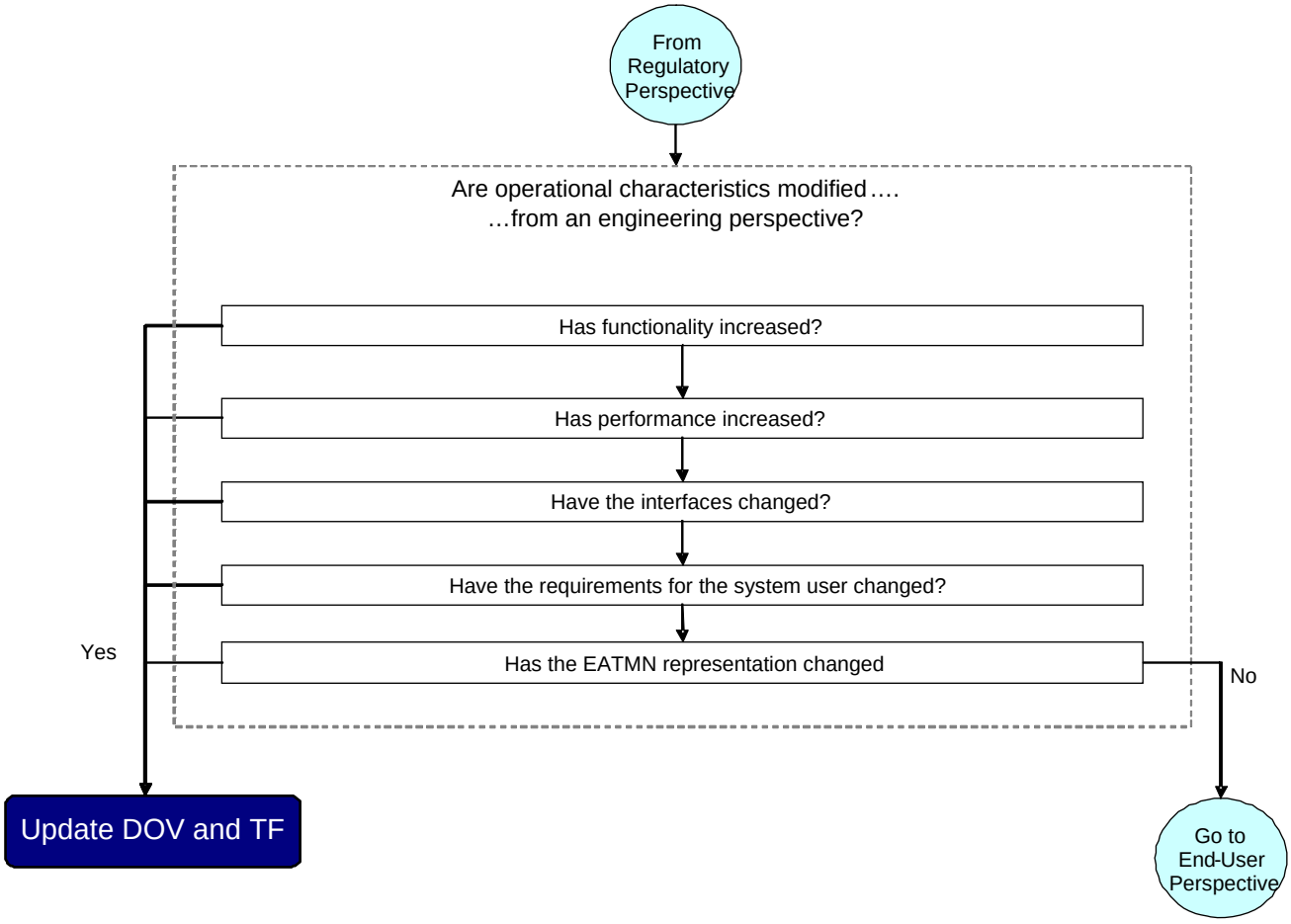

Figure 18: Determining operational characteristics from an engineering perspective

