



## TERMS OF REFERENCE

**Task No:** RMT.0469 and RMT.0470

**Issue:** 1

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**Regulatory reference  
and reference  
documents:**

- 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<sup>1</sup> as last amended by Regulation (EC) No 1108/2009 of the European Parliament and of the Council of 21 October 2009 in the field of aerodromes, air traffic management and air navigation services and repealing Directive 2006/23/EC<sup>2</sup>.
- Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation for the single European sky<sup>3</sup>.
- 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<sup>4</sup> and its Implementing Rules.
- Commission Implementing 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<sup>5</sup>.
- Commission Implementing 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<sup>6</sup>.
- Commission Regulation (EC) No 482/2008 of 30 May 2008 establishing a software safety assurance system to be implemented by air navigation service providers and amending Annex II to Regulation (EC) No 2096/2005<sup>7</sup>.
- Regulation (EC) No 551/2004 of the European Parliament and of the Council of 10 March 2004 on the organisation and use of the airspace in the single European sky<sup>8</sup> and its Implementing Rule.
- Regulation (EC) No 552/2004 of the European Parliament

<sup>1</sup> OJ L 79, 19.3.2008, p.1.

<sup>2</sup> OJ L 309, 24.11.2009, p.51.

<sup>3</sup> OJ L 96, 31.3.2004, p.1.

<sup>4</sup> OJ L 96, 31.3.2004, p.10.

<sup>5</sup> OJ L/271, 18/10/2011, p.23.

<sup>6</sup> OJ L/271, 18/10/2011, p.15.

<sup>7</sup> OJ L 141, 31.5.2008, p. 5.

<sup>8</sup> OJ L 96, 31.3.2004, p.20.

and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network<sup>9</sup> and its Implementing Rules.

- Regulation (EC) No 1070/2009 of the European Parliament and of the Council 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<sup>10</sup>.

**1. Subject:** Requirements for safety assessment of changes to ATM/ANS functional systems

To amend the current implementing regulations in the field ATM/ANS and where necessary to develop acceptable means of compliance (AMC) and guidance material (GM) in order to complete the regulations on the requirements for the safety management and safety oversight of changes to ATM/ANS functional systems<sup>11</sup>.

**2. Problem/Statement of issue and justification; reason for regulatory evolution (regulatory tasks):**

With the adoption of Commission Implementing Regulations (EU) No 1034/2011 and 1035/2011, the extension of the Agency's competence in the field of ATM/ANS has started being implemented. As foreseen in recitals (16) of Regulation No 1035/2011 and recital (10) of Regulation No 1034/2011, as well as in Opinion No 02/2010, the Agency will now further evaluate the existing provisions dealing with the safety assessment of changes to functional systems and their safety oversight with the view to complementing the existing regulatory framework and to amending as necessary the existing provisions.

It is also important to highlight that when the former Commission Regulation (EC) No 2096/2005 (which has been repealed by Commission Implementing Regulation (EU) No 1035/2011) was adopted, the proposed Risk Classification Scheme (RCS) was incomplete. Regulation (EC) No 2096/2005 identified the need to complete the RCS and therefore the European Commission gave EUROCONTROL a mandate to further develop the regulatory material governing the safety assessment of changes and to complement the severity classification table already in the Regulation. The outcome of this mandate was a recommendation by EUROCONTROL to make a further, deeper study into the assessment of the safety of changes.

The Agency established rulemaking tasks ATM.001 and ATM.004 in order to review Regulation No 1035/2011 and Regulation No 1034/2011. Rulemaking groups were established and 6 ad-hoc groups/subgroups were set up. The Safety Assessment Task Force (SATF) was one of these subgroups. It was tasked with reviewing the provisions dealing with the safety assessment of ATM/ANS functional systems and their safety oversight and with making recommendations jointly to ATM.001 & ATM.004. SATF's work could, however, not be completed before rulemaking groups ATM.001 and ATM.004 had completed their task.

SATF identified that a solution to the difficulties in completing the existing regulatory framework did not so much lie in completing the RCS, but rather in the need for a broad-based approach to the safety assessment of change that was not specifically method-oriented. As a consequence of this, SATF suggested that additional provisions were needed in other areas of the regulations, such as the oversight of the safety assessment process and its outputs and the relationship between the Safety Management System and the safety

<sup>9</sup> OJ L 96, 31.3.2004, p.26.

<sup>10</sup> OJ L 300, 14.11.2009, p. 34.

