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Annex D
Supporting Regulatory Tasks with Safety Scanning

The Link Between Safety Fundamentals, Safety Oversight Tasks and Legislation

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Abstract

This document provides detailed information on how Safety Fundamentals are compliant with, inter alia, EU legislation. It provides more information on the legal issues related to safety and shows how safety fundamentals are of use in the day to day business to be compliant to legislative responsibilities.

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Safety scanning | Safety Fundamentals | Safety Regulation

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1. THE LINK OF SAFETY SCANNING AND SAFETY REGULATION TASKS

The Safety scanning material is intended as support for oversight authorities in their safety regulatory review activities when it comes to the evaluation of the appropriateness of safety validation methods as proposed by designer/developers and the consequential discussions with the designer/developer related to the approval process.

The objective of this deliverable is to describe the link between the Safety Fundamentals, the results of the application of the Safety Scanning Tool (SST) and safety regulatory oversight tasks as defined by ICAO and the EU.

This link could be used for setting requirements for or reviewing the appropriateness of safety approaches used by licensees[1] (e.g., developers, implementers, service providers). This link could also be used for generating a safety oversight argument of an NSA. For these purposes;

- Chapter 2.1 describes the legal basis for safety oversight, which is the basis for the tasks oversight authorities need to conduct.
- Chapter 2.2 describes the notion of liability to achieve safety.
- Chapter 2.3 discusses key issues of oversight, which need to be considered by oversight authorities and
- Chapter 3 and Appendix B describe the compliance of Safety Fundamentals with EU legislation.

This document needs to be seen in close relation with the deliverable Safety Fundamentals for Safety scanning [SRC DOC 46 – Annex A, Safety Fundamentals], which describes the rationale of the Safety Fundamentals and their regulatory basis. Also the report needs to be seen in close relation to the Tips and Tricks for a safety analyst [SRC DOC 46 – Annex C, interpreting], which describes how to handle the results of a Safety scanning event in detail and where a detailed decision mechanism is suggested how to use the scanning results within the remit of the oversight authority.

The following chapter goes into more detail of the formal notion of law in the safety area and the way the role of oversight authorities (in the context of ATM notably the NSAs) is encapsulated in these laws. As laws change over time[2] it needs to be noted that this guidance material was written at the beginning 2010.

2. THE LEGAL BASIS FOR SAFETY OVERSIGHT IN AVIATION

2.1 Safety Oversight as a Legal Institution to Achieve Safety

Law is an instrument to achieve socially desirable conditions. These conditions represent socially desirable conditions and progress over time towards higher objectives. The Legislator makes general-abstract (i.e. objective based) provisions to capture all kind of circumstances based on the various objectives (e.g. safety, environmental protection, efficiency) of different legal sources.

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1 *The term "licensee" is introduced in the documents in order to subsume the range of potential service providers that need to be regulated (in the context of ATM it comprises in particular ANSP, Airport Operations, Airlines, ground based manufacturers, aircraft manufactures).*

2 *Like new EASA regulations in the domain of ATM*

Referring to aviation safety, the legislator gives instructions (e.g. requirements for ANSPs) whose compliance is verified by the NSAs who have adequate legally based competence and an effective oversight organizational structure.

For example in case of (changes to) ATM safety, the main aim to maintain as minimum the current air traffic safety standards but also to enhance safety over time.

Regulators (competent authorities) have the general task to oversight whether a licensee is meeting the legislative requirements. Oversight authorities in law hence need to verify that the socially desirable conditions are achieved. Safety oversight authorities (e.g. NSAs) have a key safety role to play in the EC legal context. In order to enable the work of the NSAs, the "ATM-Legislation" empowers them to regulate ATM and conduct ongoing oversight of its safety performance. This ongoing oversight includes the review of planned changes to ATM or the conduct of audits.

Key objective of oversight is to further outline the legislative objectives into detailed requirements and structured guidelines, so that a licensee is informed about detailed requirements that need to be fulfilled in order to comply with law. This guidance material will provide a (more theoretical) description of the functionality of the law based on existing legislation in order to workout essential safety criteria (from the legal point of view) oversight authorities have to proof against the general-abstract rules under the designated legal framework. To that regard the safety oversight function of the competent authorities should conform to the *critical elements for safety oversight* as defined by ICAO and being applied by ICAO audits (USOAP).

In order to achieve such proof, the competent authorities give own applicable instructions or are even involved in the development or adoption of new regulations (e.g. EASA).

In case of minor changes, standards need to be checked on their suitability and need to be adapted or amended. Bigger changes potentially request also to change the legislation (e.g., functional airspace blocks would require a legal agreement of the member states). Therefore the oversight authorities are also providing the binding link between legislation and service provision.

2.2 Liability Law as an Instrument to Achieve Safety

2.2.1 The Compensation Function (Ex Post Observation) of Law

A key function of law is to provide safety to the citizens. Adjustments by public authorities (i.e. regulation) are usually not needed to ensure safety, because most cases to ensure safety are adequately addressed by the liability law. Liability law works according to the compensation function (ex post observation), which determines the liability after an event happened.

