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SAFETY METHOD REVIEW

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| Abstract | | |
| <p>This document provides an overview of the development of the Safety Method Review Tool (SMRT), as part of the safety scanning methodology. It provides a detailed overview of the activities conducted by the SRCCG TF, which was given the task for this development.</p> <p>Safety Method Review aims to support competent authorities in the execution of their oversight task during development of changes to the Total ATM System by giving advice about the appropriateness of a safety assessment method proposed by the ANSP.</p> | | |
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F.3 DOCUMENT APPROVAL

The following table identifies all management authorities who have approved this document.

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F.4 AMENDMENT RECORD

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| 0.01 | 15-Feb-11 | First draft of SRC Doc 48. | All |
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| 1.0 | 14-Jun-11 | Document formally released following SRC approval (RFC No. 1113). | References |

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F.6 EXECUTIVE SUMMARY

The Single European Sky, thinking in terms of “Total System” and “multi-stakeholder”, introduces a partial amendment in the way safety is considered for new Air Transport concepts and how competent Safety Oversight Authorities could consequently review these changes. This is especially driven by a development to more integrated air ground systems with increasing interdependencies of related multi actor procedures and equipment performance in support of air navigation service provision.

Safety Method Review is, in short, a moderated process that aims to provide a scanning of a given safety assessment methodology against all issues important for safety methods. These issues are referred to as safety validation quality indicators, and have been developed in an iterative process with input and review of oversight and regulatory authorities, service providers, operational concept developers, and safety validation experts.

The SCAN TF developed the Safety Method Review Tool (SMRT) with support of a number of Member States and external R&D sources. The SMRT builds on the safety validation quality indicators and provides a systematic tool for Safety Methods Review in a user-friendly environment. The Tool can be applied either in a workshop environment, or on individual basis, by competent authorities.

Application of the SMRT assists the Regulator in the systematic gathering of audit evidence and in doing so; (a) The competent authority can inform the party who will be making the safety case what they expect regarding safety methods, and use the Tool to explain these expectations. (b) The competent authority can review the Preliminary Safety Case or Safety Case developed on sufficiency and completeness with respect to the methods used and the issues addressed by the safety case.

The SRC supports the further refinement of SMRT as part of their aviation safety policy.

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1. INTRODUCTION

1.1 Occasion

Air traffic is expected to double within the next 20 years, which requires large changes in airspace structure and organisation. As ECAC identified [A35-WP/220] and accepted in the 35th ICAO Assembly (2004), there is no internationally agreed safety validation approach that could evaluate all components and their interactions during the (early) design, system development, operational trials and implementation phase of these major changes in air transport operations. As a follow-up, The Netherlands took initiative to study new approaches to validate safety of (major) changes in air transport operations and the identification of associated risks. In close coordination with Eurocontrol, The Netherlands developed a framework for a new safety validation approach (SAFMAC) with the objective to contribute to the establishment of an internationally agreed standard approach.

SAFMAC consists of two elements: A framework of safe concept development processes, and a set of 32 safety validation quality indicators.

The framework of safe concept development processes consists of four processes: (1) Joint goal setting, which is the process in which the stakeholders of the air transport operation determine their goals, and harmonise them to arrive at a joint goal for all stakeholders. (2) Development of concept of operations (ConOps). (3) Validation, which is the process in which the ConOps is validated against the joint goal of the stakeholders, and which provides effective feedback to the concept developers to improve the operation. (4) Stakeholder allocations, which is the process in which responsibilities and requirements (including validation responsibilities), are allocated to appropriate individual stakeholders. The four processes have to be synchronised during the development stages of an air transport operation. These stages are aligned with those of the E-OCVM Concept Lifecycle Model (CLM), see [E-OCVM, 2010], i.e. V0 (Needs), V1 (Scope), V2 (Feasibility), etc. The SAFMAC framework of processes is described in [Safety Science, 2008].

The second SAFMAC element, i.e. the 32 safety validation quality indicators, provides a set of required aspects of a safety validation approach for large changes in air transport operations. These indicators can be used to guide a review of a safety validation method. They are described in [ISSC, 2007].

