



Flight Standards Directorate

Practices for risk-based oversight

Document ref.	Status	Date
Risk-based oversight practices	Draft	04/07/2015
Risk-based oversight practices	Edition 1	22/11/2016
The document will be reviewed periodically as part of the continuous improvement process. Comments should be forwarded to the address below:		
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This document is published under the provision of Art. 5(3) of Regulation (EU) No 628/2013: “The Agency shall provide competent authorities of Member States with relevant information to support the uniform implementation of the applicable requirements.”		

Executive Summary

Nowadays data governs more and more of our processes and decision-making as well as the management of risks. This evolution has also hit aviation, particularly the way competent authorities manage information and oversee aviation activities under their responsibility.

ICAO Annex 19 calls for the oversight of the areas of greater safety concern or need. EASA Implementing Rules in all domains ATM and ATCO (Regulations (EU) No. 1034/2011 No. 1035/2011, No. 2015/340), Aircrew (Regulation (EU) No. 1178/2011), Air Operations (Regulation (EU) No. No.965/2012) and Aerodromes (Regulation (EU) No. 139/2014) introduce the concept of Risk Based Oversight (RBO). However, no sufficient guidance is so far available to ensure smooth and uniform implementation of the requirements.

To support this approach, EASA collected RBO practices from 13 European states that agreed to share their experience and practices in this area. Moreover, there were also exchanges of ideas on RBO with the Federal Aviation Administration (FAA). As in the ATM domain, the RBO concept has been already introduced for some years; coordination was ensured with the National Supervisory Authority (NSA) Cooperation Platform working group on safety oversight and on-going compliance, where ATM authorities' experts are sharing practices and experience whilst aiming at developing a risk-based audit plan.

While proposing some definitions for clarification and a conceptual model for RBO, this collection of practices related to RBO proposes several assessment models of organisation risk profiles and the oversight planning / execution. It further elaborates on the tools and enablers today available for the continuous review of the risk profile and the oversight planning considering the safety performance of the organisation and their management of change policies. The document also suggests some basic guidelines for the conduct of RBO audits and finally includes some success stories.

This document:

- Highlights the relationship between RBO and the (safety) management system, the management of change, the overall performance of the organisation and the oversight cycle.
- Describes the interconnection, availability and exchange of data, which will significantly change the relationship between the authority and their regulated entities, as well as their ongoing management of safety ;
- Does not constitute regulatory material nor means of compliance nor guidance material. It reflects the RBO state of play to date, in an effort to gain a common understanding and look ahead;
- Can be used as guidelines for the Authorities having to implement RBO.

Finally, as already stated in the [EASA paper on a Performance-Based Environment](#), this document further provides recommendations, which highlight the need for a strategic vision of the Competent Authorities on why and how to evolve and move towards the planning and implementation of RBO, including reflections on how their inspectors should think and work in the future. For convenience, these RBO recommendations are repeated below:

Recommendation 1:	The oversight planning and determination of oversight cycle for each organisation should take into consideration the risk profile and the assessment of the safety performance. When the risk profile relies on expert judgment, the decision making should be made by consensus by a team of experts.
Recommendation 2:	For each organisation, RBO parameters should be continuously monitored at an appropriate frequency in order to identify any trend and to review the oversight programme, its cycle and the safety objectives. The competent authority should continuously follow-up and improve the overall RBO system.
Recommendation 3:	The ICAO state safety programme (SSP) should be established and used as a background framework for RBO and the competent authority should have a functioning management system, as required by the rules.
Recommendation 4:	The state oversight system should be mature enough before it can be complemented by RBO. This oversight approach should be linked to the objectives of the SSP and of the management system of the competent authority. EPAS actions should also be taken into consideration.
Recommendation 5:	The management system of the competent authority should capture the different risk profiles of the regulated entities according to a model. When determination of a risk profile relies on expert judgment, decision making should be made by consensus by a team of experts.
Recommendation 6:	RBO should be progressively deployed and the extension of RBO to additional domains should be consistent and appropriate. Initial introduction of RBO could be facilitated by a dedicated team of “champions”.
Recommendation 7:	A system for the collection, analysis, and exchange of safety data at the level of State and regulated entity is a prerequisite for RBO, as well as safety management principles and a just culture environment. Exchange of information on safety risks between competent authority and regulated entities should be established. Development of an integrated risk picture in and across different domains should be done in partnership with involved stakeholders.
Recommendation 8:	Competent Authorities should develop arrangements for cooperation on oversight, exchange of collected safety information, sharing of RBO experience, feedback on experience with the SSP etc....
Recommendation 9:	Initial and continuous training should be given to inspectors implementing RBO, to cover: <ul style="list-style-type: none"> - development of proper culture when interacting with industry - use of expert judgment, especially when safety performance and “gut feeling” are blended - use of RBO-specific tools available at the competent authority. Support and coaching should be available during the initial phase of RBO deployment.