Consideration	Affect on operational characteristics
General	Maintenance process (ISO 12207) or equivalent - The maintenance process will document modifications and change requests to the system. This documentation will be important to understand the reasons for the change and, through configuration management, the aspects of the system that will be affected. - It is under this process that the change will be analysed to determine its type, scope and criticality. These guidelines should be consulted as part of this process to determine the impact of the change on operational characteristics. Acquisition and supply processes (ISO 12207) or equivalent - The acquisition process (ISO 12207) or equivalent will identify the nature of the change and an initial set of system requirements that may be changed. This should be used in conjunction with the outputs of the supply process (ISO 12207) or equivalent in which the magnitude, scope and complexity of the change will be specified.
Has **functionality** increased significantly?	Development process (ISO 12207) or equivalent - Newly enabled outputs, inputs, functions or capabilities generally infer a change in operational characteristics. - **System requirements analysis and specification**: A change to the system requirements that modifies functional or performance requirements can be considered a **change to the operational characteristics of the system.** - A change to the **system architectural design** that does not result in a change to the system requirements is not considered to change the operational characteristics of the system. (e.g. a change to the underlying data protocol may change software without altering the functionality or HMI) - changes to the **testing requirements** or procedures will only impact upon operational characteristics if those changes also modify the system requirements specification. Increasing the test coverage or changing the testing methods should not be considered a change to operational characteristics. Maintenance process (ISO 12207) or equivalent - **Periodic updates**, such as configuration changes, do not change the operational characteristics. Impact on SE lifecycle documents. The TF and potentially the DoV, will require updating if the proposed change is reflected in software engineering lifecycle requirements documents (e.g. Operations Concept Document (OCD), User Requirements Document (URD), Specifications Requirements Document (SRD), Software Requirements Specification (SRS), System/Subsystem Specification (SSS)).

Has **performance** increased significantly?	Development process (ISO 12207) or equivalent The outputs of the *development process* (ISO 12207) or equivalent will be helpful: - **System requirements analysis and specification**: A change to the system requirements that modifies functional or performance requirements can be considered a change to the operational characteristics of the system. - Increasing/decreasing the **rate, quantity or quality** of the output modifies the operational characteristics. Maintenance process (ISO 12207) or equivalent - A **replacement** part that performs differently (i.e. has increased/decreased relative performance) is a modification of operational characteristics. Impact on SE lifecycle documents. The TF and potentially the DoV, will require updating if the proposed change is reflected in the performance sections of software engineering lifecycle requirements documents (e.g. Operations Concept Document (OCD), User Requirements Document (URD), Specifications Requirements Document (SRD), Software Requirements Specification (SRS), System/Subsystem Specification (SSS)).
Have the **interfaces** changed significantly?	Development process (ISO 12207) or equivalent - If, in the **detailed design**, the interface, with either: the user; or other systems, is modified then the operational characteristics can be considered to have changed. - Changing the **overall assembly** of constituents, without affecting the system requirements would not result in a change to operational characteristics. Operation process (ISO 12207) or equivalent - Modifying or renegotiating a **service level agreement** for the services that support the system (e.g. MET, COM) will infer a change to operational characteristics. Impact on SE lifecycle documents. The TF and potentially the DoV, will require updating if the proposed change is reflected in the software engineering lifecycle documents (e.g. Operations Concept Document (OCD), User Requirements Document (URD), Software User Manual (SUM), Software Center Operator Manual (SCOM), Computer Operation Manual (COM), Training Manual).

Have the requirements for the **system user** changed significantly?	Development process (ISO 12207) or equivalent - If, in the **detailed design**, the interface, with either: the user; or the external components of the system, is modified then the operational characteristics can be considered to have changed. - An increase in the **quantity or method of interaction** of the existing output could cause the user to react differently, thus inferring a need for training and a change in operational characteristics. Operation process (ISO 12207) or equivalent - Changes to the system that compromise or invalidate **standards or operating procedures** for operating the system should be considered a change to the operational characteristics. - If a change occurs that means the **user documentation** needs to be updated then it is likely that the operational characteristics have changed. - Users will have clear expectations on and experience with the system and their **feedback** will provide a useful source for identifying changes to operational characteristics that may not have been identified in other documentation. - The necessary provision of **training** to accommodate the change is an indicator that operational characteristics of the system have changed Impact on SE lifecycle documents. The TF and potentially the DoV, will require updating if the proposed change is reflected in software engineering lifecycle documents (e.g. Operations Concept Document (OCD), User Requirements Document (URD), Software User Manual (SUM), Software Center Operator Manual (SCOM), Computer Operation Manual (COM), Training Manual).

G.4 The end-user perspective

G.4.1 Overview

The final perspective to consider is that of the controller or airspace user. If the controller or airspace user experiences a change to the services provided by the ANSP as a result of a system upgrade, then that system should require a new DoV.

The intent is to capture instances where there are no changes to the baseline for conformity assessment and no significant engineering change to the underlying system but still impact the service that is visible to the controller or airspace user. These situations will be limited and this perspective is intended as a final check that no DoV update is required. In particular it verifies that the impact of system changes considered minor within the engineering perspective, have no impact on the controller or airspace user.

An impact on a controller or airspace user could be:

- Additional carriage requirements for avionics.
- Modified operational procedures including revised flight procedures or phraseology.
- Modified communication, navigation or surveillance service interfaces.

From an end-user (controller/airspace user) perspective, operational characteristics are defined solely by the services offered by systems. The system's operational characteristics are thus changed if it results in a change to the service perceived at the airspace user level.