1.2 Assignment SRCCG SCAN TF

- According to the Terms of Reference (see Appendix A.2), endorsed by SRCCG13, the mission of the SRC CG SCAN TF is to participate in, and support, SRC's work in the definition and the development of a Safety Scanning Tool (SST) and a Safety Method Review Tool (SMRT) to support the NSAs safety regulatory reviews.
- The development of SST is outlined in [SRC DOC 46]. The SST is based on the SESAR Safety Screening Tool (SST1.0) and the SAFMAC framework of safe concept development processes, and is built on a set of "Safety Fundamentals" [SRC DOC 46 – Annex A, Safety Fundamentals], developed by University of Kassel and ASRO. The SST1.0 was developed at the request of Eurocontrol SESAR officials, as a concerted action in the context of the SESAR definition phase.
- The development of SMRT is outlined in the current SRC DOC 48. The SMRT is built on the 32 SAFMAC safety validation quality indicators.

1.3 The Way SCAN TF did the Job

1.3.1 Identification of the needs of oversight authorities

The development of the 32 safety validation quality indicators, on which the SMRT has been built, started with the identification of the needs of the oversight authorities and other stakeholders in safe concept development and validation, such as ANSPs.

To identify these needs, a brainstorm session with experts was organised. Participants of this brainstorm were qualified representatives of the Netherlands Ministry of Transport (MoT), the Netherlands Air Traffic Control service provider (LVNL), the Netherlands National Supervisory Authority (NSA), of Eurocontrol (Head Quarters and Experimental Centre), and NLR experts on safety validation and on air transport operational concept development. The output of the brainstorm was complemented with a variety of sources from literature. The literature sources included reports on dependability of computer systems, on information quality guidelines for federal agencies, on system analysis techniques, and on human reliability and human error techniques. The combined result of brainstorm and literature was a long list of potentially relevant indicators for the quality of a safety validation.

1.3.2 Consolidation of needs of the oversight authorities

In the next phase, the list of potentially relevant indicators for the quality of a safety validation was summarised, analysed and consolidated through an iterative process, in which review comments of a Supervision Group of stakeholders were incorporated. The Supervision Group included representatives of Eurocontrol, the Netherlands Air Traffic Control service provider, MoT the Netherlands, and the NSA.

The result of the consolidation process was a consolidated set of 32 “safety validation quality indicators”. Each of these safety validation quality indicators describes one required aspect of a safety validation approach for large changes, and the complete set describes all aspects. The consolidated set includes safety validation quality indicators related to the scoping of safety validation, to coverage of certain aspects of the operational concept, to risk assessment, to feedback to concept of operations development, to organisation of safety assessment, and to supporting decision and policy makers.

These safety validation quality indicators were subsequently used as guidance to review several international safety risk assessment methodologies. The experience was used to improve the indicators as well as how they were formulated. The result was presented as a conference paper [ISSC, 2007].

1.3.3 Development of Tool by External Outsourcing

In 2009, MoT the Netherlands awarded a consortium of NLR, University of Kassel (UniKs) and Helios Ltd. with the development of a Safety Method Review Tool (SMRT). The SMRT uses the set of 32 safety validation quality indicators as a baseline, and asks a number of questions relevant to each of these indicators. The set of questions is implemented in a software environment which guides the user through all issues important for safety methods in a systematic and comprehensive way, provides online initial results that show the strong points and weak points of the method reviewed, based on the answers provided to the questions, and automatically generates a report to which a safety method analyst can add their own detailed analysis and conclusions.

1.3.4 Feedback from NSAs and Relevant Stakeholders

Feedback from NSAs and relevant Stakeholders was provided both on the consolidated set of 32 safety validation quality indicators, and on the SMRT.

For the 32 safety validation quality indicators, all intermediate results have been documented for traceability, and have been reviewed by a Supervision Group including representatives of Eurocontrol, LVNL, MoT the Netherlands, and the NSA. The process and result of the safety validation quality indicator development have been presented at an international conference, and feedback from the audience has been documented and used as input to the SMRT.

For the SMRT, NSAs and SCAN TF have reviewed the work as part of the development of the more detailed questions and the supporting software environment. In addition, on the first of April 2010, all SRC-members were offered an Information package including the SMRT and guidance material, for getting some hands on experience of this tool.