<sup>11</sup> The term 'functional system' is used here as defined in Commission Implementing Regulation (EU) No 1035/2011 i.e. it includes people, procedures, equipment (hardware and software that can be on-board, on the ground or in space) and the organisation of these component parts of the system.

assessment of change. Such a relationship is necessary to establish the goals for the safety of a change and to identify when changes should be performed.

A draft implementing rule has been developed by SATF, which has been commented on by the ATM.001 and ATM.004 rulemaking groups. The spirit of the proposals was accepted by both groups as were the concepts underpinning the proposals. However, the ATM.001 and ATM.004 rulemaking groups commented that the rules seemed to replace current practice rather than supporting and extending it. Whilst not accepting this view, SATF nonetheless proposed to develop explanatory material for the concepts behind the proposed draft rules in order to show how these could be implemented within the current safety assessment framework. Such explanatory material would be the basis for the development of AMC and GM.

Within the timescales allocated to the ATM.001 and ATM.004 rulemaking tasks, there was not sufficient time for SATF to develop this explanatory material or the AMC and GM that is also needed. However, as SATF has been working on these tasks for a considerable period of time, it already has detailed plans for the development of the necessary material and even has some of the explanatory material.

The Agency has therefore decided to complete the work initiated by SATF and consequently to establish a new and separate rulemaking task.

### **3. Objective:**

Having due regard to the Basic Regulation (particularly Articles 17.2(a), 18(a) and 18(c)) and to the previous work carried out under rulemaking tasks ATM.001 and ATM.004, in particular the work carried out by the SATF, this task shall propose amendments<sup>12</sup>, as necessary to existing provisions in the field of the safety management of changes to ATM/ANS functional systems. These proposals shall:

- cover the safety management of changes to functional systems, which includes:
  - changes that involve more than one organisation (including organisations in other fields of air transport and unregulated bodies);
  - the procedures used during a change and their outputs;
  - the safety oversight of these procedures and their outputs (including the risk-based proportionate review of the output of the change assurance procedures);
  - the safety oversight of the change once implemented;
  - the relationship between the safety of the change and the safety policy of the organisation;
  - the safety assessment of the change and how this may lead to the need for mitigation;
  - the assurance that the change is safe enough; and
  - the roles and responsibilities of the different types of ATM/ANS service provider.
- justify the proposed changes;
- use terms, logic (inferences) and semantics that are potentially suitable for use in all other aviation domains; and
- review the provisions related to the safety management of changes, proposed or applied, in other aviation domains, such as aircraft operations, aerodrome operations

<sup>12</sup> The proposed amendments may cover implementing rules (IR) and where appropriate additional rulemaking material (such as AMC and guidance material). Proposals may include the creation, disposal and change of content and structure of the regulatory material relating to the safety management and oversight of changes to ATM/ANS functional systems.

and aircraft manufacture and maintenance and make recommendations for amendments that would aid movement towards a total systems approach.

The last two bullets are there to facilitate, as far as is feasible, the total system approach for civil aviation safety. This approach is aimed at promoting regulatory efficiencies stemming from a consistent regulatory structure and common general requirements on authorities and organisations.

#### 4. Specific tasks and interface issues (Deliverables):

On meeting the objectives of section 3, the following shall be delivered:

- an assessment of the different regulatory approaches that may be used to accomplish the task and an evaluation of the impact of each approach. This will be part of the Regulatory Impact Assessment (RIA);
- draft provisions for implementing regulations, amending and completing, as applicable, in relation to the safety management of changes to ATM/ANS functional systems, the existing provisions in Commission Implementing Regulation (EU) No 1035/2011 and associated AMC and GM;
- draft provisions for implementing regulations, amending and complementing, as applicable, in relation to the safety oversight of changes to ATM/ANS functional systems, the existing provisions in Commission Implementing Regulation (EU) No 1034/2011 and associated AMC and GM; and
- a report summarising the outcome of the review dealing with the consistency of the management of changes in other aviation domains (e.g. aerodromes, aircraft operators, airworthiness).