Liability provisions are constituted in contracts as well as in non-contractual provisions (e.g. tort law) and capture all involved actors and circumstances in each sector and level (e.g. service provider, producer, supplier, individual persons and entities) even if contractual relations do not exist.

Because of the legal consequences of the breach of legal duties to maintain safety (i.e. wrongful act and omission) all actors should be interested to comply with liability provisions in order to avoid accountability (liability), and take all appropriate pre-cautions to ensure safety.

The duty of care principle is explicitly part of the jurisdiction of the Member States and is also known in other States. For the judging of the breach of duties, the jurisdiction (when involved) surveys a whole organisation including all processes and persons.

For example, duty of care can range over:

- personnel selection: an entity can exculpate itself from accountability (liability), if it can demonstrate the appropriate compliance with the duty of care in the selection of operating personnel. That means that the entity is interested to select persons with necessary capabilities for a workplace to avoid damages and liability for them;
- operating instructions;
- organisational structure and management;
- selection of equipment;
- quality management;
- provided services, procedures and products (including manufacturing defects and design faults).

An investigation into duty of care is not limited to the timeframe of an accident or incident and can range from the life cycle development (e.g. design faults) to the end-of-life-phase of a system or product (e.g. duty to provide instructions and surveillance). The level of duty of care is subject to the appreciation or interpretation of the jurisdiction. There are no care standards written in the law, there is no benchmark. The necessary and appropriate care level is decided case by case considering the risk of hazards in terms of a subject (expected damages vs. expenses to prevent damages).

The liability law offers incentives to all actors (individual persons or entities) for the avoidance of a breach of duty of care.

2.2.2 The Preventive Function (Ex Ante Observation) of Liability Law

However, the existence of duty of care alone is not sufficient to cause safety and liability awareness. Additionally, there is a need for addressing the duties to responsible persons and objective attribution for ensuring safety. The safety oversight obligations of a State in (major) ATM changes encompass a wide range of disciplines in aviation and require the establishment of an adequate safety oversight organization, infrastructure and procedures.

Oversight authorities are therefore not only determined based on the compensation function, but on the preventive-function (ex ante observation) of liability law, which requires from any person to allocate adequate compensations to obvious risks to citizens as integral part of their license and associated SMS. Such preventive-function needs a safety oversight argument showing that the legislation is met as well as sufficient prevention is provided.

Objective attribution is essential in two respects (chain of causation);

- Causality of damage (in more practicable words: causality for the lack of safety); that is to identify through which “failure” damage is generated. Referring to aviation safety that means to find out, which hazards can come from each part of a system. For this purpose, it is necessary to know the (intended) functions of a system and each part of them, and
- Allocation of responsibility; that means to identify to whom (individual or entity) the duties of care are addressed. Referring to aviation safety it means the knowledge about whose area of responsibility is affected of a system and its each of its parts and functions.

This exemplary description should show that these three pre-conditions (duty of care, responsibility and objective attribution) must be positively and verifiably addressed in order to ensure safety.

2.2.3 The Use of Safety scanning to Provide the Preventive Function of Liability Law

The considerations above show and explain the functions of the three safety criteria in a regulatory regime:

- Duty of care: tasks, obligations or requirements (safe standards);
- Responsibility: allocation (1) to actors and key-actor (3);
- Public authority: independent oversight of (1) and (2).

These criteria are considered in the Safety scanning and are specifically addressed in the area of "Regulation framework". Hence the Safety scanning offers a structured approach to detect safety critical aspects and is an applicable instrument to provide safety-related information in the safety review of planned changes to ATM. This report therefore suggests using the Safety scanning to construct the safety oversight argument.

In view of above-mentioned, the Safety scanning can support the oversight authorities to accomplish an appropriate preventive-function. From legal point of view, the above-mentioned points are general safety criteria.

These criteria are intrinsically reflected in the Safety Fundamentals, not just in the regulatory area but also in the Safety Fundamentals for safety architecture, operational safety and safety management.

Safety critical sectors, like aviation, are deemed to require more legislative attention then duty of care. They need to be regulated by public authorities. Beside safety considerations, the need for consistent procedures in cross-border activities is the reason for aviation regulation.

In the description above it is assumed that compliance with duty of care principles is based on the (negative) incentive of liability law. Under a regulatory regime, compliance is demonstrated by approval and ongoing oversight by a public authority (e.g. NSA).

It needs to be stressed that also under a regulatory regime the above-mentioned (liability) principles are valid. This is because these principles have been captured in a legislative context (provisions) and consequently liability law (e.g. tort law) is legally applicable in parallel to specific safety regulation[3].