Besides the governmental track via the SRC, an External Review Group is installed, which includes CFMU, LVNL, NATS, LPS, Austro Control, Croatia Control, Skyguide, KLM-Air France, Amsterdam Airport Schiphol, TuD, University of Kassel and NLR.

1.4 What do we offer



This series consists of six documents:

SRC DOC 46;

SRC DOC 46 – Annex Book:

- Safety Fundamentals for Safety scanning;
- Guidance for moderating a Safety scanning session and interpreting the results;
- Guidance safety regulatory process.

SRC DOC 48;

Several SCAN TF Deliverables:

- SST questions;
- SMRT questions;
- Further Work, to be published during the launch of the Tools (Spring 2011).

2. THE REGULATOR'S PERSPECTIVE

2.1 Benefits to the Regulator of the Current Tool

NSAs and EASA have the responsibility to act in the public interest to ensure that air transport operations are safe. From the safety regulatory perspective, it is therefore of great importance to gain confidence that essential needs for safety validation, in their widest sense, are identified in a structured and verifiable way and consequently managed in an effective manner.

Using the SMRT may assist the competent safety oversight authorities in managing their safety validation and managerial risks. The application of the Safety Method Review is aiming to be a supporting tool and benchmark for NSAs in effectively meeting their safety validation oversight responsibilities.

Application of the SMRT assists the Regulator in the systematic gathering of audit evidence and in doing so;

- a) The competent authority can inform the party who will be making the safety case what they expect regarding safety methods, and use the tool to explain these expectations.
- b) The competent authority can review the Preliminary Safety Case or Safety Case developed on sufficiency and completeness with respect to the methods used and the issues addressed by the safety case.

With this, the Safety Method Review provides an early indication as to whether the Regulator will accept a change made with a safety case based on an appropriate safety method. In more detail and in order to increase the effectiveness of the competent authorities; the application of Safety Method Review assists competent authorities to consider;

- Application of (inter)national regulations, and of national policy applicable to the validation of the change;
- Effective safety feedback and communication to design;
- The level of safety expertise required for the safety validation of the change;
- Appropriate coverage of interactions and the environment in a safety validation;
- Technical and operational safety aspects related to the safe development of a change;
- The uncertainty margins in the safety validation results due to the assumptions adopted and approximations analysed during the safety assessments;
- Transparency of the results;
- Etc.

2.2 Potential benefits to the Regulator following further development SMRT

Currently used tools often take a functional perspective: humans and technical systems are regarded as organised sets of functions and tasks, and risk and safety (or success) are considered to come from failure or success of executing these tasks and functions.

Such approaches lead to a few challenges during early lifecycle stages, particularly in case of major changes in air transport operations. At the early stages of concept development, concepts are not described yet in terms of functions and tasks. Rather, at these stages, there are actor goals, wishes and needs, which need to be lined up in a joint goal setting process. This makes that at early stages, approaches that rely on functions and tasks do not have sufficient input to provide effective and reliable safety feedback to design. In addition, many activities of human operators are not typically identified as functions, such as informal coordination activities, activities beyond written procedures, maintaining situation awareness, or opportunistic behaviour in order to catch up on delays. Moreover, these approaches, by way of their focus on functions of individual actors, tend to forget about the functions of a group of multiple actors, which functions emerge from their interactions. And finally, major changes in air transport operations, such as those envisioned by SESAR or NextGen, often include completely new functions and shifts of safety responsibilities, which create completely new emerging interactions.

Elements and issues of the air transport operation that are not or cannot be addressed by the safety validation approach used, will need to be formulated as “assumptions” and “approximations”. Assumptions and approximations of which the effect on the safety risk result is not understood, lead to uncertainty in the results, hence make the safety validation and the feedback to design less effective or even counter-effective. Future developments of the SMRT will address the needs of safety validation methods to cover emerging issues. The benefits to the regulator are that there will be smaller uncertainty margins in safety risk assessments and safety requirements.

As part of the further developments of the SMRT, there will also be need for more guidance material on the use of the Tool as well as its results. Benefits to the regulator are that this guidance material helps them in more effective application of the tool, which, together with the coverage of emergent issues, leads to improvements of safety validation methods, which saves considerable effort in terms of fewer auditing cycles required.

