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NLR Air Transport Safety Institute
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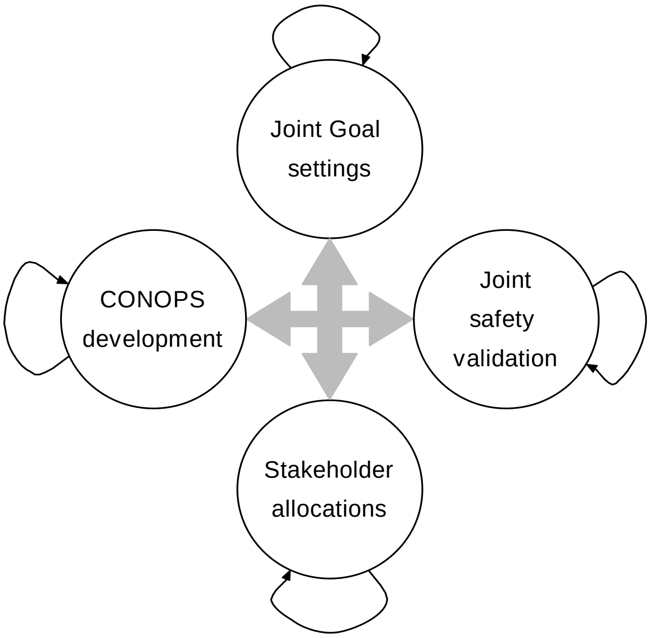
## Executive summary

# DEVELOPING A FRAMEWORK FOR SAFETY VALIDATION OF MULTI-STAKEHOLDER CHANGES IN AIR TRANSPORT OPERATIONS



**Problem area**
The aviation community expects the volume of air traffic over Europe to double within the next 15 years or so, without jeopardising high safety records of aviation. Such safe increase of volume requires challenging developments in air transport operations and their management, with possibly changing stakeholder responsibilities.

According to regulations posed by the International Civil Aviation Organisation, the national authorities are responsible for the safety within their country's airspace. Hence, before a change in air transport can become operational, the national authorities will require ensuring that the targeted operation is safe, that it will remain safe during an applicable period, and that any issues that may compromise safety are mitigated. The process to ensure

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this is referred to as Safety Validation.

## Objectives

The objective of this paper is to develop a safety validation framework that emphasises the active roles that have to be played by the multiple stakeholders during the development phases of a major change in air transport operations. The development of this safety validation framework is referred to as SAFMAC (SAFety validation of MAjor Changes).

The appropriate safety validation of a drastic 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 traffic 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 aligning with other international air transport developments. What appears to be missing is guidelines on when and how to involve the various stakeholders in the development process, and to take into account the necessary alignment of their responsibilities and their goals.

## Description of work

This paper first explains what we mean by air transport operations and concept of operations, and gives a taste of the numbers and the diversity of the stakeholders involved. Next, it presents single-stakeholder validation views from literature and analyses these views regarding issues which need to be addressed when developing major changes in air transport operations. Subsequently, the paper outlines multi-stakeholder validation views from literature, and analyses whether these address the open issues relevant for air transport operations. After this, the strong points of all validation views are collected and integrated into one framework. This framework includes a Macro stage, in which all stakeholders work together on their joint goal, which is followed by a Meso stage in which each stakeholder works on their individual requirements in line with the joint goal. Finally, this framework is elaborated for the early concept development phases.

**Results and conclusions**

Through a process of analysis, evaluation, review and consolidation, including an alignment with important European developments in the field, this paper develops a safety validation framework that consists of four processes: Joint goal setting by all stakeholders; CONOPS development; Joint safety validation process; Allocation of responsibilities and requirements (possibly including functionalities and information flow developments and validation responsibilities), to appropriate individual stakeholders. The framework is referred to as SAFMAC (SAFety validation of MAjor Changes).

In order to further these results, the SAFMAC developments will be focused along two tracks: a policy track, and a follow-up study track. The policy track aims for obtaining further acceptance, nationally, within Europe, within the USA, and within ICAO.

The main issues to be addressed in the follow-up study track are:

- Further clarifying the roles and responsibilities of the different stakeholders within the process of developing a safety validated CONOPS. In particular, attention should be paid to the role of the regulator and the supervisory authorities, including the need for missing regulations.
- Development of a set of safety validation quality indicators.
- Embedding of safety methods into the safety validation process, and further development of safety validation process, including mapping to the individual stakeholders.
- Application of the framework to one or more interesting (national) major changes in air transport operations.

A first national application has been started for a project on merging civil and military airspace management. The early experience in this project already shows that thinking about joint goal setting works remarkably refreshingly for the participating stakeholders and causes them to look beyond their own familiar contexts.

Ongoing developments regarding the identified validation views and newly emerging validation views will be considered in the further SAFMAC development as well.

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# DEVELOPING A FRAMEWORK FOR SAFETY VALIDATION OF MULTI-STAKEHOLDER CHANGES IN AIR TRANSPORT OPERATIONS

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# ABSTRACT

The high volume of air traffic over Europe is expected to double within the next 15 years. This requires changes in the airspace structure and in the organisation of air transport operations that involve multiple stakeholders. Changes, by regulation, require a sufficient safety validation, in order to show that the changed situation is safe and will remain safe during an applicable period. Many methods and techniques exist that can be used to support such safety validation process. However, for air transport operations, the stakeholders involved are numerous and diverse, and there are no guidelines on how to address their roles, responsibilities and goals during development and validation.

This paper develops a safety validation framework that emphasises the active roles and collaboration of multiple stakeholders during the development phases of air transport operations. The framework is developed in three steps: First, established validation views from literature are identified and analysed to reveal open issues when it comes to their use for multi-stakeholder changes in air transport operations. Next, validation views emerging beyond the established ones are identified, and evaluated on whether they address the open issues. Finally, the strong points of established and emerging views are combined into a novel framework.

# CONTENTS

# 1 INTRODUCTION

The aviation community expects the volume of air traffic over Europe to double within the next 15 years or so (SESAR, 2007), without jeopardising high safety records of aviation. Such safe increase of volume requires challenging developments in air transport operations and their management, with possibly changing stakeholder responsibilities.

According to regulations posed by the International Civil Aviation Organisation (ICAO Annex 11), the national authorities are responsible for the safety within their country's airspace. Hence, before a change in air transport can become operational, the national authorities will require ensuring that the targeted operation is safe, that it will remain safe during an applicable period, and that any issues that may compromise safety are mitigated. The process to ensure this is referred to as *Safety Validation*. The use of the term validation is in line with the common definition of 'validation', as answering the question "are we building the right system?", as opposed to 'verification', which is defined as answering the question "are we building the system right?"

The objective of this paper is to address this problem by developing a safety validation framework that emphasises the active roles that have to be played by the multiple stakeholders during the development phases of a major change in air transport operations. The development of this safety validation framework started in (Everdij et al., 2006) and is referred to as SAFMAC (SAFety validation of MAjor Changes).

The appropriate safety validation of a drastic change in air transport operations is very challenging. Since a new operation design in air transport potentially creates emergent behaviour, e.g. (Shah et al., 2005), 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 traffic 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 aligning with other international air transport developments. What appears to be missing is guidelines on when and how to involve the various stakeholders in the development process, and to take into account the necessary alignment of their responsibilities and their goals.

This paper is organised as follows. Section 2 explains what we mean by air transport operations and concept of operations, and gives a taste of the numbers and the diversity of the stakeholders involved. Section 3 presents single-stakeholder validation views from literature and analyses these views regarding issues which need to be addressed when developing major changes in air transport operations. Section 4 outlines multi-stakeholder validation views from literature, and analyses whether these address the open issues relevant for air transport operations. Section 5 integrates the strong points of all validation views collected into one framework. This framework includes a Macro stage, in which all stakeholders work together on their joint goal, which is followed by a Meso stage in which each stakeholder works on their individual requirements in line with the joint goal. Section 6 provides an elaboration of this framework for the early concept development phases. Section 7 gives concluding remarks.

# 2 AIR TRAFFIC OPERATIONS AND THEIR STAKEHOLDERS

In this paper, 'air transport operations' refers to the set of all air transport movements in the airspace that have the intention to transport passengers and/or goods, with support from all infrastructure and services that are necessary to establish these movements in an efficient and safe way. All together, it forms a large joint cognitive system (Hollnagel and Woods, 2005). A concept of operations (CONOPS) is a description on how these air transport operations are proposed to be organised and managed in a safe and effective way. It outlines the roles and responsibilities of all operators, the procedures and the functions of the technical systems, and their interactions. A CONOPS is generally designed and developed in several iterative phases, and the sequence of phases from the beginning to the end is referred to as the lifecycle.

In air transport, such CONOPS development requires adequate involvement of various stakeholders. The number of stakeholders involved in or affected by a major change in air transport operations is very large. Fig. 1 gives an overview which divides them into groups, and with a few example stakeholders per group indicated. Note that some stakeholders may fall under two or more groups; for others, the choice of group may be argued, and it may also be argued if governments are stakeholders or organisations beyond the stakeholders. However, the overview in Fig. 1 may paint a good first picture of their variety and of the consequential complexity of designing a CONOPS of advanced air transport operations.

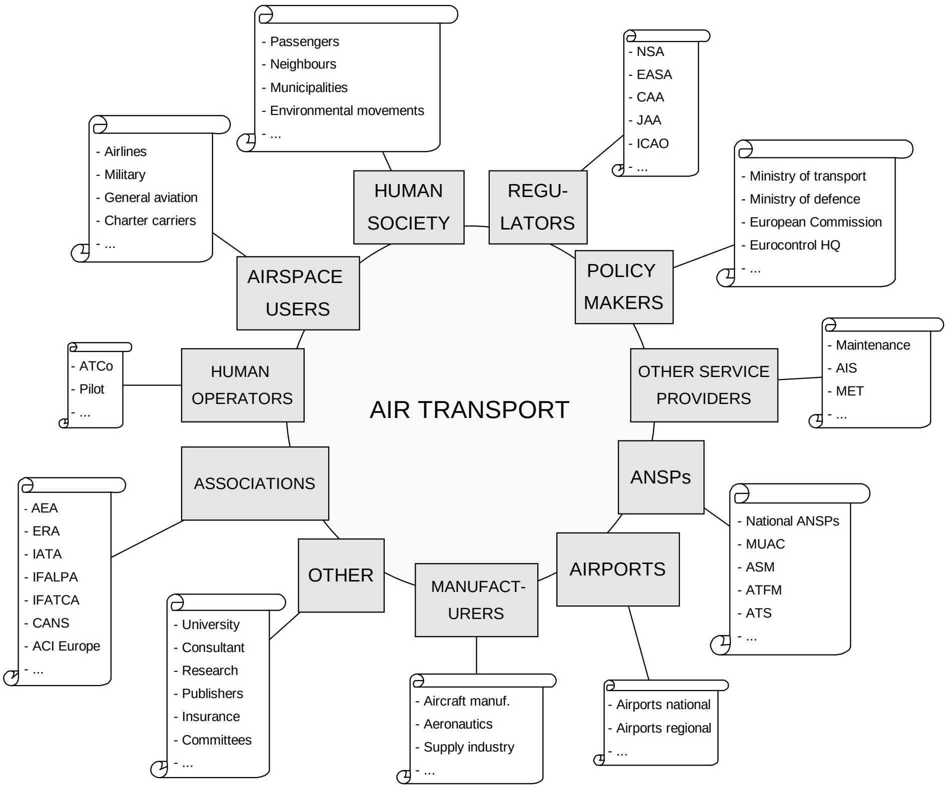

*Figure 1: Overview of stakeholders in air transport operations. The explanation of the abbreviated organisation names falls beyond the scope of this paper.*

It is also interesting to identify the relation with potential victims of accidents. First party victims are aircraft crews involved in the accident, who typically are employed by an airspace user, e.g. an airline. Second party victims are passengers aboard an unlucky aircraft. Third party victims are any human victims outside the unlucky aircraft, e.g. victims that happened to be at the aircraft crash site. Thus, first, second and third party victims fall within a few stakeholder types only. Their future safety critically depends of a proper conops design.