2.3 Key Oversight Activities as Represented in Existing Legislation

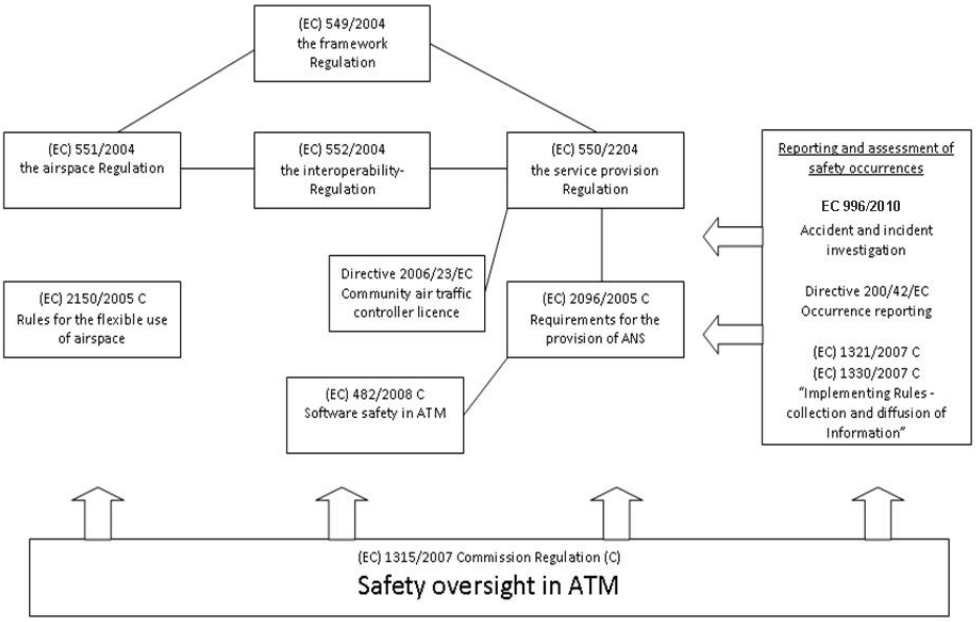
2.3.1 Existing Legislation at European Level

Oversight arrangements are based on existing legislation. On the European level, the creation of a regulated and overseen industry is captured in the Single European Sky Legislation. This legislation again has sub-elements.

Picture 1 provides an overview of the interrelation between elements of the SES legislation, which relates to oversight authorities. The way safety oversight is to be conducted by the Member States is described in (EC) 1315/2007.

[3] *The use of these two criteria (duty of care and responsibility) is more appropriate for this exemplary observation and considers sufficiently the objective attribution. Because this point is an urgent pre-condition for the applicability of liability law, it was explicitly listed.*
The objective attribution is a particular aspect of the liability law. Because the liability law does not just seek to the breach of duty of care, it is necessary to allocate the breach to the caused damages. In order to justify liability, there is a need for evidence of a chain-of-causation from the damage to the act of a responsible person. Under a regulation, the causal context to damage is not needed. The regulation seeks only to compliance with provisions and a damage occurrence is not necessary for the legal applicability. Nevertheless, the objective attribution is also completely considered under provisions of a regulation, even the connection to a damage occurrence is mentioned. Just the pre-condition of damage occurrence is not needed for the applicability of the regulation. By addressing the provisions (with specified tasks, obligations and requirements) to responsible persons, the objective attribution is considered.

Here the general tasks of safety-level assessment, safety regulatory audits, verification of compliance, oversight and review procedure of changes, or oversight capabilities are captured. Further detailing of these tasks is supported through underlying directives.



Picture 1. ATM regulations for oversight

The framework Regulation **(EC) 549/2004** ensures the SES development in consideration of superior laws (ICAO, EC-treaty) and stakeholder interests. This regulation establishes a statutory basis for further regulations (especially for common requirements and actions) in conjunction with:

- Regulation (EC) 551/2004 (the airspace Regulation);
- Regulation (EC) 550/2004 (the service provision Regulation);
- Regulation (EC) 552/2004 (the interoperability Regulation).

The framework Regulation **(EC) 549/2004** prescribes the establishment of an independent NSA(s) in each Member State (MS) in order to assume the tasks assigned under the regulations (and implementing rules) noted above. This Regulation vests the Commission with competencies for implementing rules (mostly (parts of) ESARRs (Article 8)). It also includes “feed-back-rules” and rules about committee procedures/consulting (industry, Member States, stakeholder; most are prescribed for implementing rules).

The airspace Regulation (**(EC) 551/2004**) describes the (desired) airspace architecture and the use of airspace in the SES. This is the basis Regulation to support the concept of a progressively more integrated operating airspace and to establish common rules (Article 1). It is prescribed that the use of airspace has to support the operation of ANSPs as a coherent and consistent whole. The Member States get information about their tasks and responsibilities by means of this Regulation (further regulations are provided).

The interoperability Regulation **(552/2004)** governs the interoperability between the different systems, constituents and associated procedures of the EATM (Article I). Essential requirements are laid down in Annex II. The implementation of community specifications is intended. Verification of compliance is implemented by means of EC-declarations.

The service provision Regulation **(550/2004)** describes the rules for the provision of services (Certification procedure of ANSPs, relations between service providers, relations with military authorities, designation of ATSP etc.) and announces common requirements.