3. METHODOLOGY

3.1 Aim of the Methodology

The appropriate safety validation of a large change in air transport operations is very challenging. Since a new operation design in air transport potentially creates emergent behaviour, an appropriate safety validation approach should identify and analyse both known and yet unknown behaviours. The approach should be able to address advanced concepts of operations in a wide context, such as an airspace with several airports, including approach and departure procedures, air transport routes, separation criteria, system performance, with inclusion of institutional, organisational and human aspects and with attention to integral aircraft/ground aspects. A complicating aspect is that air transport operations are characterised by a large number of diverse stakeholders involved, for which responsibilities are likely to change. The challenging developments in air transport operations can only become effective with a timely and adequate involvement of all these stakeholders, and by proper alignment with other international air transport developments.

It is of great importance to gain confidence that essential needs for safety validation, in their widest sense, are identified in a structured and verifiable way and consequently managed in an effective manner. The purpose of the SMRT is to systematically review a safety validation method regarding all aspects important for safety validation. The SMRT is a self-assessment tool, which shows stakeholders the loose ends that require further attention from safety validation.

In initial phases of the life-cycle of an operational concept, the SMRT supports coordination and communication awareness and understanding of safety validation needs between oversight authorities and stakeholders, and gives a level of confidence of how safety validation is being addressed in a project. In later phases it supports regulators in developing acceptance criteria for safety evidence. Use of the SMRT ensures:

- Awareness and better information about safety validation issues.
- Promotion of a common understanding and common view on safety validation issues and sharing of safety validation concerns.
- Early consideration of the potential impacts of safety regulation.
- The preparation of a sound safety validation plan.

- A reduction in project risk and project delay, caused by, e.g., quick fix of problems, cost intensive recovery, or unclear safety performance.
- Information to the regulator on the suitability of a proposed method as an appropriate basis for a safety case.

In the SMRT, as intended for the competent safety oversight authorities, there will be a supporting element to either assess the appropriateness of proposed methods or to provide generic guidance in case no methods are proposed.

3.2 Safety Method Review Tool

The SMRT is built on a set of 32 ‘safety validation quality indicators’ [ISSC, 2007], which are indicators for measuring to what extent a given safety validation method can be used to develop a good safety case. Examples of these indicators are:

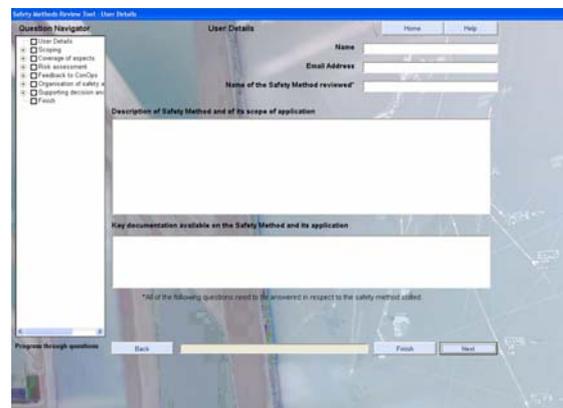
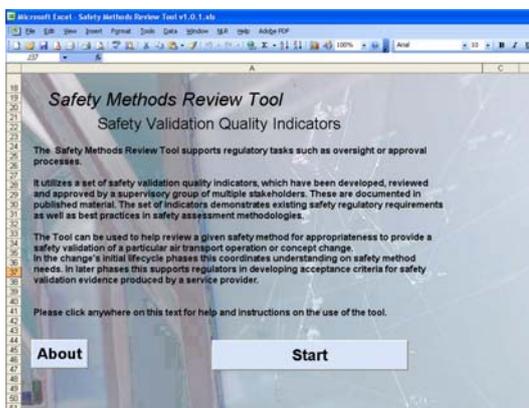
- Information / data needed,
- Identifying hazards,
- Interactions and environment,
- Approximations analysed,
- Feedback and communication,
- Level of safety expertise required
- Transparency of results, and
- Support to decision makers.