# 3 SINGLE-STAKEHOLDER VALIDATION VIEWS

The lifecycle of an air transport operation is a stepwise description of the evolution of the operation. The lifecycle of future operations starts with the formulation of the Mission and of Strategic Objectives by stakeholders. The lifecycle ends after the economical life span of the operation. Obviously a lifecycle consists of many phases and subphases. In order to keep things manageable throughout the lifecycle, two things should be arranged: for each subphase the responsible actor(s) should be identified, and it must be possible to assess in an objective way if a particular subphase is completed. The latter assessment steps are commonly referred to as validation and verification steps. Since validation deals with examining the question if the right system is being developed, validation itself depends on the one hand on the actor groups and on the other hand on the phase of the lifecycle of the system.

In various fields, people are designing and building systems, which includes proving that the right system is being built (validation) and that the system is being built right (verification). For complex systems there is a clear need for a structured approach towards validation and verification throughout the complete lifecycle of the system. Consequently, a pile of literature is available on verification and validation. While verification is always seen as comparing the outputs of some system development phase with the inputs it received from an earlier phase, various differing interpretations of validation appear in literature. The simple reason is that the interpretation depends on the people to which one poses the validation question “are we building the right system?” The aim of this section is to give a brief literature overview of established validation views. It appears that these all address a single stakeholder only. The section uses input from Blom et al., (1996).

## 3.1 SYSTEM DEVELOPMENT MODELS

For complex systems, there are two basic system development models known in the literature: the V-model and the Spiral model. They give complementary views to the development of a system. Consequently, in practice these two models are often used in a combination. They are briefly explained next.

The V-model can be seen as a refinement of the ‘waterfall model’. In the waterfall model, system developments are done sequentially so that there are clean phases which do not repeat processes carried out in previous phases; the outputs of one phase form the input of the next. However, in the case of complex developments which must be heavily decomposed for design and production, it is often necessary to check that the outputs of one stage are verified against the specifications at the input, and furthermore that those outputs meet the requirements of the real world application. This leads to the V-model, Fig. 2, with the left-hand-side of the V representing refinement of the specification (i.e. of the waterfall model) and the right-hand-side of the V representing production and assemblage. The correctness of each step is verified before proceeding to the next, whilst validation of the refinement "specifications" against the "productions" is effected across multiple design phases as shown in the diagram.

A standard safety-directed development approach established in aviation is the SAE's (Society of Automotive Engineers) Aerospace Recommended Practices (ARP 4754, ARP 4761). Like the V-model, this approach is based on the notion of hierarchical system decomposition during development. It contains processes for requirements capture, validation, system development and verification, and gives guidelines and methods for conducting the safety assessment process on civil airborne systems and equipment.

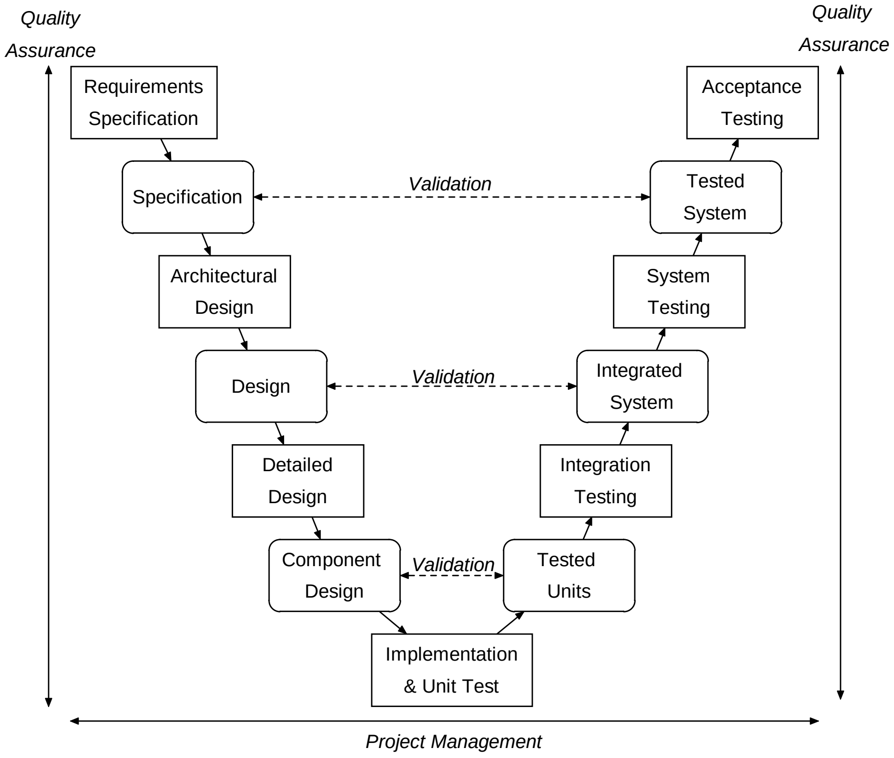

*Figure 2: The V lifecycle model, e.g. (Whytock, 1993).*

The spiral model is based on the premise that not all events that may arise during complex developments can be foreseen from the onset. When unforeseen events happen, steps in the development strategy and plan are adjusted, with obvious effects on target end-dates and confidence in the final outcome. By iterating through requirements-specification-design-implementation stages and progressively refining the solution, the risk can be evaluated and quantified. In the spiral model (Fig. 3) each cycle progressively comes closer to the eventual solution. The model includes the possibility of change within the development processes. This risk-driven approach recognises that unpredictable events may occur and provides a strategy for their timely discovery and handling. The cyclic iterations in the spiral allow the selection from options and optimisation by gradual incremental change. A segment projected from the centre of the spiral embraces the same processes across the iterations. Thus the spiral model is similar to a repeated waterfall model. The inner cycles represent early analysis and prototyping techniques; the outer cycles embrace development techniques. A segment of each spiral is devoted to risk analysis to decide if and when sufficient cycles have been undertaken.

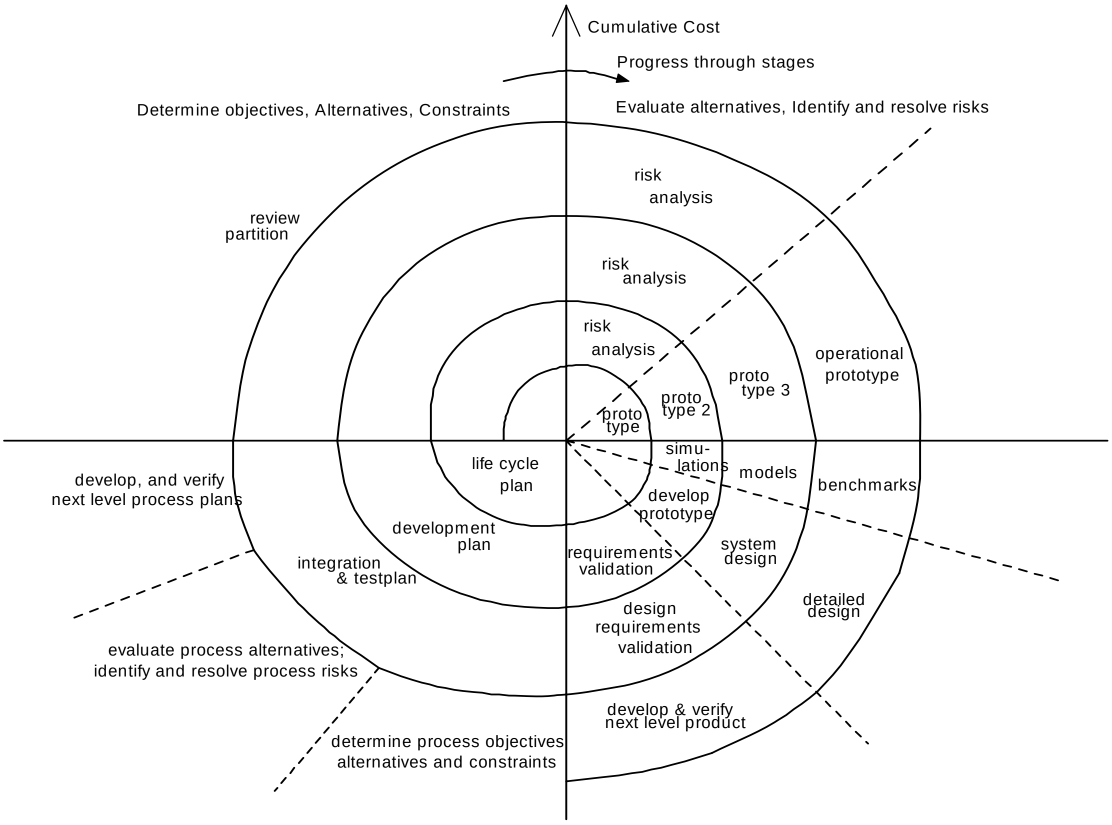

*Figure 3: The spiral lifecycle model, e.g. (Whytock, 1993).*

Both in the V-model and in the Spiral model we recognize that the verification and validation steps play a crucial role in deciding if a particular phase is completed or not. Neither of these two development models, however, provides details about their verification and validation steps. As such it is of crucial importance to understand the literature views on verification and validation when one goes into a detailed elaboration of very complex developments.