***Note:** these recommendations are repeated throughout the document where they are relevant to the described topic.*

Contents

Executive Summary	3
1. Objective of the document.....	7
2. Introduction.....	8
2.1 Why RBO.....	8
2.2 Definitions, conceptual model and link with the EASA rules	10
2.3 EPAS, SSP and management system as drivers to RBO	13
2.4 Limits of RBO	14
3. Risk Profile and oversight planning	16
4. Enablers and tools	18
4.1 Management of safety information	18
4.2 Information sharing with other Competent Authorities	19
4.3 Training and qualification of inspectors	20
5. Conduct of Risk-Based Audits.....	22
5.1 UK experience: transforming the CAA and strengthening the people capability to operate in a RBO environment	22
5.2 Risk based audit: issues for discussion	23
5.3 Attitude during the conduct of risk-based audits.....	26
5.4 Accountabilities and enforcement	28
6. Experiences – success stories	30
6.1 RBO in practice by Switzerland.....	30
6.2 Success stories from UK-CAA.....	31
6.2.1 At the level of the Competent Authority.....	31
6.2.2 From the CAA blog - a personal view on the front line	31
6.3 Success story from Ireland (IAA).....	33
6.4 An approach scaled to one specific sector – helicopter safety in Norway.....	33
6.5 Experience from Sweden.....	35
Appendices	37
I Risk profiling – Some examples	38
I - 1 The Austrian example of risk profiling.....	38
I - 2 The Irish method – another simple model	40
I - 3 The Spanish risk profile - the integration of different CAA components	41
I - 4 The Swiss risk profile linked with the SSP.....	45
I - 5 The Finnish example of risk profiling.....	48
II Tools supporting RBO	50

II - 1	SMICG tools	50
II - 2	ICAO tools	50
III	Questionnaire used for the collection of the RBO practices	52
III - 1	Introduction	52
III - 2	Questions on Risk Based Oversight	52
IV	Guidelines for Risk Based Oversight by NSAs	55
1	Objective.....	58
2	Scope	59
3	<i>RBO Criteria</i>	60
4	<i>RBO Related Processes</i>	64
4.1	Safety data collection	64
4.2.	<i>Safety data analysis</i>	67
4.3.	<i>Surveillance programme and appropriate measures</i>	70

1. Objective of the document

During the last two years, several initiatives took place towards the implementation of Risk-Based Oversight (RBO), such as the issuance of the first edition of ICAO Annex 19, (EU) No. 628/2013 related to the EASA standardisation inspections¹ and the **recently-published** Opinion 07/2016 **related** to the EASA level of involvement in the certification of products, parts and appliances (in Part-21).

Within the European regulatory framework, the EASA Implementing Rules (IR) for Aircrew and Air Operations introduced in paragraph ARx.GEN.305 the concept of RBO as follows: “For organisations certified by the competent authority, the oversight programme shall be developed taking into account the specific nature of the organisation, the complexity of its activities, the results of past certification and/or oversight activities required by ARx.GEN and ARO.RAMP and shall be based on the assessment of associated risks”.

Also implementing rules applicable to other domains call for the same approach in performing oversight in a risk-based manner, they are:

- Regulation (EU) No. 2015/340, for ATCO training
- Regulation (EU) No. 139/2014, for Aerodromes
- Regulations (EU) No. 1034/2011 and No. 1035/2011 for Air Navigation Services

For simplicity the rest of the document will refer to the EASA Aircrew and Air Operations rules but it equally applies to any other aviation domain.

However, no guidance was provided to Competent Authorities on how to comply with such requirements when developing oversight programmes. Competent Authorities requested at various levels and on many occasions to have appropriate indications on how to set-up and perform RBO.

During summer 2014, as a consequence of the EASA RBO workshop held in 2013 and the issuance of the [Harmonised European Approach to a Performance-Based Approach](#)², the EASA took the decision to interview the Member States and Partners who have already started to implement RBO within their activities. The questionnaire is available in Appendix III.

By compiling practices from Competent Authorities willing to share their experience so far, this document outlines basic concepts and offers some practical guidelines to RBO, as well as indications and examples on how to conduct RBO audits.