The Tool guides the user, by asking for each indicator up to five questions [SCAN TF 2011, SMRT questions] systematically through these safety validation quality indicators, in the way as the Safety Scanning Tool does with Safety Fundamentals. The answers to be given to these questions are multiple-choice (Yes, Partially, No), and a written justification of each choice is required. When all questions have been answered, the user receives a qualitative overview of the safety method aspects that require further attention, as well as an automatically generated report of all answers and justifications provided. The SMRT is programmed in MS-Excel.

The SMRT starts with an opening screen, which provides information on the development of the tool as well as access to a screen for user details.

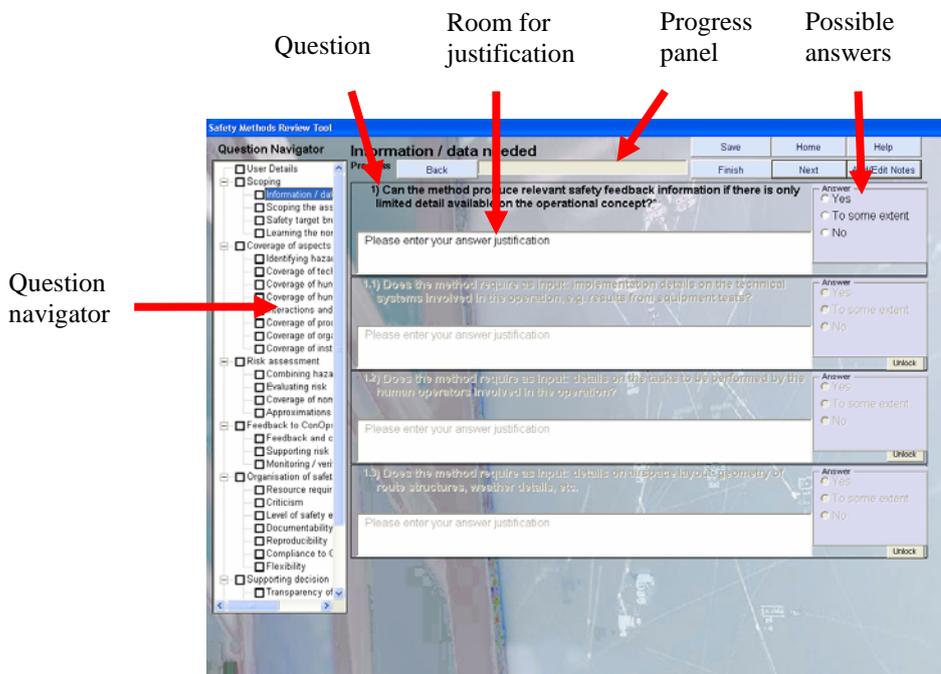
Opening screen

User details screen



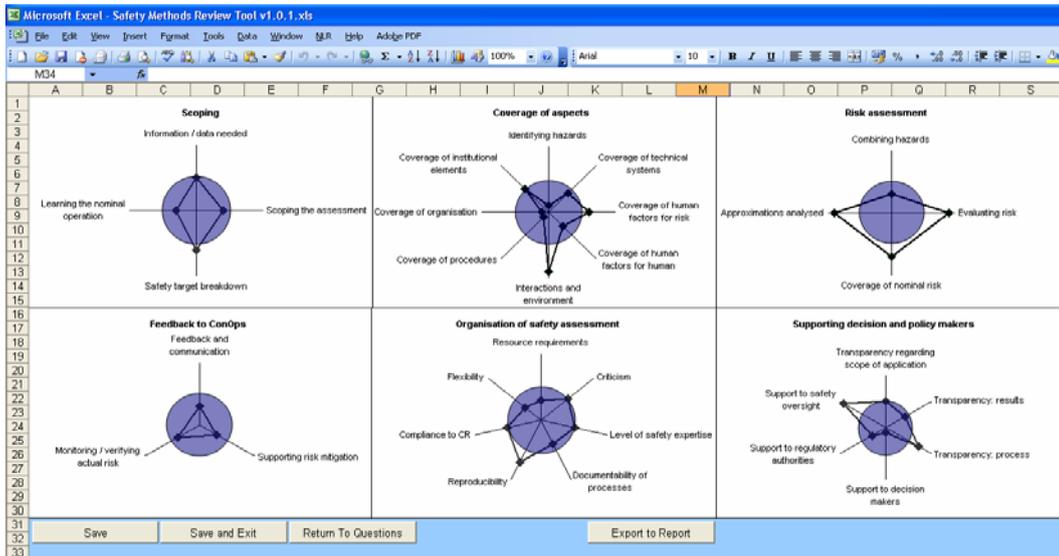
Next, the SMRT contains one screen of questions per safety validation quality indicator. The safety validation quality indicators are organised into six main groups (Scoping, Coverage of aspects, Risk assessment, Feedback to ConOps, Organisation of safety assessment, Supporting decision and policy makers). The questions related to the safety validation quality indicators may be addressed in the given order, or in any alternative order as appropriate.