These Regulations can be seen as preliminary measures for the development of the SES and announce further Regulations. Additionally, they specify first tasks, responsibilities, obligations of the Member States, NSAs and organisations.[4]

Directive 2006/23/EC defines standards for air traffic controllers (community licence) to ensure that minimum requirements are fulfilled in each Member State.

(EC) 2096/2005 lays down the common requirements for the provision of ANS.

(EC) 482/2008 extends the common requirements for the provision of ANS in respect to software safety aspects and prescribes the implementation of a software safety assurance system.

(EC) 2150/2005 supports the concept of the flexible use of airspace by setting principles and rules for the flexible use and management of airspace and prescribes a more coordinated procedure with military authorities.

The **Directives and Regulations about reporting and assessment of safety occurrences** do not only contain Member States obligations. Dealing with information about safety occurrences is also necessary for the safety management, which is a major part of the common requirements which puts requirements on ANSPs.

(EC) 1315/2007 gives instructions to NSAs for the safety oversight in ATM (ANS, ATFM, and ASM).

Relating to safety, all these Regulations can be summarised in line with the following principle; “Ensure safety and the safe provision of services, and exercise the powers of public authority in consideration of superior laws and the development of SES”.

2.3.2 Essential Oversight Tasks as Reflected in the ATM Regulations

The existing legislations as outlined above define essential oversight tasks as listed below;

- Ensuring safety by authority for a system operation – This includes approval of a way ahead for a change as suggested by a licensee;
- Ensuring safety by assurance of a system or a change of a system – This includes review of a safety case for a change of a licensee;
- Ensuring safety by oversight of operations – This includes oversight of the Safety Management System (SMS) of a licensee;
- Ensuring safety by competence of the NSA system – This includes capability for incident analyses.

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[4] *Amended by Regulation (EC) No 1070/2009 in order to improve the performance and sustainability of the European aviation system (has not been considered in this paper)*

These essential oversight tasks are further outlined in the following table.

Ensuring safety by Authority	Ensuring safety by Assurance	Ensuring safety by Oversight	Ensuring safety by NSA Competence
Check compliance with requirements Certification of ANSP • Certificate • Monitor • Enforce • Check/approve agreements Licensing of ATCO • License • Monitor • Enforce • Certificate training providers Technical/engineering personal • Oversight and regulate Interoperability of systems, constituents and procedures	Take appropriate measures • Corrective actions • Safety directives • Revocation of certificates • Actions in respect of operating organization and tech./engineering personal • Safeguards (in cases of incorrect EC-declarations) • Sanctions	Perform safety regulatory audits Referring to Airspace • Military authorities • Member States Referring to ANSPs • clearly split responsibilities Referring to oversight • Clearly split oversight responsibilities • Working relationship, information exchange	Evaluate safety occurrences • Ensure collection and division of the information • Ensure the correct assessment and implementation in safety management To the Commission • Annual reports (safety-level, advancement, compliance-level) • Inform about taken measures referring to ANS or airspace • Inform about incorrect EC-declarations • Inform the relevant Member States about measures

Table 1. Overview of oversight tasks

Additionally, the safety oversight tasks need to be considered as written in Regulation (EC) 216/2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, concerning the regulation of aeronautical products, parts and appliances, as well as personnel and organisations involved in the design, production and maintenance of such products, parts and appliances. And also personnel and organisations involved in the operation of aircraft (Article 1).[5]

3. SAFETY FUNDAMENTALS TO LINK SAFETY SCANNING WITH EUROPEAN LAW

This section provides a mapping of the Safety scanning onto the European law. The aim of this mapping is to underline the reality that Safety scanning is not an abstract idea but is a mature conceptual approach, which is already implicit part of the SES legislation. Picture 2 provides an overview of the relationship, which is further outlined in this section.

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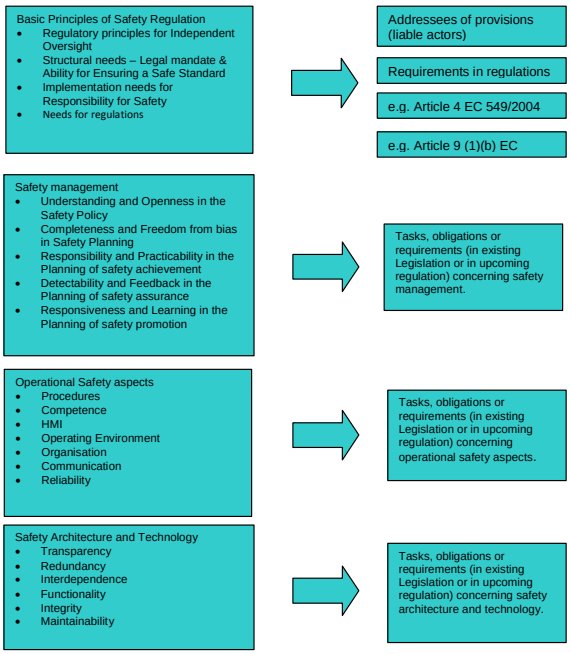
[5] *Has not been considered in the scope of this document but should be considered if this method is applied in the relevant regulatory field.*



Picture 2. Safety Fundamentals and oversight tasks

For the purpose of this argument, notably Commission Regulation (EC) No 2096/2005 and Commission Regulation (EC) No 1315/2007 were mapped to the Safety Fundamentals. Other SES legislation could have been included as well but was left out because of the ongoing changes to the SES legislation.