This document can be used as guidance for the Authorities having to implement RBO. Some recommendations for the content, planning and implementation of RBO will be highlighted within the document in order to accompany the changes that RBO will bring to the Authorities’ working methods.

These RBO practices were collected between summer 2014 and summer 2015 and do not constitute regulatory material, means of compliance or guidance material. They reflect the state of the play for RBO in 2015, in an effort to gain a common understanding and look ahead.

¹ [\(EU\) No 628/2013](#) calls for: 1- the monitoring of the application by competent authorities of the requirements to be continuous and risk-based; 2 – the inspection programmes to be adjusted to the emerging risks.

² This document set the scene for the performance-based regulation (PBR) and the performance-based oversight (PBO). In its section 8, it is mentioned that EASA will further substantiate the two concepts by spring 2015. This gave birth to the current document you are reading.

2. Introduction

2.1 Why RBO

The need for moving towards Risk Based Oversight is triggered by many elements at various levels within the European Aviation system. Each of them deals with a different perspective and, at the same time, contributes to providing good reasons for implementing RBO.

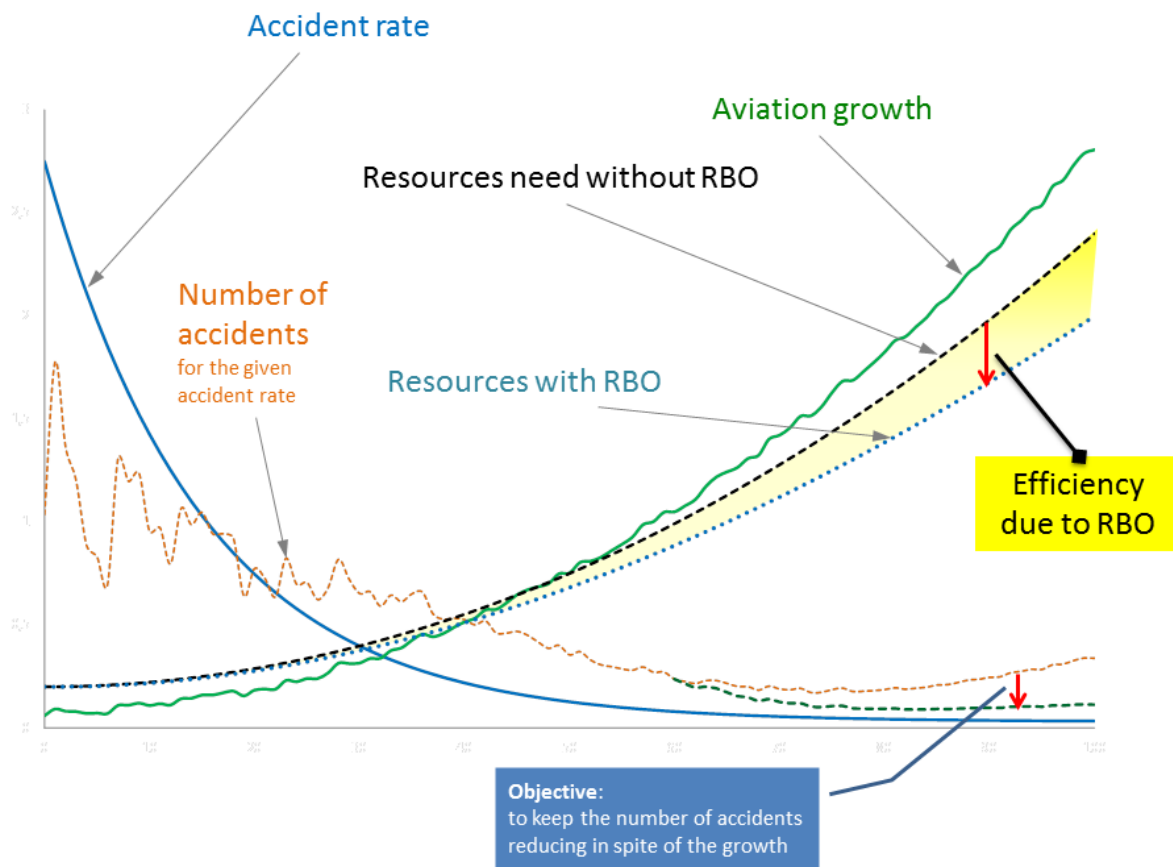
Political level

The report 'Flightpath 2050 Europe's Vision for Aviation' sets a goal for year '2050 of reducing the accident rate of commercial aircraft flights to less than one per ten million flights, i.e. half the current level. However, whilst the aviation accident rate continues to decline, the rate of decline has slowed markedly since 2004 and at the same time we are seeing a continued growth in the number of flights, which are set to almost double by 2030. As a consequence, in order to preserve the current low level of fatalities resulting from air accidents, we must ensure that the rate of accidents continues to decline in order to counterbalance the predicted growth in the number of flights. One tool to achieve this is risk-based oversight.