Each question screen is split into three sections: a Progress Panel, a Question Navigator, and the Questions themselves. The Progress Panel controls the sequencing through the questions, the Question Navigator shows the structure of the hierarchy of questions and the Questions consist of one high-level question and up to four more detailed low-level questions. For each question, there are three possible answers, an area to enter a justification for the answer selected and an explanation of the question that can be accessed in an additional window.



Based on the completed questions, the 'Initial results' screen shows a summary of the Safety Method Review by six web-charts, i.e., one each for the Scoping, Coverage of aspects, Risk assessment, Feedback to ConOps, Organisation of safety assessment, Supporting decision and policy makers results. Each spoke in a web is coupled to one safety validation quality indicator. Issues on a web outside the blue circles indicate a need for attention in further safety validation and management.

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The 'Export to report' feature extracts the completed questions, their answers and the justifications into a formatted MS Word document. This document can be modified and provides a convenient starting point for a written report on the Safety Method Review outcome.

3.3 When to Use and by Whom

The Tool is ideally used iteratively in the course of a lifecycle of an operational concept. It shows the gaps and loose ends that require further attention from safety validation.

In the concept Scope or Feasibility stages, the competent authority can inform the party who will be making the safety case what they expect regarding safety methods, and use the tool to explain these expectations. During the Integration or Pre-operational stages, the competent authority can review the Preliminary Safety Case or Safety Case developed on sufficiency and completeness with respect to the methods used and the issues addressed by the safety case.

Issues that are not sufficiently addressed present an opportunity or need for improvement, which could be covered by alternative or additional methods. During the Operational stages, if the Operation does not appear in reality to be as safe as predicted by the Safety Case, the competent authority can do another review of the Safety Case on sufficiency and completeness with respect to the methods used and issues addressed. In addition, at any point when a safety method is being developed, used or selected to be used to develop a safety case or part of it, a safety analyst can apply the tool in order to identify issues for improvement of this safety method, which could be covered by alternative or additional methods.

It is noted that the SMRT has been designed for assisting in safety validations that consider relatively large changes in air transport operations. For relatively small changes, regulators are generally less demanding regarding the use and output of safety methods. It is noted though that even in those cases, the tool may still be useful as a checklist to see that nothing important has been missed.

Safety method review is intended as a method to be used by competent safety oversight authorities in their respective safety regulatory review process. However, since the answers to the questions are to be provided by aviation stakeholders such as ANSPs, these stakeholders could use these questions as a reference baseline to improve upon their own processes as well.

3.4 How to Use the Method

Input to the Safety Method Review is a (set of) proposed safety validation method(s), a safety case or safety validation in which a particular safety validation approach has been used. The Tool could be used by one or a few persons, or in a session environment, attended by stakeholders involved in or affected by the safety validation.

The SMRT is run on a laptop or personal computer, which may be connected to a screen for all participants of the session to see. Depending on the size of the project, one or two moderators could guide the participants through the questions and providing explanations where necessary, by interacting with the computer, typing the answers and their justification, provided through discussion between the participants. At the end, the moderator together with the safety validation project manager will highlight the automatically generated initial findings.

Depending on the size of the group and the nature of the safety validation method being reviewed, the session takes up to one working day. Following the session, the moderators and the project manager, together with operational safety validation experts, will complete a written report. This report includes an interpretation of the results and a list of actions that need to be addressed to support further safety validation and feedback to design. The results may also be used in the further development and improvement of the method or approach, and may be used by the oversight authority to monitor the progress with respect to results of a previous review.