G.4.2 Method for determining a change to operational characteristics from the end-user perspective

Having concluded that the change does not affect either the compliance with the baseline for conformity assessment, or the operational characteristics from an engineering perspective, the figure and accompanying table below highlight the key considerations to take into account to finally determine whether operational characteristics have changed, by considering the end-user perspective.

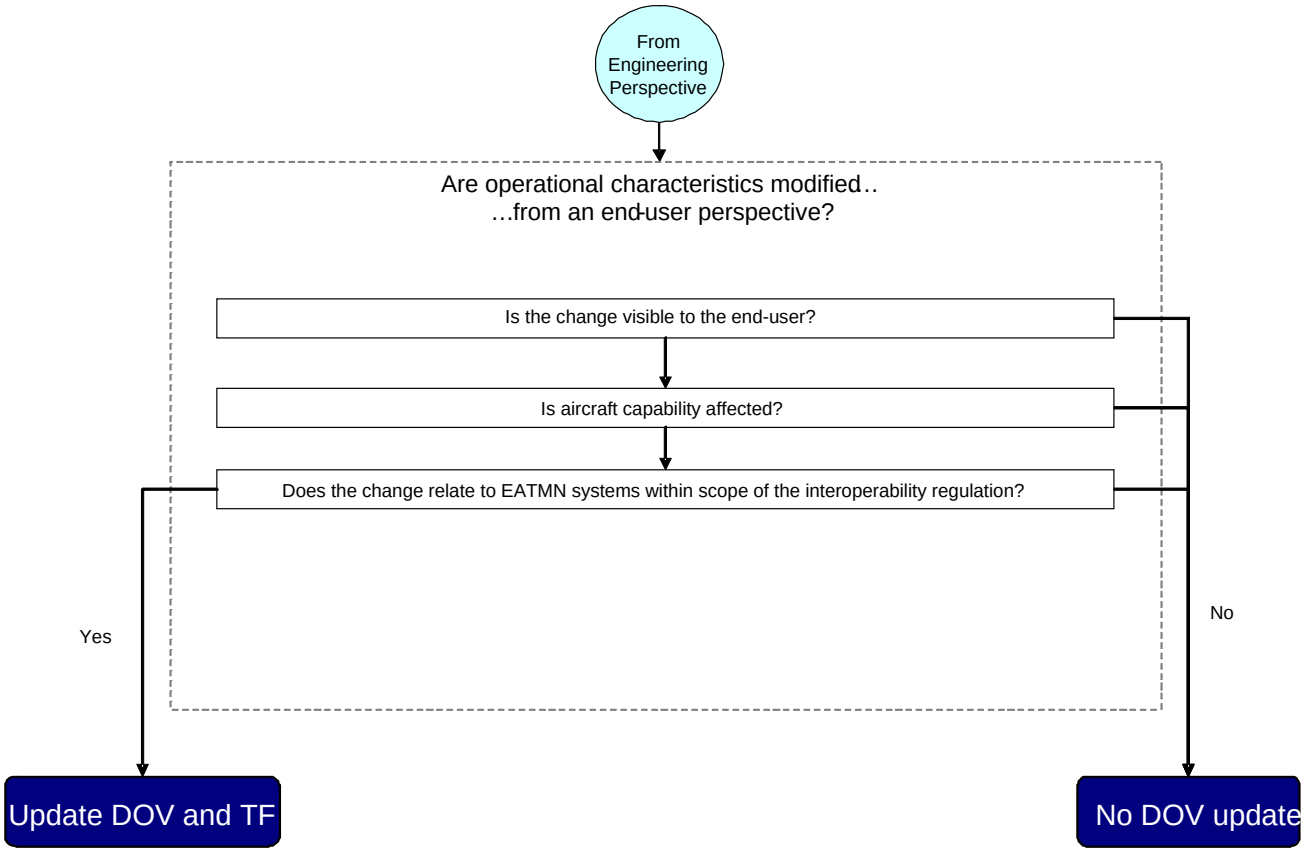

Figure 19: Determining operational characteristics from an end-user's perspective

Consideration	Affect on operational characteristics
Is the change visible to the end-user?	A system change may (intentionally) have no noticeable impact on the controller or airspace user and thus no impact on the operational characteristics (from the airspace user perspective) Training or equipage requirements provide clear indicators of the impact of a change.
Is aircraft capability affected?	Imposing equipage requirements on the airspace user is a clear indicator that the operational characteristics of the underlying system have been modified. This equipage may already be onboard the aircraft but, until now, has not been enabled.
Does the change relate to EATMN systems within scope of the interoperability regulation?	Determining whether or not a service change has been caused by an upgrade to a particular system should take into account the SESAR mapping between concepts and technical enablers. Operational characteristics are only of concern to systems within the scope of the interoperability regulation.

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