## 3.2 SYSTEM ENGINEERING VIEWS ON VALIDATION

With the V-model we actually came across a particular interpretation of validation: comparing the output of subsequent development phases against the specifications at the beginning of these development phases. In this case the question “are we building the right system?” obviously has been posed to people who are responsible for delivering an integrated system according to the specifications. What is missing in that case is the validation of those initial specifications. Obviously, it is quite well possible to extend the V-model with validation steps which handle these omissions.

Another common situation is that the validation question is posed to people who are designing the system, in which case we arrive at the view held in software engineering (Deutsch, 1982, p. 8): validation is a matter of comparing a result against user requirements. Fig. 4 shows the resulting phase-wise verification and across-phase validation efforts (Sage, 1992, p. 136). What is missing in that case is the validation of the user requirements themselves.

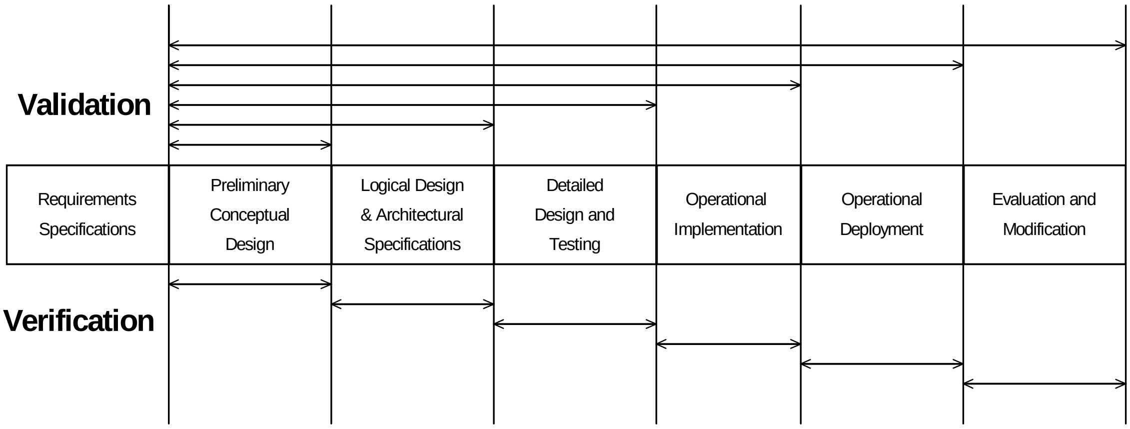

*Figure 4: System designer's view on verification of validation (Sage, 1992, p. 136).*

Another interpretation of validation comes when posing the question “are we building the right system?” to customer-oriented designers. In that case validation stands for comparing a design result with the “stated or implied user needs", e.g. (Roes, 1993, p. 208) Fig. 5. This pre-assumes that the "stated or implied user needs" are flawless. It is left to the customer to validate the "stated or implied user needs".

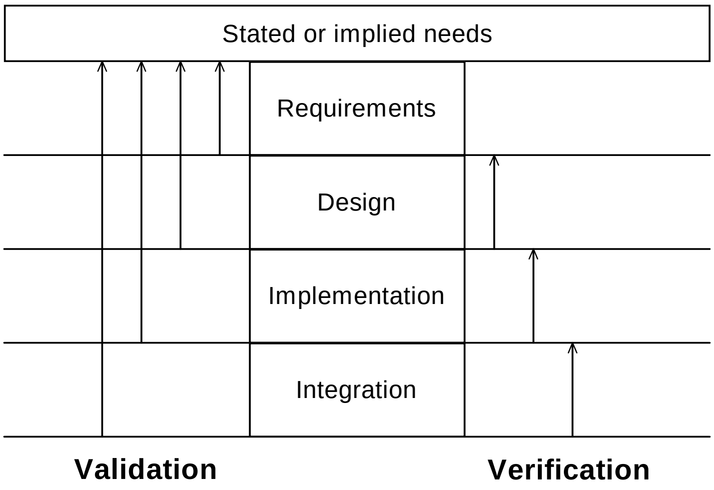

*Figure 5: Customer-oriented view on verification/validation (Roes, 1993, p. 208).*

From studies on dependable computing and fault-tolerant systems, e.g. (Randell et al., 1995), it has become clear that the basic validation question "are we building the right system?" should be followed by the additional validation question "and for how long will it be right?" This additional validation question takes into account that the user needs may evolve with time, and that the economic life is limited.

## 3.3 HUMAN FACTORS VIEW ON VALIDATION IN SYSTEM DEVELOPMENT

Like for system development, different development models can be identified for the side of the human. The characteristic of a psychological model for the human side is that it pays more attention to the human in connection to their responsibilities, rather than the system engineering approach of considering the human operator simply as another sub-system. An example can be seen in Fig. 6 (Stubler et al., 1993), where the model starts from a mission statement and takes into account possible errors and cognitive demands of the human as well as human-system aspects to test the concept before starting the actual validation and verification process.

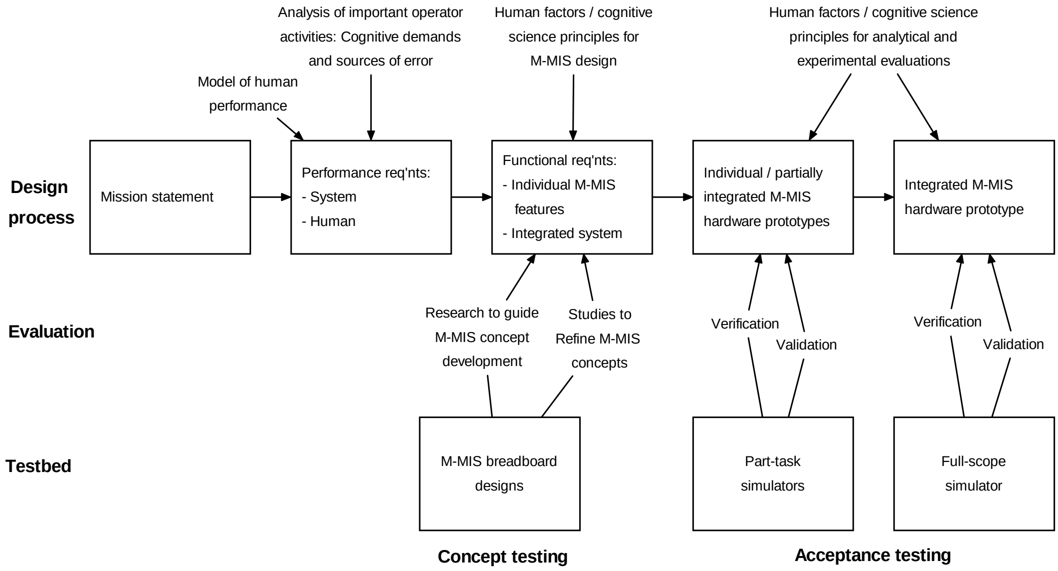

*Figure 6: Development from human factors point of view (Stubler et al., 1993). M-MIS denotes man-machine interface system.*

There are other human development models, e.g. (Plant, 1993, p. 201; Westrum, 1993, p. 409; Jackson, 1989), which all have in common that the validation question “are we building the right system?” is posed to a human factors expert rather than a system designer. Similar as for system engineering, there are multiple human factors interpretations of the validation question possible. For example if we put the validation question both to a human factors designer of human machine interfaces and to a developer of human centred automation strategies, then we will get quite different answers. A good impression of the large variety in human factors interpretations of validation can be found in Wise et al. (1993).

## 3.4 BUSINESS MANAGEMENT VIEW ON VALIDATION

Usually the management of the lifecycle of a system is not an objective that stands on its own. From a business need perspective the objective is rather to best ensure market competitiveness through a cost-effective handling of all elements and factors involved with the products under consideration (e.g. customer satisfaction, continuous improvement, robust design, variability reduction, statistical thinking, management responsibility, supplier integration, quality control, education and worker training, teamwork, cultural change and stakeholder interfaces). Basically it is a business need of improving the product which makes it worthwhile to invest in a new system. Thus from a business need perspective, the common validation question “are we building the right system?” is only part of the more general validation question “are we designing and planning for the right product, and for how long?”. This generalised validation question has two important implications:

1. Insufficient validation and verification during the early phases of a design of a new production system may undermine a cost-effective lifecycle, since the farther a production facility progressed in the design process, the more costly the modifications will become since one change has all sorts of implications that impose the need for yet other changes.
2. Validation and verification of a new production system does not stop when production starts, but continues throughout the productive stage of its lifecycle.

A well known approach in organizing these business-directed validation and verification steps, both during development and operational phases, is known as Total Quality Management (TQM). TQM realizes strategic management for quality consciousness and assurance at four levels (Sage, 1992, p. 191):

- Inspected quality, to assess if performance satisfies pre-specified norms.
- Statistically controlled quality, using cost-effective performance metrics.
- Quality built-in through design and planning at operational task level.
- Proactively managed quality, through the involvement of all organizational elements involved in the process and products under consideration.

All four levels ask for verification and validation steps. At the first three levels the generalised validation question “are we designing and planning for the right system?” is dealt with by the management only. At the fourth level, however, this question is dealt with by all entities participating in the production. If the latter level is being omitted, then we speak of Quality Management. Thus the involvement of all entities at the fourth level is specific to TQM.

Implicitly, quality incorporates safety. Nevertheless, in safety related business one sometimes refers to TQSM (Total Quality and Safety Management) in order to clarify that safety consciousness and assurance should explicitly be incorporated at the four levels identified:

- Inspected quality and safety, to assess if quality and safety satisfies pre-specified norms.
- Statistically controlled quality and safety, using cost-effective performance metrics.

- Quality and safety built-in through design and planning at operational task level.
- Proactively managed quality and safety, through the involvement of all organizational elements involved in the process and products under consideration.

A further elaboration of TQM has been done by EFQM (European Foundation of Quality Management) and resulted in the EFQM (EFQM, 2002), which embeds the principles of excellence in a framework that helps organizations assess their capabilities and strengths in order to achieve their particular goals Fig. 7.