This mapping is done by combining the regulations with the detailed description of the Safety Fundamentals [SRC DOC 46 – Annex A, Safety Fundamentals]. The appropriate Safety Fundamental was mapped to a regulation if it was deemed to describe obligations associated with essential criteria for safe design as described by the fundamentals.

This mapping is non-exhaustive and is merely intended as indicative of the level of implicit conformity with currently applicable SES legislation. Appendix B provides an overview of the mapping. This table contains 5 elements;

- Number of the Fundamental;
- Title of the Fundamental;
- Description of the Fundamental;
- Reference to SES legislation;
- Excerpt of the referred SES legislation.

The link of the Safety Fundamentals with the European Regulations does provide evidence that the Safety scanning can be used to construct a safety oversight argument, which an NSA can use to show compliance to European Regulations.

4. REFERENCES

- Commission Regulation (EC) No 1315/2007
- Commission Regulation (EC) No 1315/2007. Safety oversight in air traffic management

- Commission Regulation (EC) No 1321/2007
- Commission Regulation (EC) No 1321/2007. Central occurrence repository
- Commission Regulation (EC) No 1330/2007
- Commission Regulation (EC) No 1330/2007. Occurrence dissemination
- Commission Regulation (EC) No 2096/2005
- Commission Regulation (EC) No 2096/2005. Common requirements for the provision of air navigation services
- Commission Regulation (EC) No 2150/2005
- Commission Regulation (EC) No 2150/2005. Rules for the flexible use of airspace
- Commission Regulation (EC) No 482/2008
- Commission Regulation (EC) No 482/2008. Establishing a software safety assurance system to be implemented by ANSPs
- Commission Regulation (EC) No. 996/2010 on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC
- Directive 2003/42/EC
- Directive 2003/42/EC of the European Parliament and of the Council. Occurrence reporting
- Directive 2006/23/EC
- Directive 2006/23/EC of the European Parliament and of the Council. Community air traffic controller licence
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- SRC DOC 46 – Annex A, Safety Fundamentals – SCAN Task Force, Safety Fundamentals for Safety scanning.
- SRC DOC 46 – Annex B, moderating – SCAN Task Force, Guidance for moderating a Safety scanning event.
- SRC DOC 46 – Annex C, interpreting – SCAN Task Force, Guidance on Interpreting and Using the Safety scanning results.
- SRC DOC 48 – SCAN Task Force, Safety Method Review.

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APPENDIX A – THE REGULATORY RISK INVOLVED IN ASSSESSING A CHANGE TO A PART OF ATM

Introduction

The following introduces the concept of a 'risk-informed approach' to the audit of changes to promote more consistent and defensible decision-making on the part of the National Supervisory Authority (NSA).

General

European National Supervisory Authorities (NSAs) are committed to implementing the Single European Sky (SES) regulations.

Extract from: COMMISSION REGULATION (EC) No 1315/2007 of 8 November 2007 on safety oversight in air traffic management and amending Regulation (EC) No 2096/2005.

> *"The role and functions of national supervisory authorities have been established in Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation), Regulation (EC) No 550/2004, Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation) and Commission Regulation. (EC) No 2096/2005 of 20 December 2005 laying down common requirements for the provision of air navigation services. These regulations include requirements on the safety of air navigation services. While the responsibility for the safe provision of service lies with the provider,* ***the Member States should ensure effective supervision through national supervisory authorities****."*

Objective guidance on what aspects to audit, how deeply to audit and how much to audit in order to be able to demonstrate **effective supervision** does not exist. To provide objective guidance on this aspect of regulatory oversight, the notion of **regulatory risk** needs to be addressed.

Regulatory risk deals with the probability and consequences of a regulatory failure; e.g. the regulator has not noticed that a safety argument is incomplete or has not noticed the most risky part of an argument. The dimensions of regulatory risk are likely to be related to: supplier competence, safety risk of change, novelty of change, size of change and complexity of change. Without objective guidance, judgements of what and how deeply to audit to reduce the regulatory risk to a sufficiently low level are merely subjective. Consequently, this could leave the regulator open to criticism in the event that an accident or incident shows an audit to be insufficient.

The Safety Scanning Tool assists the Regulator in the systematic gathering of audit evidence and in doing so provides guidance in terms of 'what aspects' to audit.

It should be noted that with further research into Regulatory Risk the tool has the potential to be extended to provide guidance on 'how deeply' to audit or 'how much' to audit commensurate with the previously mentioned dimensions of regulatory risk.