4. A WAY FORWARD

4.1 Work for the Short Term

Two issues are identified as part of the further work for the short term:

- There is need for guidance material on the SMRT, which should explain more precisely the scope of the Tool, how to use it, and how it relates to the Safety Scanning Tool (SST).
- There is a need to improve some of the questions (and/or their explanations) in the SMRT regarding explicit coverage of stakeholders, and safety regulations¹.

4.2 Work for the Longer Term

Four issues are identified as part of the further work for the longer term:

- There is a need to make the SMRT scalable to the lifecycle phases V0-V7 of the E-OCVM.

¹ *MoT-NL has offered SRCCG NLR-support in their review of SAME. Also the EASA-SATF considers the use of this Tool. The experiences from these reviews could be input for further improvements of the questions.*

- There is a need to explicitly address relationships with other validation aspects rather than only safety, including the balancing of these aspects.
- There is a need to provide more automated support on the availability of alternative methods, in case the safety method being reviewed has limitations.

And finally, it is suggested to develop validation quality indicators and the corresponding tools for other performance areas beyond safety.

5. REFERENCES

5.1 Relevant Papers & Documents

- ISSC, 2007 – Paper by NLR in ISSC 2007 “Study of the Quality of Safety Assessment Methodology in Air Transport”
- Safety Science, 2008 – Paper by NLR, MoT-NL and QSA in Safety Science “Developing a framework for safety validation of multi-stakeholder changes in air transport operations”, 2008
- A35-WP/220 – ICAO working paper “Development of a global gate-to-gate safety assessment methodology”, 2004
- SCAN TF (2011, SMRT questions) – SCAN Task Force, Development of a Set of Questions for the Safety Methods Review Tool, Edition 1.1, 11 April 2011, M.H.C. Everdij, O. Straeter, J.W. Nollet, H. Korteweg.
- E-OCVM, 2010 – European Air Traffic Management Programme, European Operational Concept Validation Methodology E-OCVM, Volume I, Version 3.0, February 2010. http://www.eurocontrol.int/valfor/public/standard_page/OCVMSupport.html
- SRC DOC 46 – Safety scanning methodology, including Safety Scanning Tool, 2011
- SRC DOC 46 – Annex A, Safety Fundamentals – SCAN Task Force, Safety Fundamentals for Safety scanning.

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APPENDIX A – SCAN TASK FORCE

1. TF Members

Chairman: Jos W. Nollet [NSA - the Netherlands]

Contract manager [2009]: Henk Korteweg, formerly EUROCONTROL/ASRO

Administrative support SRU: [2009] Françoise Girard, [2010] Gary Morton

Members: Terry Longhurst, CAA-UK; Lt-col. Edgar Reuber, EUROCONTROL/CMAC; Arnoud Limousin, DSAC.

Specific support: Andrew Burrage, Helios Ltd; Mariken Everdij, NLR; Henk Korteweg, EUROCONTROL/CFMU; Bert Kraan, QSA; John Penny, CAA-UK; Oliver Sträter, University of Kassel.

2. Terms of Reference SCAN TF

The following tasks were defined:

- *Needs*
 - To draft a document identifying the NSA and EASA needs with regard the use of a Safety Scanning Tool supporting the safety regulatory reviews for validation at concept level and for new developments.
- *Specification*
 - To evaluate the current version of the Safety Scanning Tool on EGNOS as test case of a project where there are more than one NSA involved.
 - To review existing “specifications” of the safety scanning tool to take into account the NSA needs and the result of the evaluation of the current version on EGNOS.
 - To discuss the contents of the work packages of the project;
- *Work to be done*
 - To review the deliverables of the project;
 - To assist the assessment of the Safety Scanning Tool on a test case of a programme or project where there are more than one NSA involved at EU level (an Operational Improvement of SESAR will be chosen)
- *Acceptance*
 - To present to SRCCG a final report for approval.
 - Subject to the SRCCGs approval, to run the Safety Scanning Tool on the GNSS related projects identified at the last SRC meeting (i.e. “SBAS APV” and “APV Baro VNAV”) and to compare the findings against the GNSS Preliminary Safety Case (PSC).
 - To present to SRCCG a final report to discharge.

(***)