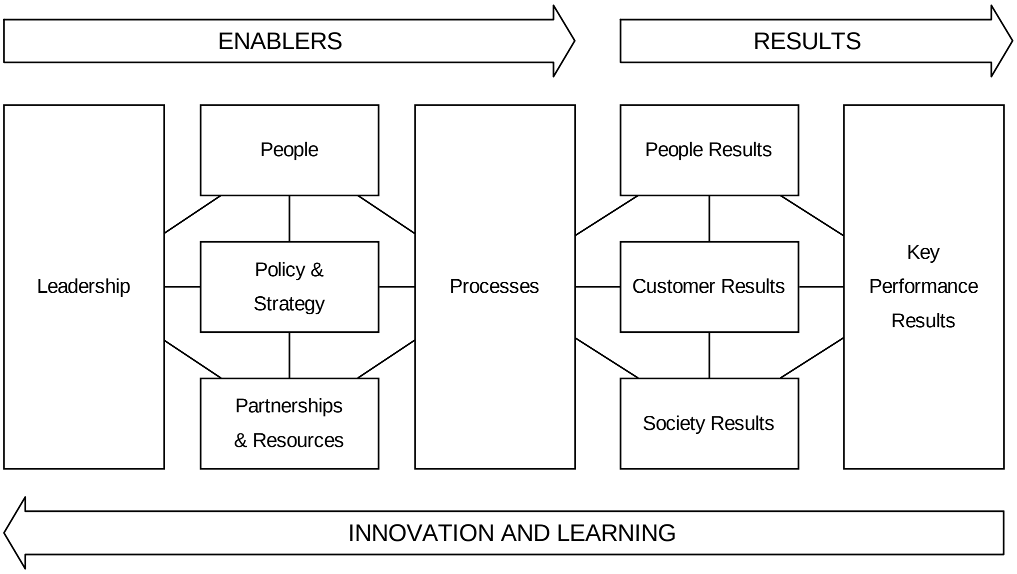

*Figure 7: EQFM model.*

## 3.5 SAFETY MANAGEMENT AND MODERN SAFETY CASE

The safety validation of a safety-critical operation is documented in a *Safety Case*, which is a series of documents describing the results of a safety validation process. The Safety Case thinking has evolved in parallel with the safety management and certification thinking. The original certification regime for an operator of, e.g. an offshore petrochemical plant posed requirements to the systems, procedures and crew, which were of a prescriptive nature. To put a new or changed petrochemical plant into operation, the operator of that plant had to build a Safety Case for approval by the national authorities. This Safety Case had to provide the high level arguments and the supporting evidence that for each normal and failure mode of that plant, the combination of frequency of occurrence and severity of effects was acceptable.

During the last two decades, the safety management and certification thinking has rapidly evolved by positive experiences in safety-critical domains. It was the report by Cullen (1990) on the Piper-Alpha accident of 1988 that made clear that for complex safety critical operations in the petrochemical industry, there was a need to introduce two major improvements: (1) replace the prescriptive certification requirements by goal-setting ones (e.g. in terms of risk), and (2) implement appropriate safety feedback loops at all management levels (Andlauer et al., 1999). This goal-oriented safety management depicted in Fig. 8 shows that goal setting is an iterative process in itself, even when restricting to a single stakeholder. However, it does address the validation of actor requirements, i.e. making sure that the identified actor requirements, wishes or needs are all consistent with the goals of the design.

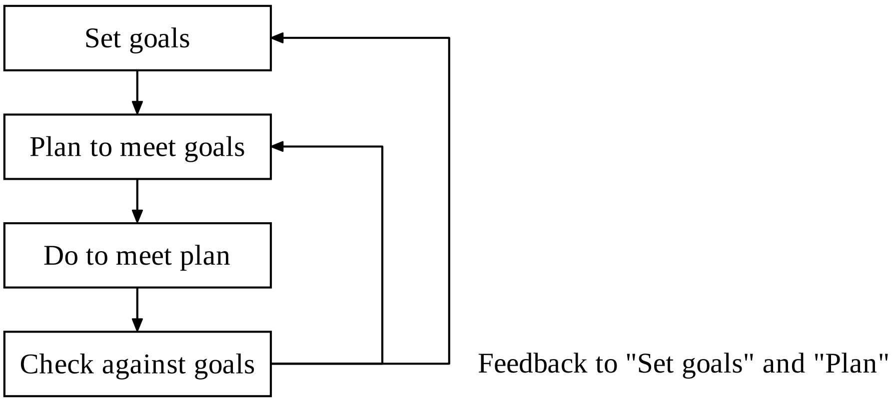

*Figure 8: Goal-oriented Safety Management process.*

Under a classical prescriptive regime, a Safety Case tends to provide an instantaneous picture of the possible failure modes and their effects. Under a modern goal-setting safety management regime, the scope of a Safety Case is much wider: (1) it is aimed to cover anything that may influence safety, e.g. all hazards but also all positive safety behaviours rather than failure modes only (Fowler et al., 2007), and (2) it takes the impact of the safety management approach of the responsible actors into account. Thus, a *Modern Safety Case* incorporates the elements of a classical safety case, plus a description of the safety management approach and a hazard register, see Fig. 9.

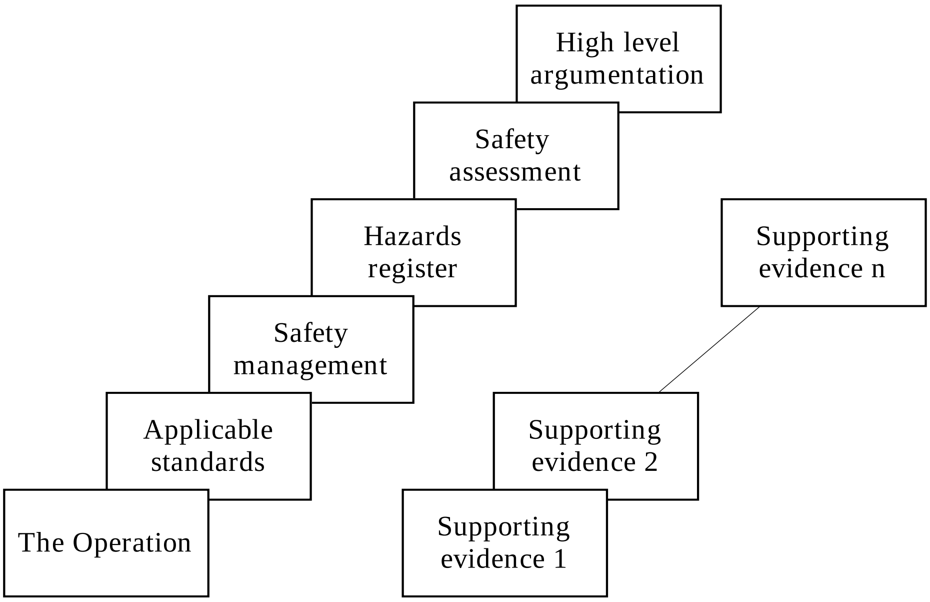

*Figure 9: Modern Safety Case under goal-setting safety management.*

A complementary development is that top level management has recognised the Modern Safety Case as a valuable decision-support management tool during all lifecycle stages of a safety critical operation (e.g. Short, 1998). For example, during the conceptual development stage of a new safety critical operation, top level management may have to make a decision with respect to further improving the design first, or starting the preparation and procurement for the operational implementation of a new or improved operation. In order to be fully informed, top level management rather needs the complete picture provided by a Modern Safety Case, than the partial picture provided by several technical evaluations. A related development is that, for a safety-critical operation, insurance companies reduce the insurance premium if a Modern Safety Case is available, e.g. in petrochemical industry.

## 3.6 ANALYSIS OF SINGLE-STAKEHOLDER VALIDATION VIEWS

Finally, we analyse the established validation views presented in this section. Here we start with the good news: these views are all well established for the design of technical systems in aviation, and a lot of practical experience exists with their application to a variety of problems. In particular, the Aerospace Recommended Practices (ARP) of the Society of Automotive Engineers are considered a standard for the development of civil airborne systems and equipment (ARP 4754, ARP 4761). Each of the established validation views highlights issues important for particular stakeholders.

When considering validation of major changes in air transport operations, also several questions can be posed regarding the established views. Below, these questions are referred to as issues A-D:

A. Are multiple stakeholders addressed? There are many different stakeholders involved in air transport operations; e.g., Airspace users, Human society, Regulatory and supervisory authorities, Policy makers, Air Navigation Service Providers, Airports, Manufacturers, Human operators, etc. Each of these groups of stakeholders has its own goals, and each will have their influence on future air transport operations. None of the established validation views address the development process for more than one stakeholder.
B. Is integration with complementary views addressed? For major changes in air transport operations, different validation aspects need to be addressed. Safety aspects often require other validation perspectives than economy or human factors aspects. These aspects should eventually be balanced and integrated. For none of the established validation views it is explained how it can be integrated with any of the other views. A related issue is that the established validation views do not acknowledge the same phases in the operation's development lifecycle.
C. Is joint validation of multiple actors requirements addressed? The goal-oriented safety management process described in Section 3.5 asked if the requirements of an individual stakeholder are validated with respect to the goal of this stakeholder. Due to the high complexity of air traffic management and the multiple stakeholders vested interests, in practice it is even more demanding to set joint goals for all stakeholders together, let alone start with requirements that are validated against the joint goal setting. None of the established views handle this.
D. Is the role of government policy makers taken into account? Government forms a special stakeholder. In addition to being one of the stakeholders of the previous issues A and C, it has a role as visionary policy maker for its people. For major changes in air transport operations, the role of the policy maker is of particular relevance due to the part they play as investors in infrastructure and in coordinating with neighbouring countries. In some situations (e.g. as in the Netherlands), the policy maker is also the national regulator, who has a special additional role in major changes. None of the established validation views addresses this; the only elements that are arranged are the certifying authorities, but these have no role to play in the economic judgement.

# 4 MULTI-STAKEHOLDER VALIDATION VIEWS

This section presents some validation views from literature, which are considered to go beyond the established ones, and analyses if they address the main open issues A-D.

## 4.1 EUROPEAN OPERATIONAL CONCEPT VALIDATION METHODOLOGY (E-OCVM)

A lack of clear and understandable information to support decision making on air traffic management system implementation in the mid 1990s motivated validation research in Europe. The project VAPORETO (Validation Process for Overall Requirements in Air transport operations) (Blom et al., 1996) laid the foundation: in this project, most of the established validation views of Section 3 were identified and several shortcomings were revealed. The European Commission provided continuous support for addressing this (Fassert et al., 1998) and brought together industry, research and development (R&D) organisations, and service providers. From this point onwards, through a sequence of other projects (e.g. CAVA, Concerted Action on Validation of Air traffic management systems; MAEVA, Master Air traffic management European Validation plan) the findings were eventually converged into the European Operational Concept Validation Methodology (E-OCVM) (E-OCVM, 2007).

E-OCVM includes three aspects of validation that, when viewed together, help provide structure to an iterative and incremental approach to concept development and concept validation: (1) The Concept Lifecycle Model facilitates the setting of appropriate validation objectives and the choice of evaluation techniques, shows how concept validation interfaces with product development and indicates where requirements should be determined; (2) The Structured Planning Framework facilitates programme planning and transparency of the whole process; (3) The Case-Based Approach integrates many evaluation exercise results into key ‘cases’ (safety case, business case, environment case, human factors case) that address stakeholder issues about air traffic management (ATM) performance and behaviours. These three aspects fit together to form a process. This process is focused on developing a concept towards an application while demonstrating to key stakeholders how to achieve an end system that is fit for purpose. The Concept Lifecycle is the central aspect of the validation process, see Fig. 10. Note that the case based approach within E-OCVM is under further development in (CAATS II, 2006).