APPENDIX B – MAPPING OF THE SAFETY FUNDAMENTALS TO EUROPEAN DIRECTIVES

FUNDAMENTAL			LEGISLATION	
Fn	**Title**	**Description**	**EC**	**Excerpt**
F1	Regulatory principles for Independent Oversight	Regulatory principles relate to the notion of Independent Oversight, which comprises that the standards of safety to be achieved should be approved and monitored (i.e. oversight) by a competent body acting in the public interest, which is independent of service providers and designers/producers.	1315/2007	*1. National supervisory authorities shall provide regular monitoring and assessment of the levels of safety achieve d in order to determine whether they comply with the safety regulatory requirements applicable in the airspace blocks under their responsibility.*
F2	Structural needs – Legal mandate for Ensuring a Safe Standard	Legal mandate refers to Responsibility for Safety, which is based on the acceptance that the prime responsibility for the safety of a service or product rests with the service provider or designer/producer.	1315/2007	*1. National supervisory authorities shall exercise safety oversight as part of their supervision of requirements applicable to air navigation services as well as to ATFM and ASM, in order to monitor the safe provision of these activities and to verify that the applicable safety regulatory requirements and their implementing arrangements are met.* *&* *1. National supervisory authorities shall provide regular monitoring and assessment of the levels of safety achieve d in order to determine whether they comply with the safety regulatory requirements applicable in the airspace blocks under their responsibility.*
F3	Structural needs – Ability for Ensuring a Safe Standard	Ability refers to Ensuring a Safe Standard, which refers to the duty of all service providers and designers/producers to take all reasonable precautions to ensure that their services or products are safe.	2096/2005 & 1315/2007	*Within the operation of the SMS, a provider of air traffic services shall:* *- ensure that risk assessment and mitigation is conducted to an appropriate level to ensure that due consideration is given to all aspects of the provision of ATM (risk assessment and mitigation)* *&* *3. Within the inspection programme required by Article 7 of Regulation (EC) No 2096/2005, national supervisory authorities shall establish and update at least annually a programme of safety regulatory audits in order to:* *- ensure that sufficient audits are conducted over a period of two years to check the compliance of all these organisations with applicable safety regulatory requirements in all the relevant*

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				areas of the functional system; *&* *Organisations shall only use procedures accepted by their national supervisory authority when deciding whether to introduce a safety-related change to their functional systems*
F4	Implementation needs for Responsibility for Safety	Refers to organisational clarity and or organizational accountability		(See laws on Product liabilities)
F5	Needs for regulations	Refers to the notion of understanding regulations and the willingness to discuss possible amendments to existing regulations, the creation of new regulations or the withdrawal of regulations.		(no legal obligation for reviewing validity of ATM regulations exist yet)
F6	Understanding and Openness in the Safety Policy	Safety policy is based on Understanding and Openness which are defined as the degree to which the commitment to safety and setting out the strategic safety aims is performed in such a way that all opinions and considerations within an organization or from other organizations are taken into account in the safety policy. Understanding and Openness are essential elements of an effective safety culture and are key requirements to an SMS and the safety regulatory confidence in the operation of an SMS.	2096/2005 & 1315/2007	*An air navigation service provider shall produce a business plan covering a minimum period of five years. The business plan shall:* *- set out the overall aims and goals of the air navigation service provider and its strategy towards achieving them in consistency with any overall longer term plan of the provider and with relevant Community requirements relevant for the development of infrastructure or other technology;* *&* *2. National supervisory authorities shall use the results of the monitoring of safety in particular to determine areas in which the verification of compliance with safety regulatory requirements is necessary as a matter of priority.*
F7	Completeness and Freedom from bias in Safety Planning	Safety planning is based on Completeness and Freedom from bias which are defined as the appropriateness of the aims of the organization, the resources and management structure chosen and the processes established in order to have the best safety-related solution.	2096/2005	*An air navigation service provider shall produce a business plan covering a minimum period of five years. The business plan shall:* *contain appropriate performance objectives in terms of quality and level of service, safety and cost-effectiveness.* *&* *A provider of air traffic services shall, as an integral part of the management of its services, have in place a safety management system (SMS) which:*

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				- ensures that while providing air traffic services, the principal safety objective is to minimise its contribution to the risk of an aircraft accident as far as reasonably practicable (safety objective). *&* *The results, associated rationales and evidence of the risk assessment and mitigation processes, including hazard identification, shall be collated and documented in a manner which ensures that:* *- complete arguments are established to demonstrate that the constituent part under consideration, as well as the overall ATM functional system are, and will remain tolerably safe by meeting allocated safety objectives and requirements .*
F8	Responsibility and Practicability in the Planning of safety achievement	Safety achievement is based on Responsibility and Practicability, which are defined as the detailed means of translating the plan into reality by means of clear responsibilities for, and practicability in safety achievement.	2096/2005	*An air navigation service provider shall produce a business plan covering a minimum period of five years. The business plan shall:* *- contain appropriate performance objectives in terms of quality and level of service, safety and cost-effectiveness* *&* *Within the operation of the SMS, a provider of air traffic services shall:* *- ensure that a safety management function is identified with organisational responsibility for development and maintenance of the safety management system; ensure that this point of responsibility is independent of line management, and accountable directly to the highest organisational level.*
F9	Detectability and Feedback in the Planning of safety assurance	Safety Assurance is based on Detectability and Feedback, which are defined as the detectability of safety issues by continuously monitoring of safety performance (feedback) in order to realize safety assurance.	2096/2005 & 1315/2007	*An air navigation service provider shall have in place at the latest two years after entry into force of this Regulation a quality management system which covers all air navigation services it provides according to the following principles. It shall:* *- perform reviews of the quality system in place and take remedial actions, as appropriate* *&* *Within the operation of the SMS, a provider of air traffic services shall ensure that:* *- all personnel are actively encouraged to propose solutions to*