#### 5. Working Methods (in addition to the applicable Agency procedures):

The applicable Agency rulemaking procedures shall apply:

- Agency Management Board Decision No 01-2012<sup>13</sup>
- PR RPRO 00001-001 - Process a rulemaking task<sup>14</sup>
- WI RPRO 00044-001 - Determination of the membership of Rulemaking groups<sup>15</sup>
- WI RPRO 00046-002 - Regulatory Impact Assessment (RIA) Methodology<sup>16</sup>
- WI RPRO 00045-001 - Rule of Procedure for Rulemaking Groups<sup>17</sup>
- FO.RPRO.00028-001 - Contact details of candidate for rulemaking group<sup>18</sup>

<sup>13</sup> <http://easa.europa.eu/management-board/docs/management-board-meetings/2012/01/EASA%20MB%20Decision%2001-2012%20Revised%20MB%20Decision%20RM%20Process%20.pdf>.

<sup>14</sup> <http://easa.europa.eu/rulemaking/docs/procedures-and-work-instructions/PR%20RPRO%2000001-001%20Process%20a%20rulemaking%20task.pdf>.

<sup>15</sup> <http://easa.europa.eu/rulemaking/docs/procedures-and-work-instructions/WI%20RPRO%2000044-001%20-%20Determination%20of%20the%20membership%20of%20Rulemaking%20groups.pdf>.

<sup>16</sup> [http://easa.europa.eu/rulemaking/docs/procedures-and-work-instructions/WI.RPRO.00046%20%20Regulatory%20Impact%20Assessment%20\(RIA\)%20Methodology.pdf](http://easa.europa.eu/rulemaking/docs/procedures-and-work-instructions/WI.RPRO.00046%20%20Regulatory%20Impact%20Assessment%20(RIA)%20Methodology.pdf).

<sup>17</sup> <http://easa.europa.eu/rulemaking/docs/procedures-and-work-instructions/WI%20RPRO%2000045-001%20-%20Rule%20of%20Procedure%20for%20Rulemaking%20Groups.pdf>.

<sup>18</sup> <http://easa.europa.eu/rulemaking/docs/procedures-and-work-instructions/FO%20RPRO%2000028-001%20Contact%20details%20of%20candidate%20for%20rulemaking%20group.pdf>.

- TE.RPRO.00034-002 - Notice of Proposed Amendment (NPA)<sup>19</sup>
- TE.RPRO.00055 - Full RIA<sup>20</sup>

The Agency proposes to make use of a rulemaking group to assist in accomplishing this task. In addition, where further expertise is required, specific subject matter experts may be identified by the chairman and the Agency and their assistance may be requested. Ideally, the size of the group should not exceed eight participants at any given time.

The role of the rulemaking group is to assist the Agency in its rulemaking task, but the Agency is fully in charge of the preparation of the drafts for the NPA, CRD and Opinion/Decision taking into account the inputs provided by the rulemaking group experts.

Appropriate coordination will be ensured by the Agency between this task and the work of the Agency in the field of aerodromes.

Appropriate coordination will be facilitated by the Agency between this task and the work of SESAR (particularly the work in working package (WP) 16.06.01 'Safety Support and Coordination Function).

The Agency will provide necessary secretarial support and facilities for the work of this group.

Any amendments to the scope of the work, the objectives, the deliverables or the working methods described in this ToR will result in an amendment of the ToR. The rulemaking advisory bodies will be consulted on these amendments as far as it is necessary.

The rulemaking group will meet 6 times to accomplish the rulemaking task. All meetings will be held at EASA premises in Cologne.

Each meeting is expected to last 3 full days.

#### **6. Time scale, milestones:**

- The Notice of Proposed Amendment (NPA) containing the draft implementing rules and relevant AMC and GM is to be published by 2013/Q2.
- The Comment Response Document (CRD), the Agency's Opinion and the associated Regulatory Impact Assessment (RIA) will be issued subsequently and in accordance with the Agency's rulemaking procedure by 2014/Q1.
- The related Executive Director Decision(s) containing the relevant AMC and GM will be issued in accordance with the Agency's rulemaking procedure, once the relevant Commission Implementing Rules have been adopted by the European Commission.

<sup>19</sup> [http://easa.europa.eu/rulemaking/docs/procedures-and-work-instructions/TE.RPRO.00034-002%20Notice%20of%20Proposed%20Amendment%20\(NPA\).pdf](http://easa.europa.eu/rulemaking/docs/procedures-and-work-instructions/TE.RPRO.00034-002%20Notice%20of%20Proposed%20Amendment%20(NPA).pdf).

<sup>20</sup> <http://easa.europa.eu/rulemaking/docs/procedures-and-work-instructions/TE.RPRO.00055%20%20Full%20RIA.pdf>.