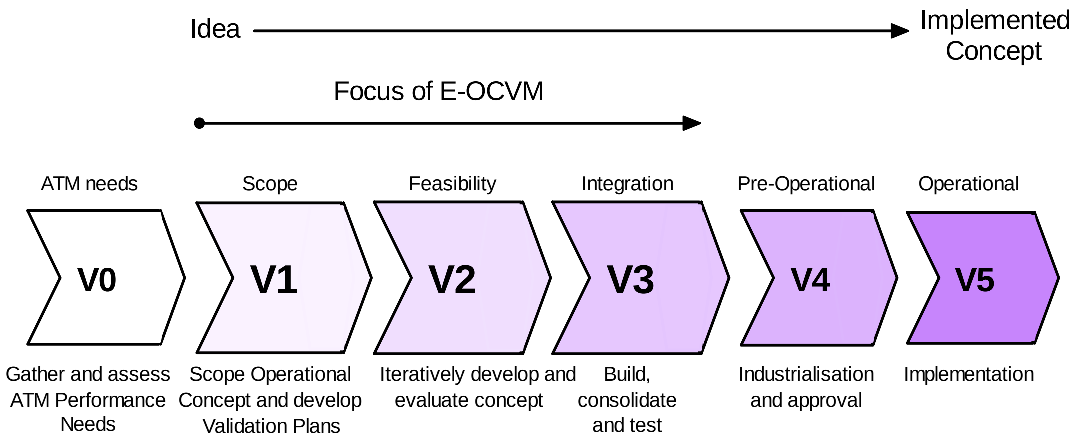

*Figure 10: E-OCVM Concept lifecycle model, from E-OCVM (2007).*

The six phases of the Concept Lifecycle Model are:

- V0 ATM Needs – The ATM performance needs and barriers must be identified. The concept must show that it can alleviate these barriers enough thus enhancing ATM performance to the anticipated required level.
- V1 Scope – The concept should be described in sufficient detail to enable identification of the potential benefits mechanism. Unknown or unclear aspects of the concept may exist as a number of options to be assessed during the further validation process.
- V2 Feasibility – The concept is developed and explored until it can be considered operationally feasible. During this phase, system prototypes will be used that make assumptions about technical aspects in order to avoid system engineering which can be costly and lengthy. Aspects that should be focused on are operability and the acceptability of operational aspects. Operational procedures and requirements should become stable and be thoroughly tested.
- V3 Integration – Any required functionality is integrated into pre-industrial prototypes, by using realistic scenarios that are representative of what the concept must be able to manage. The focus is therefore on system level behaviour, performance and establishment of standards/regulations necessary to build and operate the required technical infrastructure.
- V4 Pre-Operational – Pre-operational prototypes will be transformed into industrial products ready for implementation and all institutional issues concerned with procedures approval should be addressed.
- V5 Implementation – This is the phase when products and procedures are combined to create an operational system.

E-OCVM (2007) integrates several complementary established validation views (issue B in Section 3.6). In particular, it addresses multiple validation aspects by combining three different approaches, i.e. (1) The concept lifecycle model, (2) the structured planning framework, and (3) the case-based approach. In addition, it identifies the need to integrate views within these approaches, e.g. from safety case, business case, environment case, human factors case, etc. Regarding the issue of multiple stakeholder roles (issue A in Section 3.6), the E-OCVM explicitly includes steps that identify the multiple stakeholders involved, and that identify the objectives and needs of each of the stakeholders. Subsequently, it uses the requirements of the individual stakeholders to develop a validation strategy, which is regularly reviewed and updated. E-OCVM however does not explicitly address how the requirements of different stakeholders are being balanced and does not explicitly address the joint validation of stakeholder requirements (issue C); implicitly it is expected that regular reviews and updates would be sufficient. Policy makers (issue D) are implicitly addressed as one of the stakeholders involved, but their special role as investors in infrastructure is not explicitly addressed.

Summarising, the E-OCVM is particularly strong at addressing issue B, although parts of it are under development (particularly for safety and for human factors). Issue A is also addressed, but the coverage of issues C and D is not clear.

## 4.2 INTEGRATION FRAMEWORK IN COMPLEX SYSTEMS ENGINEERING DESIGN

In order to integrate safety in the design and construct of major projects (Stoop, 2005) develops a new notion of systems engineering design and system architecture, which consists of three principal elements: (DCP). These elements can be interrelated along three dimensions: (1) a systems dimension, (2) a lifecycle dimension and (3) a design dimension. Together they constitute an integrated systems architecture prototype: the DCP diagram, Fig. 11.

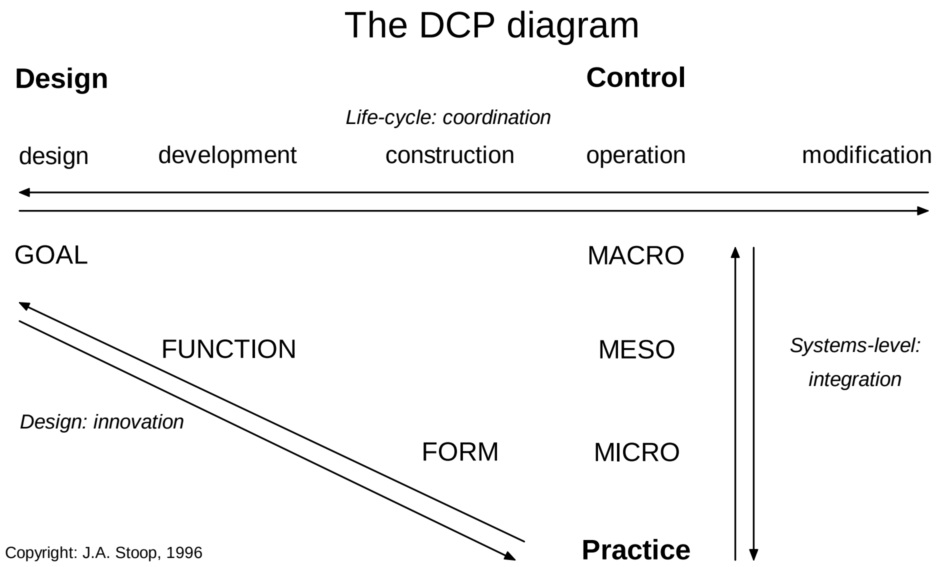

*Figure 11: Systems architecture model: The DCP diagram, from Stoop (2005).*

The systems dimension defines three levels: the *Micro* level of the user/operator, the *Meso* level of stakeholders' organisation and operational control, and the *Macro* level of institutional conditions, i.e. the interactions between stakeholders' organisations and operational control. At this dimension the issue of integration of administrative and emergency organisation across the various levels is crucial.

The lifecycle dimension defines a series of subsequent phases, being design, development, construction, operation and modification. At this dimension, the coordination of decision making among actors across the phases is crucial.

The design dimension identifies three principal phases in design, being goal (expressed by a program of requirements, concepts and principles), function (expressed by design alternatives) and form (expressed by detailed design complying with standards and norms). At this dimension, the potential of technical innovation for new safety solutions is crucial.

The DCP model addresses the integration of complementary views (issue B in Section 3.6) by the inclusion of the levels Macro, Meso and Micro. In addition, the three DCP dimensions can be regarded as three complementary views, which are being coupled in one DCP diagram. Requirements joint validation (issue C) is addressed by the inclusion of and checking against "goal" at the Macro level. Multiple stakeholder roles (issue A) are addressed across all three DCP dimensions, starting during the Macro phase, and maintained later on. Policy makers (issue D) are addressed as one of the stakeholders, but their special role is not explicitly acknowledged.

Summarising: the DCP model addresses issues A, B, and C. Its strength is in identifying a Macro phase coupled to stakeholder joint goal setting at an early stage of the concept lifecycle.

## 4.3 JOINT GOAL-ORIENTED SAFETY MANAGEMENT

The introduction of goal-oriented safety management thinking by airlines, airports and ATM service providers may easily create an increasing tension between individual actors due to the desired evolution in goal-settings and operational solutions. In order not to jeopardise the valuable world-wide standardisation process, airlines, airports and ATM service providers should also be actively involved in the harmonised evolution of both individual and joint actor's goals at the national, regional and international levels. This leads to an extension of the goal-oriented safety management to a Joint goal oriented safety management (Blom and Nijhuis, 2000), and is depicted in Fig. 12.

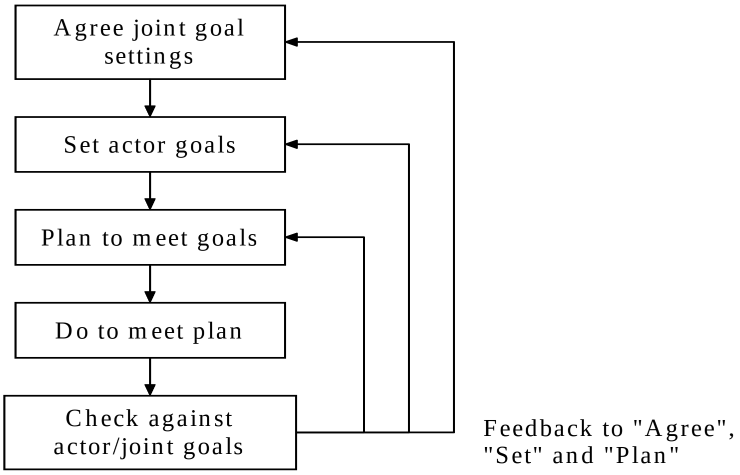

*Figure 12: Integration of Safety Management processes in air transport is enabled by goal-setting co-ordination at national, regional and international levels, and by the exchange between collaborating actors of adequate safety feedback at all management levels (Blom and Nijhuis, 2000).*

The co-ordination between air transport operation directed stakeholders often starts at a national level and involves policy makers, regulators, airlines, airports and ATM service providers. The same variety of actors should also be involved at the regional and international levels, since pilots from various countries have to collaborate with controllers all over the world. The airlines, airports and ATM service providers should collaborate on the joint identification of their actor goals under various operational concepts and against jointly elaborated high level objectives for various air transport demands and environments.

Because the various stakeholders of the novel operational concept to be developed are all collaborating, a modern Safety Case per stakeholder does not suffice anymore. There also is need of a Joint Safety Case that should be produced with proper collaboration of all stakeholders (Blom and Nijhuis, 2000; Blom et al., 2000). As has been well explained in Hollnagel and Woods (2005) and Hollnagel et al. (2006), this should take into account organisational and joint cognitive systems aspects that influence safety of the operation.