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				identified hazards, and changes are made to improve safety where they appear needed (safety improvement). *&* *1. National supervisory authorities shall provide regular monitoring and assessment of the levels of safety achieve d in order to determine whether they comply with the safety regulatory requirements applicable in the airspace blocks under their responsibility.* *&* *3. The national supervisory authority shall assess the corrective actions and the implementation determined by the audited organisation and accept them if the assessment concludes that they are sufficient to address the non-conformities.*
F10	Responsiveness and Learning in the Planning of safety promotion	Safety promotion is based on Responsiveness and Learning which are defined as the totality of ensuring a continuous improvement process, timely corrective actions (responsiveness) and dissemination of lessons learned (learning) Promotion	2096/2005 & 1315/2007	*Within the operation of the SMS, a provider of air traffic services shall ensure that:* *- the lessons arising from safety occurrence investigations and other safety activities are disseminated within the organisation at management and operational levels (lesson dissemination),[…]* *&* *1. The national supervisory authority shall communicate the audit findings to the audited organisation and shall simultaneously request corrective actions to address the non-conformities identified without prejudice to any additional action required by the applicable safety regulatory requirements.*
F11	Procedures	Procedures describe what is required by the human operators to deliver a service. It includes definition of roles and responsibilities, and procedure structure, content, detail, and realism. From the safety regulatory oversight point of view it is necessary to clearly identify the responsibilities of different actors: e.g. the airspace designers, the inspectors for calibration in flight, the AIS providers and the providers of digital data to avionics, in relation to instrument procedures.	2096/2005	*The organisational structure shall define:* *- the authority, duties and responsibilities of the nominated post holders, in particular of the management personnel in charge of safety, quality, security, finance and human resources related functions;* *&* *An air navigation service provider shall provide and keep up-to-date operations manuals relating to the provision of its services for the use and guidance of operations personnel. It shall ensure that:* *- operations manuals contain instructions and information required by the operations personnel to perform their duties; […]*

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F12	Operating environment	The Operating Environment is defined as the conditions under which the system operates such as variations of weather conditions, traffic mix, airspace classification, etc.	2096/2005	*The hazard identification, risk assessment and mitigation processes shall include:* *(a) a determination of the scope, boundaries and interfaces of the constituent part being considered, as well as the identification of the functions that the constituent part is to perform and the environment of operations in which it is intended to operate;*
F13	Competence	Competence is defined as the capabilities of the staff working on the technical and procedurals aspects of the system they are working in. It could be competence of controllers, pilots but also of maintenance and other safety related staff, management, oversight authorities or competent authorities.	2096/2005	*An air navigation service provider shall employ appropriately skilled personnel to ensure the provision of its services in a safe, efficient, continuous and sustainable manner.* *&* *Within the operation of the SMS, a provider of air traffic services shall* *- ensure that personnel are adequately trained and competent for the job they are required to do,*
F14	Human-Machine interaction	Human-machine interaction is defined as the quality of the interaction between the system and the human resources required to operate it and to provide the intended service.	2096/2005	*The hazard identification, risk assessment and mitigation processes shall include:* *- a determination of the safety objectives to be placed on the constituent part, incorporating:* *- an identification of ATM-related credible hazards and failure conditions, together with their combined effects,*
F15	Organization	Organization is defined as the managerial aspects of the working environment.	2096/2005	*A provider of air traffic services shall, as an integral part of the management of its services, have in place a safety management system (SMS) which:* *- ensures […] that managers are responsible for the safety performance of their respective departments or divisions and that the top management of the provider carries an overall safety responsibility (safety responsibility)[…]* *&* *The organisational structure shall define:* *- the authority, duties and responsibilities of the nominated post holders, in particular of the management personnel in charge of safety, quality, security, finance and human resources related functions;* *&* *An air navigation service provider shall have in place at the*