Staff Resources' level

The introduction of Risk-based Oversight will allow for a more effective use of the available oversight resources. That is clearly one of the actions which competent authorities have to undertake within the European aviation system in order to achieve the objective above. RBO provides more flexibility to authorities to better allocate their staff, e.g. more intensive oversight for organisations having a high-risk profile or less performing or sustaining major management changes. However RBO should not be seen as a means to reduce the staff resources, especially in the case of sustained aviation growth;

The chart below gives an overview of the RBO's benefits. While aviation is growing, traditional oversight will remain but will also request a similar increase in the number of required resources. RBO, through increased efficiency would keep this requested increase at a lower level. Moreover, it would also increase effectiveness of oversight and contribute to achieving the objective of keeping a reducing trend in the number of accidents in spite of the increased exposure.



State Safety Programme (SSP) and European Plan for Aviation Safety (EPAS) 2016 – 2020, previously the European Aviation Safety Plan (EASp) 2014 - 2017.

Element 3.3 of ICAO Annex 19 SSP framework calls for 'Safety-data-driven targeting of oversight in areas of greater concern or need', i.e. States should establish procedures to prioritize inspections, audits and surveys towards those areas of greater safety concern or need, as identified by the analysis of data on hazards, their consequences on operations, and the associated safety risks. Such an improved knowledge of risks will enable better targeted safety actions, thus complementing oversight in achieving the safety objectives set out by the SSP. This approach is also supported by the EPAS as further explained in section 2.3 of this document.

Safety Management

At State's level, RBO provides a mechanism for better identifying hazards, measuring associated risks as well as demonstrating effective mitigation of these risks. Ultimately it allows the Competent Authority to focus its attention on organisations that require additional or higher attention, strengthening the efficiency of the oversight. At the same time, an improved understanding of the risks across the aviation system will enable better calibration of the oversight, on the basis of an improved risk picture that takes into account the causal factors of all safety occurrences, from isolated events to incidents and accidents.

At organisational level, RBO relies on the evaluation of the effectiveness of the organisation's management system and an assessment on the maturity of the organisation's management system.

2.2 Definitions, conceptual model and link with the EASA rules

To achieve a shared understanding of the concept of RBO and of its constituting elements, some definitions and a schematic representation are needed.

For the purpose of this document, the following operation definition is used:

Oversight: The function by means of which a competent authority, ensures that the applicable requirements are met by regulated entities.

It's worth noting that the above aligns very well with two definitions that have been developed in other contexts and proposed at a later stage.

- 1) the proposal from the European Commission to amend the Basic Regulation, in Article 2 reads: **oversight** means the verification, by or on behalf of the competent authority, on a continuous basis that the requirements on the basis of which a certificate has been issued or the requirements in respect of which a declaration has been made, continue to be complied with.
- 2) the latest draft definition proposed by the ICAO Safety Management Panel in the context of amendment of Annex 19 and endorsed by the ICAO Air Navigation Commission reads: **Safety oversight**. A function performed by a State to ensure that individuals and organizations performing an aviation activity comply with safety-related national laws and regulations.

Risk Profile: The elements of risk that are inherent to the nature and the operations of the regulated entity, this includes:

- the specific nature of the organisation;
- the complexity of its activities;
- the risks stemming from the activities carried out

By nature, an organisation has its own risk profile, that derives from the specificity of its operations, e.g. the location of an airport situated in a difficult environment e.g. in a valley or the type of aircraft operated. These individual risk profiles can be grouped into families with similar types of operations. However as the specific elements of the organisation change, it can move to another family due to e.g. change of business model, new type of operations.

Safety performance: the demonstration of how effectively can a regulated entity mitigate its risks, substantiated through the proven ability to:

- comply with the applicable requirements;
- implement and maintain effective safety management;
- identify and manage safety risks;
- achieve and maintain safe operations;

The results of past certification and/or oversight also need to be taken into account.

Safety performance is continuously changing over time, as it is the direct outcome of the continued operations of the regulated entity.