The Joint goal oriented safety management model addresses requirements joint validation (issue C in Section 3.6) by explicitly identifying the goal setting level plus feedback to it from check against joint goals. Multiple stakeholder roles (issue A) are addressed by means of the joint actors goal setting level plus feedback to it from check against joint goals. Policy makers (issue D) are only implicitly included as one of the stakeholders. The model does not explicitly integrate complementary views (issue B).

Summarising, the Joint goal oriented safety management model addresses issues A and C. Its particular strength is in the step that the stakeholders need to develop their joint goal, which is updated after feedback from other steps.

## 4.4 MULTI-STAKEHOLDER SAFETY MANAGEMENT

Following a recommendation in RAND (1993), an initial multi-stakeholder safety management approach has been established in 1995 by the Netherlands air transport sector. Recently, this platform of and for the sector to improve air transport safety (ground and flight safety) at and around Amsterdam airport structurally and collectively has been further improved (VpS ToR, 2006). The activities of this platform are aimed at the interfaces between business processes of the sector parties at the airside. Safety at these interfaces is seen as collective responsibility of the sector and as boundary condition for optimal and safe airport operations. Membership of this platform is mandatory for all businesses that execute safety-critical activities at Amsterdam airport. This is laid down in a 'Transactions Regulation', which also commits members to have a form of Safety Management System, aimed at jointly managing safety (i.e. quality, risk, and incidents).

This multi-stakeholder safety management platform explicitly addresses multiple stakeholders roles (issue A in Section 3.6). The role of policy makers (issue D) is addressed implicitly. However, the platform addresses the operational phase only, not the design phase, hence the platform neither integrates complementary validation views (issue B) nor addresses requirements joint validation (issue C). Summarising, the Multi-stakeholder safety management model addresses issues A and D. Its strength is that it gives a particular view to the joint goal setting step of the Joint goal-oriented safety management model in Section 4.3, which makes it less generic.

## 4.5 ROLES OF GOVERNMENT

A picture that shows involvement of multiple stakeholder groups, including the government, as part of risk management is given in Rasmussen and Svedung (2000), see Fig. 13. It shows that there are close links and many nested levels of decision-making involved in risk management and regulatory rule-making to control hazardous processes. The challenge to a safety validation framework is to take all these issues into account in an integrated way.

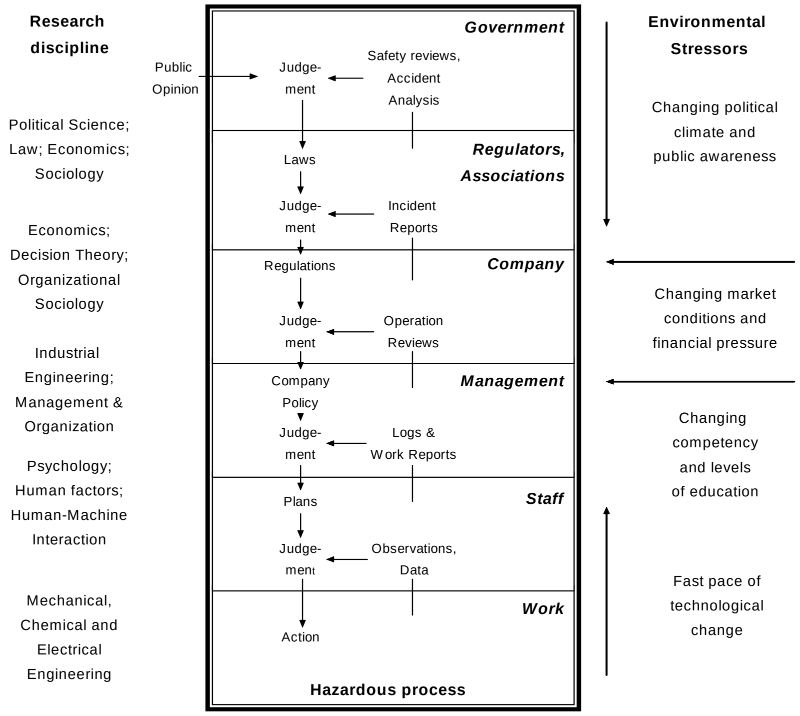

*Figure 13: This figure from Rasmussen and Svedung (2000) shows how many nested levels of decision-making are involved in risk management and regulatory rule making to control hazardous processes. This social organization is subject to severe environmental pressure in a dynamic, competitive society. Low risk operation depends on proper co-ordination of decision making at all levels. However, each of the levels are often studied separately within different academic disciplines.*

In the two models of Fig. 14, the government (ministries and national supervisory authority) is included in two different ways. The dashed box denotes a Project Development Office, which is made responsible for developing a novel operational concept and a corresponding Safety Case. The Safety Case is judged by the national supervisory authority. In the model on the left-hand-side, a Ministry directs a Project Development Office towards the commercial stakeholders. This Project Development Office acts as a commissioner/client on behalf of the Ministry; process integration is central. In the model on the right-hand side, the Project Development Office sits around the commercial stakeholders.

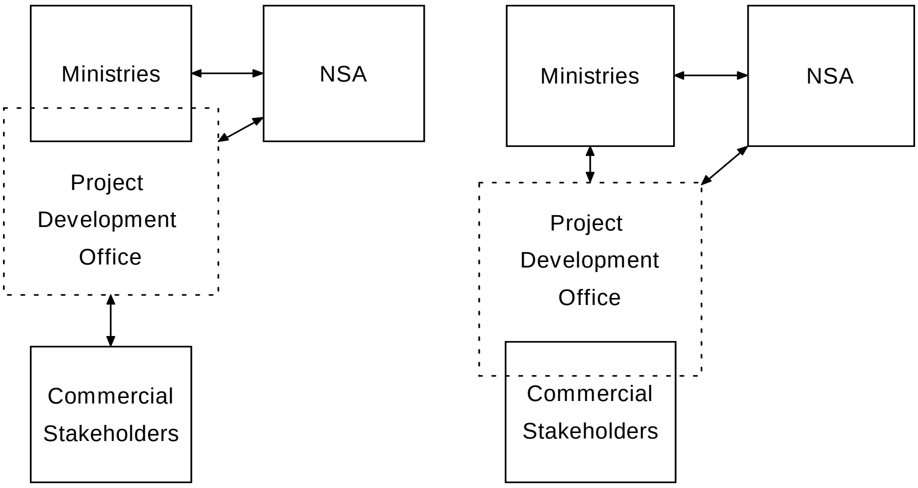

*Figure 14: Two models of possible government involvement in combination with a project development office.*

Variations of these models are possible, e.g. by taking into account a special role for an air navigation service provider as an independent governing body that is responsible for its own tasks, but that can also be regarded as part of the government. This represents the situation of the air navigation service provider in the Netherlands.

The three models presented above address the role of policy makers (issue D in Section 3.6), and to some extent the issue of multiple stakeholder roles (issue A), but neither the integration of complementary views (issue B) nor the joint validation of requirements (issue C).

Summarising, these models address issues A and D only.

## 4.6 SUMMARY AND USE OF STRONG POINTS OF THE VALIDATION MODELS IDENTIFIED

Table 1 summarises whether the various models identified in this section give support to cover the issues A-D, for which none of the established validation views provides a good coverage during development process. In all cases, "Yes" means that this model addresses the issue; this does not imply a judgement of the extent to which the issue is addressed. An underlined Yes denotes which model addresses the issue best with emphasis on the early concept life cycle phases.

*Table 1: Support to coverage of open issues by models identified in Section 4. Yes denotes the issue is addressed; an underlined Yes denotes which model addresses the issue best; – denotes not addressed*

| | A | B | C | D |
|---|---|---|---|---|
| | Multiple stakeholders roles | Integrating complementary views | Requirements joint validation | Role of policy makers |
| E-OCVM | Yes | Yes | – | – |
| DCP model | Yes | Yes | Yes | – |
| Joint goal-oriented safety management | Yes | – | Yes | – |
| Multi-stakeholder safety management | Yes | – | – | Yes |
| Roles of Government | Yes | – | – | Yes |

Table 1 shows that Issue A (multiple stakeholders roles) is addressed to some extent by all five models. However, when it comes to balancing the roles of these stakeholders, coverage is implicit for E-OCVM, Multi-stakeholder safety management, and Roles of government. Issue B (the integration of complementary views) is addressed by both E-OCVM and the DCP model. E-OCVM stands out by integrating different cases for various key areas, although these approaches are still under development. The DCP model and the Joint goal-oriented safety management model clearly acknowledge the need to bring stakeholders together in balancing their goals and roles from an early stage, issue C. The latter emphasises the role of providing assessment feedback to the stakeholders. Finally, issue D (the role of policy makers) is addressed best by the Roles of government models and to some extent by Multi-stakeholder safety management, although the other models do implicitly acknowledge policy makers as one of the stakeholders. This opens the door for the government to additionally play a part in bringing the stakeholders together and encourage the joint goal setting.

# 5 INTEGRATION INTO SAFETY VALIDATION FRAMEWORK

The aim of this section is to integrate the strong points of the established and novel validation views analysed in the previous sections. The integrated safety validation framework first addresses the Macro phase of an operation, during which multiple stakeholder roles need to be balanced, and in which a CONOPS (concept of operations) is agreed on (at some high level) by all stakeholders. In this Macro stage, the integration of validation views focuses on the multi-stakeholder views of Section 4. Next, during the Meso and Micro phases, detailed operational scenarios describing procedures, working practices and system specifications will have to be developed to enable CONOPS implementation. In these Meso and Micro phases, the established validation views come in focus. Fig. 15 shows that the Macro phase roughly corresponds with phases V0-V3 of the E-OCVM, and the Meso phase runs from V4.

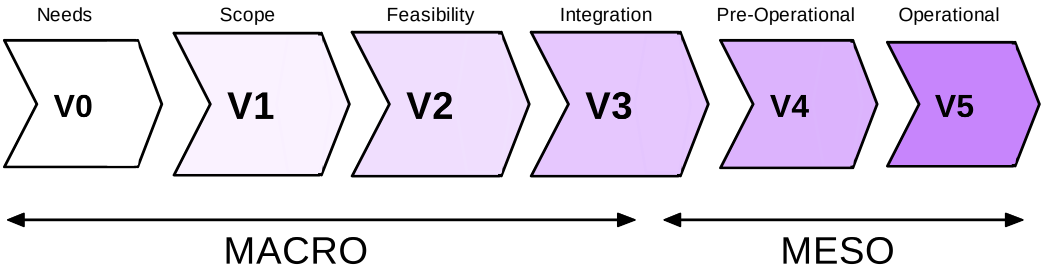

*Figure 15: Coupling of phases V0-V5 to phases Macro and Meso.*

## 5.1 APPROACH TO COMBINING STRONG POINTS OF VALIDATION VIEWS

Section 4.6 showed that when it comes to insight into the extent to which multiple stakeholders need to balance their roles (issue A in Section 3.6), the DCP model provides the best view. The DCP's systems dimension (vertical axis) defines three levels: Macro (institutional conditions), Meso (organisation and operational control) and Micro (user/operator). The need to jointly balance stakeholder roles is largest at the Macro level. At the design dimension (diagonal axis) in the DCP model, the Macro level is coupled to a Joint Goal setting, which provides the link with issues A and C in Section 3.6, which is explained further

below. Hence in order to address these issues A and C, we need to particularly focus on the Macro level first.
The lifecycle dimension (horizontal axis) of the DCP model is also adopted by the E-OCVM, hence this will be another important dimension to cover. However, it appears that the lifecycle phases in the E-OCVM and the phases in the DCP model are not aligned. In order to make effective use of European standardisation developments, the best option appears to be to adopt the phases of the E-OCVM concept lifecycle view.