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				latest two years after entry into force of this Regulation a quality management system which covers all air navigation services it provides according to the following principles. It shall: *- appoint management representatives to monitor compliance with, and adequacy of, procedures to ensure safe and efficient operational practices;*
F16	Communication	Communication is defined as the interaction between people, also including aeronautical telecommunication.	2096/2005	*An air navigation service provider shall provide and keep up-to-date operations manuals relating to the provision of its services for the use and guidance of operations personnel. It shall ensure that:* *- the operations personnel are expeditiously informed of the amendments to the operations manual applying to their duties as well as of their entry into force* *&* *Within the operation of the SMS, a provider of air traffic services shall ensure that hazard identification as well as risk assessment and mitigation are systematically conducted for any changes to those parts of the ATM functional system and supporting arrangements within his managerial control, in a manner which addresses:* *- the equipment, procedures and human resources of the ATM functional system, the interactions between these elements and the interactions between the constituent part under consideration and the remainder of the ATM functional System.*
F17	Reliability	Reliability is defined as the overall safety performance, including the potential of recovering from unwanted situations or failures in time	2096/2005	*The security management system shall define:* *- the means designed to detect security breaches and to alert personnel with appropriate security warnings;* *- the means of containing the effects of security breaches and to identify recovery action and mitigation procedures to prevent re-occurrence.*
F18	Transparency	Transparency describes the ability to specify clearly, what the system is intended to do, and to perform consistently as specified. From the safety regulatory oversight point of view this includes a clear identification of the legal responsibilities.	2096/2005	*ATS provider shall:* *ensure that the SMS is systematically documented in a manner, which provides a clear linkage to the organisation's safety policy (SMS documentation) […]* *&* *An air navigation service provider shall be able to provide an*

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				annual report of its activities to the relevant national supervisory authority. *&* *-complete arguments are established to demonstrate that the constituent part under consideration, as well as the overall ATM functional system are, and will remain tolerably safe by meeting allocated safety objectives and requirements .*
F19	Redundancy	Redundancy is defined as the use of independent components performing the same function, protecting the system against breakdown due to single component failures (single point of failure). In turn these independent components can be based on the same technology (e.g. duplicated engines or duplicated ILS transmitters) or on dissimilar technologies (e.g. radar plus ADS or line-of-sight data link plus satellite data link). From the safety regulatory oversight point of view some responsibilities (e.g. decisions on obligations to equip applies to both air operators and ANSPs, or protection of the aeronautical frequency bands or of the aerodrome surroundings) belong to governmental prerogatives, either at national or EU level.	2096/2005	*The organizational structure shall define:* *- the relationship and reporting lines between different parts and processes of the organisation.* *&* *In order to deduce the effect of a hazard on operations and to determine its severity, the systematic approach/process shall include the effects of hazards on the various elements of the ATM functional system, such as the air crew, the air traffic controllers, the aircraft functional capabilities, the functional capabilities of the ground part of the ATM functional system, and the ability to provide safe air traffic services.*
F20	Interdependence	Interdependence is defined as the degree to which the system interacts in an unintended manner with other systems (which may result e.g., in common cause failures or propagation of errors into adjacent systems).	2096/2005 & 1315/2007	*Within the operation of the SMS, a provider of air traffic services shall ensure that hazard identification as well as risk assessment and mitigation are systematically conducted for any changes to those parts of the ATM functional system and supporting arrangements within his managerial control, in a manner which addresses:* *- the equipment, procedures and human resources of the ATM functional system, the interactions between these elements and the interactions between the constituent part under consideration and the remainder of the ATM functional System.* *&*

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				2. The review shall be conducted in a manner commensurate with the level of risk posed by the new functional system or change to existing functional systems.
F21	Functionality	Functionality is defined as the correctness, consistency and un-ambiguity of the behaviour of the system.	2096/2005	*consistent with any reasonable level of overall demand for a given airspace. To this end, it shall maintain adequate technical and operational capacity and expertise.* *&* *Within the operation of the SMS, a provider of air traffic services shall ensure that hazard identification as well as risk assessment and mitigation are systematically conducted for any changes to those parts of the ATM functional system and supporting arrangements within his managerial control, in a manner which addresses:* *- the complete life cycle of the constituent part of the ATM functional system under consideration, from initial planning and definition to post-implementation operations, maintenance and de-commissioning;*
F22	Integrity	Integrity is defined as the trustworthiness of the system outputs, i.e. their freedom from errors given correct input (fail-safe principle; absence of errors of commission).	2096/2005	*The hazard identification, risk assessment and mitigation processes shall include:* *- a determination of the safety objectives to be placed on the constituent part, incorporating:* *- an identification of ATM-related credible hazards and failure conditions, together with their combined effects,*
F23	Maintainability	Maintainability is defined as the ability to maintain the system in working order throughout its life. This includes preventive maintainability, on-line maintenance, and reparability. From the safety regulatory oversight point of view it includes defining which organisations and which persons have the privilege of returning the system to service. This is totally sufficient for the aircraft case. In ATM/ANS, additionally, the systems may be maintained or re-configured during real operations without interruption of service.	2096/2005	*An air navigation service provider shall be able to provide services in a safe, efficient, continuous and sustainable manner consistent with any reasonable level of overall demand for a given airspace. To this end, it shall maintain adequate technical and operational capacity and expertise* *&* *Within the operation of the SMS, a provider of air traffic services shall ensure that hazard identification as well as risk assessment and mitigation are systematically conducted for any changes to those parts of the ATM functional system and supporting arrangements within his managerial control, in a manner which addresses:* *- the complete life cycle of the constituent part of the ATM*

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				functional system under consideration, from initial planning and definition to post-implementation operations, maintenance and de-commissioning;

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