A closer look reveals that the Macro phase of the DCP covers roughly lifecycle phases V0 through V3 of the E-OCVM. The follow-up lifecycle Meso phase of DCP covers roughly lifecycle phases V4 and V5, see Fig. 15. A key output of the Macro phase consists of jointly validated requirements for different stakeholder types as input to the Meso phase.

Section 4 also showed that Requirements joint validation (issue C in Section 3.6) is addressed by two of the models, i.e. DCP model and Joint goal-oriented safety management. A key common aspect of these models is that stakeholder joint goal-setting takes place at an early stage in concept design. In addition, regarding the multiple stakeholder roles (issue A), the DCP model and the Joint goal-oriented safety management model clearly acknowledge the need to bring stakeholders together and balance their goals and roles from an early stage. In particular for safety, at the Macro level, the Joint goal-oriented safety management view provides four types of activities:

(1). 'Joint goal setting',
(2). 'Plan' (CONOPS development),
(3). 'Do' (what does this mean per stakeholder), and
(4). 'Check' (validation).

This reveals that there are four main processes to consider, which are referred to as Joint Goal setting, CONOPS development, Stakeholder allocations, and Joint safety validation, see Fig. 16. Obviously, as depicted in Fig. 16, several interactions exist between these four processes. In addition, as shown above, since CONOPS development will be conducted in several lifecycle phases, each of these four main processes will have to be synchronised with such lifecycle phases and with each other. In particular, as argued above, these phases are to be in line with the E-OCVM concept lifecycle view, which consists of six phases V0 through V5. The synchronisation compares and integrates the results of the four main processes in each phase, so that an effective start is made with the next phase.

At the Meso phase, which starts around lifecycle phase V3-V4 (see Fig. 15), the Joint goal setting and the Stakeholder allocation processes become of a more passive nature, and the CONOPS development and Safety validations are conducted at the level of individual stakeholders. Therefore, in this phase, the established validation views of Section 3, i.e. the V-model, the Spiral model, etc., are of particular use. These established views take the jointly validated requirements developed in the Macro phase as a starting point and develop a more detailed design of the operation. It is noted that if the Meso phase starts too early, then the requirements that come out of the Macro phase may not have converged yet.

The E-OCVM also provides support to the integration with other assessments (issue B in Section 3.6), by means of its link between the Safety validation process and all non-safety validations (Economy, Environment, etc). It is noted that for the earlier phases this support is still under development.

Note that for a proper balancing of stakeholder joint goals at the Macro level we need to structure by means of a joint entity, which we refer to as Project Development Office (see dashed box in roles of government views, Section 4.4). This means that a Multi-actor safety management organisation like the one described in Section 4.3 should extend its scope and activities to the pre-operational lifecycle phases. This addresses issue D in Section 3.6.

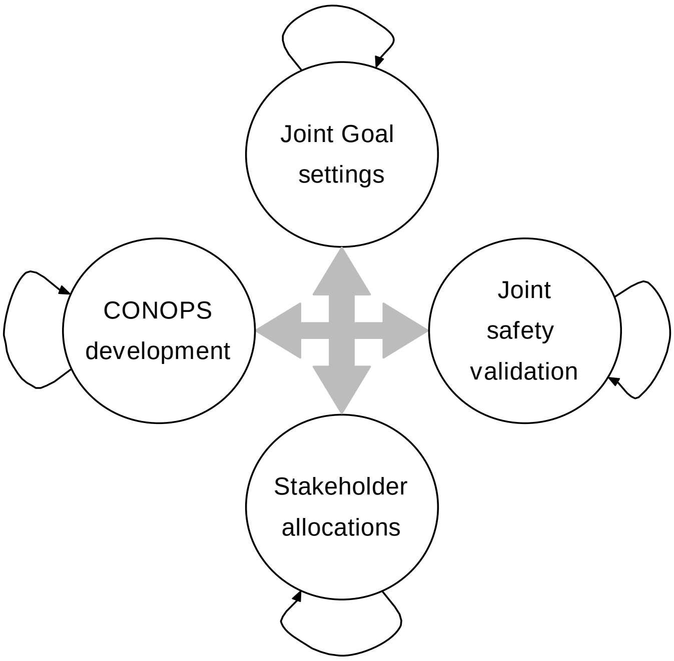

*Figure 16: SAFMAC proposed safety validation framework, in which four main 'processes' Joint Goal setting, CONOPS development, Joint safety validation, and Stakeholder allocations are elaborated through a spiral development approach.*

The following subsections outline the four major processes depicted in Fig. 16 in more detail.

## 5.2 JOINT GOAL SETTING

The development of major changes in air transport operations comprises a complex and lengthy process managed by international organisations, such as ICAO, that require agreement by a significant number of parties at the international level. These major changes do not form an issue that European regulators and air navigation service providers can attempt in isolation, and they will require significant international co-ordination and co-operation. In addition, each of the stakeholders will have their own requirements, wishes and needs, which can be formulated as goals. The process of obtaining consensus about the joint goals of the different stakeholders will be a driver of the major change in air transport operations, and will be described here as a goal setting process. To accomplish this, the problem can be decomposed into a hierarchy of sub-problems each of which could be analysed without the need to solve the next sub-problem. The solution of each of these sub-problems can only be addressed through an explicit involvement of experts in advanced operational concepts and safety experts. A general goal setting process starts with the identification of a high-level goal, after which this high-level goal is further specified into elements that explain what the high-level goal means for the different actors involved.

## 5.3 CONOPS DEVELOPMENT

The CONOPS development phases will be based on general practices of CONOPS development by major European players in the field, and should fit with the Joint Goal setting phases of the previous subsection. The phases of the CONOPS development process associated to major changes in air transport operations should be in line with the E-OCVM concept lifecycle view. The phases that fall in the Macro view identify the reasons for initiating the required changes to the operational concept as well as the evidence that the initial concept makes sense for all parties involved. The potential solutions and their enablers and/or concepts have been identified. The potential solutions identified are combined to form a high-level CONOPS.

During the CONOPS development process new insights are inevitable and may result in changing operational environment or alternative solutions, which in turn may lead to small or large modifications of the way the concept is organised. The development process as a whole is therefore highly iterative.

## 5.4 JOINT SAFETY VALIDATION

Airlines provide safety critical services directly to their passengers and thus to human society. For the safety of their flights, airlines critically depend of services by other service providers, such as air navigation service providers and airports. Whereas a Modern Safety Case is built by individual service providers, a Joint Safety Case is built by collaborating stakeholders. The Joint Safety Case should provide the high level argumentation and evidence for the total operation, while each Modern Safety Case should provide the evidence and the high level argumentation for that part of the operation that falls under the responsibility of one specific service provider. For the Joint Safety Case there are multiple approaches to setting up a useful high level argumentation. Three hypothetical approaches are:

- Hierarchical approach, in which the Joint Safety Case is being built first. On the basis of such a Joint Safety Case, the requirements to be fulfilled by each of the stakeholders involved can be identified. Subsequently, each of these stakeholders has to develop a Modern Safety Case to show that the requirements, posed by the Joint Safety Case on his own operation, are satisfied.
- Negotiation approach, in which a Joint Safety Case and generic versions of Modern Safety Cases are being built in parallel in a spiral development process, and with proper exchange between the two processes. If there are gaps and/or overlap between the various resulting generic Modern Safety Cases and the Joint Safety Case, then through negotiations between the collaborating stakeholders adequate improvements should be identified.
- Integration approach. This approach means that the generic Modern Safety Cases are being built first. Next, a Joint Safety Case is being built through integration of the material available from the generic Modern Safety Cases. The problem with this approach is that risky combinations of hazards do not show up in an early phase, and that it easily leads to a Babylonia building.

The hierarchical approach is in theory the preferred one but the negotiation approach may be more practical. Because there is little experience in developing a Joint Safety Case, the best practice remains to be developed. Obviously, it is up to the collaborating stakeholders to choose the approach that is judged to be most effective in realising their collaboration objective. The implications of the Joint Safety Case considering the complete operation, including all commercial actors involved, can best be explained in terms of the Modern Safety Case contents as depicted in Fig. 9:

The operation: The Joint Safety Case considers the total operation, while each Modern Safety Case considers that part of an operation that concerns a particular actor only. This implicitly means that Modern Safety Cases often go into more detail than the Joint Safety Case, while the Joint Safety Case should explicitly cover issues like responsibilities and accountabilities of the various stakeholders, including the interfaces/boundaries between them. In order to prevent any confusion, in particular for hazardous situations, it is necessary that all Safety Cases refer to the same description of the advanced operation.

Applicable standards: A Joint Safety Case should maintain a joint listing of all applicable (international and national) standards, while each Modern Safety Case should receive a copy of this, and should contribute to the completion of the joint listing.

Safety Management: Each Modern Safety Case relies on the Safety Management of its responsible stakeholder. A Joint Safety Case relies on how Safety Management responsibility and co-ordination is arranged for the total operation under consideration.

Hazards register: Since hazards that start under the responsibility of one stakeholder often affect the operation of another stakeholder, it is very important that a Joint Safety Case makes a joint hazard register which is as complete as is possible, while each Modern Safety Case has a copy of this joint hazard register. This also means that hazard identification and development of safety improvement measures per hazard should be done both at the level of a Joint Safety Case, and at the level of each Modern Safety Case.

Safety assessment: The Joint Safety Case should assess the safety of the complete operation, while each Modern Safety Case should assess the safety of that part of the operation that falls under the responsibility of the particular stakeholder. In effect this often means that within a Joint Safety Case it is necessary to perform a safety assessment for the operation, while within a Modern Safety Case the aim is to perform a safety assessment for the contribution by a single stakeholder. Any assumptions about the operation that have been made during the assessment should be clearly stated and justified; however obvious these assumptions may be, the implications for others involved with the project cannot always be predicted.

Supporting evidence: A Modern Safety Case may provide safety supporting evidence for the Joint Safety Case. A Joint Safety Case, however, may only provide supporting evidence for a Modern Safety Case if it is shown that this does not lead to a vicious circle. For procured equipment, a manufacturer's Safety Case may form supporting evidence both for a Modern Safety Case and for a Joint Safety Case.

Similar as applies to a Modern Safety Case, a Joint Safety Case must be developed in a way that allows for modifications, extensions or revisions, making them living documents that can be updated when, for example, new hazards have been identified and assessed during the development of the new or changed operation.

## 5.5 STAKEHOLDER ALLOCATIONS

At each phase of the development of a CONOPS, it is essential to have a translation of what the development means for the individual stakeholders, in order to get their involvement and approval at an early stage. Here, the Macro phase (roughly from V0 to V3) provides requirements for stakeholders, which are to be used as a starting point for the Meso phase (from V4 onwards). In fact, this comes down to an allocation per phase of responsibilities, functionalities, information flows and system functions of the future concept per individual stakeholder, in addition to an allocation of safety validation activities. This allocation should stimulate an early start of the development work at Meso level by each of the stakeholders. At the Meso level (i.e. from phase V4 onwards), a CONOPS description needs to be worked out in more detail.

# 6 ELABORATION OF SAFMAC FRAMEWORK PROCESSES

The final step is to couple the four 'processes' outlined in the previous subsections, through a spiral development approach, so that they form one framework process along the E-OCVM phases V0 through V5 (Section 4.1). In addition to the synchronisation after each phase that should take place, there are boundary conditions, e.g. foreign influences, and other influences, like those from government/regulator. But although there may also be several iterations across the different phases, there is a red thread that runs through the first phases (in parallel or in an undecided order) of the four processes Joint goal setting, CONOPS development, Joint safety validation, and Stakeholder allocations, after which a synchronisation takes place, and after which the red thread proceeds with the next phase of Joint goals setting, CONOPS development, etc. In Tables 2-5, the four processes are outlined for E-OCVM phases V0-V3, which focus on the Macro phases. For phases V4, V5 and beyond, the established validation views provide further detail.

*Table 2 Joint goal setting in phases V0-V3*

| **Phase** | **Joint goal setting** |
|---|---|
| V0 – Needs | The high-level joint goal is identified, including boundary conditions. The high-level joint goal should at least discuss goals for the ICAO Key Performance Areas from ICAO (ICAO Doc 9854) |
| V1 – Scope | The high-level joint goal is further detailed and specified to direct a CONOPS development that takes place in this phase, or where necessary corrected. This includes at least identification of requirements, of the roles of the human actors, and of the technology needs. |
| V2 – Feasibility | The high-level joint goal is further detailed and specified to direct a CONOPS development that takes place in this phase. |
| V3 – Integration | The agreed joint goals are revisited and verified, and where necessary further detailed, adapted or corrected, and next agreed upon. |

*Table 3: Table 3: CONOPS development in phases V0-V3*

| **Phase** | **CONOPS development** |
|---|---|
| V0 – Needs | The barriers in reaching the high-level joint goal are identified. To complete the validation of the concept in later phases, the concept must show that it can alleviate these barriers enough thus enhancing performance to the anticipated required level. Also, the operational environment is determined. |
| V1 – Scope | The concept is described in sufficient detail to enable identification of the potential benefits mechanism (i.e. the change to systems and/or operations that will enable a known barrier to be alleviated). Some aspects of the concept will be unknown or unclear at this stage. They may exist as a number of options to be assessed during the further validation process. This stage should lead to one or more High-Level CONOPSes, which can be further analyzed and refined later. |
| V2 – Feasibility | The concept is developed and explored until it can be considered operationally feasible. Prototypes will be used that make assumptions about technical aspects in order to avoid system engineering which can be costly and lengthy. Aspects that are focused on are operability and the acceptability of operational aspects. Operational procedures and requirements become stable. HMI, Operating procedures (for normal and key non-normal conditions) and phraseology become clear. |
| V3 – Integration | The concept is further developed, enabling identifying in more detail the performance in the concept of operation. Stakeholders further develop their part of the operation as part of their stakeholder allocations, without losing the view on the integrated operation. Required functionality is integrated into pre-industrial prototypes. Engineering processes are explored to provide experience that will be useful to building the end-system. Realistic scenarios that are representative of what the concept must be able to manage in the target end-system. The focus is on system level behaviour, |

| | |
|---|---|
| | performance and establishment of standards/regulations necessary to build and operate the required technical infrastructure. |

*Table 4 Joint safety validation in phases V0-V3*

| Phase | Joint safety validation |
|---|---|
| V0 – Needs | In this phase the high-level joint goal and the barriers need to be understood. For safety validation, this means that the safety aspects of the high-level joint goal and barriers must be understood. Thus, it is investigated what the goal is with respect to safety, and what the applicable safety regulations and safety criteria are. Furthermore, it is analyzed whether the current operation meets the goal, and if it does not, why this is not the case. |
| V1 – Scope | In this phase potentially many concept ideas are identified in the CONOPS development process. Only the most promising of those ideas should be further developed. The ideas are still described on a high-level. For safety validation, this means that involvement should be focused on giving feedback on which ideas are most promising from a safety point-of-view. This is best done by analyzing the concept ideas, and feeding back to the CONOPS development the main safety issues with respect to each concept idea. |
| V2 – Feasibility | In this phase it is to be analyzed whether the concept is feasible. For safety validation this means that one should become reasonably sure that all risks of the concept are tolerable with respect to the joint goal and thus the safety criteria selected. Hence, all risks should be identified and assessed, and realistic (attainable) risk mitigations should be identified which should ensure the risk to stay tolerable. After this step, it should be reasonably sure that the concept can be implemented safely. More detailed justification may follow later however. To evaluate the feasibility of the concept, the full scope of the concept should be considered, and hence all stakeholders should agree on their part of a CONOPS, and the performance of their part. |
| V3 – Integration | In this phase, a more detailed concept comes available, and more evidence is gathered for the performance of the integrated concept. For safety validation the risk mitigations are validated: evidence is gathered that they are indeed sufficient to have a concept that complies with the need and safety criteria, and it is analyzed whether the risk mitigations are indeed achievable. |

*Table 5: Stakeholder allocations in phases V0-V3*

| Phase | Stakeholder allocations |
|---|---|
| V0 – Needs | The individual performance needs and barriers per stakeholder are identified, and if needed corrected. |
| V1 – Scope | The concept that enables identification of the potential benefits mechanism is translated to what this means to the individual stakeholders in order to get their approval and involvement at an early stage. This may include identification of potential sub-solutions, and eventually lead to a sub High-Level CONOPS (that is, the stakeholder-specific part of the High-Level CONOPS). |
| V2 – Feasibility | The feasible CONOPS is translated to what this means to the individual stakeholders in order to get their approval and involvement at an early stage. |

| | |
|---|---|
| V3 – Integration | The agreed stakeholder allocations take place, and it is verified whether they constitute a CONOPS developed in V3. Where necessary, the stakeholder allocations are further detailed, adapted or corrected, and agreed upon. |

It should be noted that synchronization of the four major processes does not need to be restricted to the moments on which a phase of the Concept Lifecycle Model ends and may be recommendable within certain phases. In addition, the phases described above are expected to have potential for further improvements due to increasing experiences in safety validation. In the early phases of the development of an advanced operational concept, the SAFMAC main processes joint goal setting, stakeholder allocation, and joint safety validation have an active character: the joint goal is further specified, each time new stakeholder allocations are agreed upon, and the safety validation activities are further deepened. Once an operationally feasible CONOPS has been developed, validated and agreed upon, including stakeholder allocations, it could be sufficient to revisit the joint goal, the stakeholder allocations and the safety validation, to check whether everything is still correct, in place, and in coherence. Here, the character of these three processes may become more passive.

# 7 CONCLUDING REMARKS

The aim of this paper was to study the needs for safety validation of multi-stakeholder changes in air transport operations, i.e. changes which particularly require the balancing of the roles and responsibilities of multiple stakeholders. Through a process of analysis, evaluation, review and consolidation, including an alignment with important European developments in the field (specifically E-OCVM), this paper developed a safety validation framework that consists of four processes: Joint goal setting by all stakeholders; CONOPS development; Joint safety validation process; Allocation of responsibilities and requirements (possibly including functionalities and information flow developments and validation responsibilities), to appropriate individual stakeholders. The framework is referred to as SAFMAC (SAFety validation of MAjor Changes).

In order to further these results, the SAFMAC developments will be focused along two tracks: a policy track, and a follow-up study track. The policy track aims for obtaining further acceptance, nationally, within Europe, within the USA, and within ICAO.

The main issues to be addressed in the follow-up study track are:

- Further clarifying the roles and responsibilities of the different stakeholders within the process of developing a safety validated CONOPS. In particular, attention should be paid to the role of the regulator and the supervisory authorities, including the need for missing regulations.
- Development of a set of safety validation quality indicators (Everdij and Blom, 2007).
- Embedding of safety methods (see e.g. Safety Methods Database (2008)), into the safety validation process, and further development of safety validation process, including mapping to the individual stakeholders.
- Application of the framework to one or more interesting (national) major changes in air transport operations.

A first national application has been started for a project on merging civil and military airspace management. The early experience in this project already shows that thinking about joint goal setting works remarkably refreshingly for the participating stakeholders and causes them to look beyond their own familiar contexts.

Ongoing developments regarding the identified validation views and newly emerging validation views will be considered in the further SAFMAC development as well.

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# ACRONYMS

| | |
|---|---|
| ARP | Aerospace Recommended Practices |
| ATC | Air Traffic Control |
| ATM | Air Traffic Management |
| CAVA | Concerted Action on Validation of Air traffic management systems |
| CONOPS | Concept of Operations |
| DCP | Design, Control and Practice |
| DGLM | Directorate-General Civil Aviation and Maritime Affairs |
| EFQM | European Foundation of Quality Management |
| E-OCVM | European operational concept validation methodology |
| HMI | Human Machine Interface |
| ICAO | International Civil Aviation Organisation |
| MAEVA | Master Air traffic management European Validation plan |
| M-MIS | Man-Machine Interface System |
| QSA | Quality and Safety Systems in Aviation |
| R&D | Research and Development |
| SAE | Society of Automotive Engineers |
| SAFMAC | SAFety validation of MAjor Changes |
| SESAR | Single European Sky ATM Research |
| ToR | Terms of Reference |
| TQM | Total Quality Management |
| TQSM | Total Quality and Safety Management |
| VAPORETO | Validation Process for Overall Requirements in Air transport operations |
| VpS | Veiligheids Platform Schiphol |