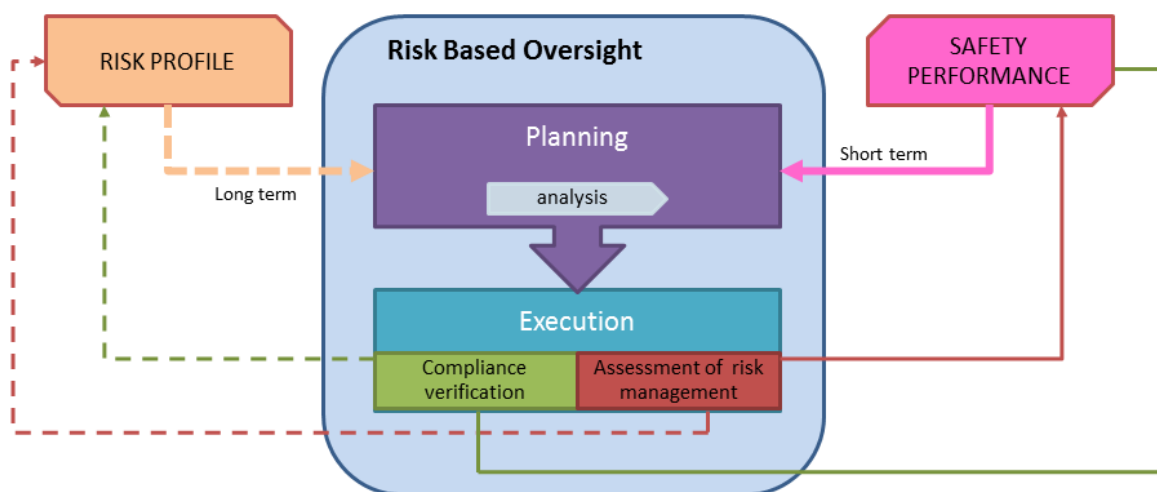
Risk-based Oversight (RBO): A way of performing oversight, where

- planning is driven by the combination of risk profile and safety performance; and
- execution focuses on the management of risk, besides ensuring compliance.

Note: Relation between “performance-based oversight” (PBO) and RBO

The concept of “performance” conveys the idea of tangibly measuring the health of the system under scrutiny and ultimately assessing its overall performance. Performance indicators, as a means to measure, may specifically help to either identify risks within that system or measure safety risks or monitoring actions mitigating these risks. This means that a PBO can also support the identification of areas of greater risks and serve the risk assessment and mitigation exercise. This is exactly where PBO meets RBO.

Based on the PLAN, DO, CHECK, ACT conceptual model in order to better visualise the feedback loops, the following RBO scheme is proposed:



RBO combines the two phases of “planning” and “execution”.

1. For the “planning” and “content”, the prioritisation of activities takes place on the analysis of the information available from the risk profile and the overall safety performance, which includes:
 - the specific nature of the organisation;
 - the complexity of its activities;
 - the Safety Performance Indicators (SPI);
 - the outcome of previous oversight;
 - an assessment of associated risks.

The above should be combined with contextual information coming from many sources of intelligence, such as isolated events, reorganisation, retirement of key employee, reported

occurrences, financial health etc. Furthermore, it is worth noting that the resulting outcome is rather dynamic.

AMC 1 ARO.GEN.305³ (b) and (d) gives further details about the determination of the oversight programme, including the management system and the management of change, which further refer to xRO.GEN.200 and its associated AMC/GM (management system). In particular, AMC 1 ORO.GEN.200 (a) 3 is of utmost importance for the oversight of the organisation's safety risk management. In this way the authority can adapt and target its oversight activity on the basis of the data available.

AMC1 and 2 to ARO.GEN.305(c) further describes the relationship between the planning cycle and the level of risk identified, the organisation's ability to effectively manage safety risks, the organisation's safety performance and its overall SMS maturity. This planning cycle may evolve from 24 to 48 months or be significantly reduced if there is evidence that the safety performance has significantly decreased.

Choice of cycle length and audit interval may be driven by availability of resources. Possible, non-exhaustive, approaches can be:

- a) for each operator taken individually, the cycle length is derived from its risk profile; then, for each area (e.g. training, dangerous goods, organisation's management system) the audit interval is derived from an evaluation of the risks in that area; or
 - b) all operators are ranked with respect to their risk profile and clustered accordingly. The cycle length is connected to each cluster of operators: those above the average will see their cycle extended while those below average will have the cycle length increased. Likewise, within an operator, the audit interval for each area is adapted to the evaluated level of risk.
2. During the “execution”, attention is paid to both “compliance” and “risk management” because compliance remains the basic element to ensure safe operations, whereas risk management looks at the effectiveness of the activities put in place to achieve the safety objectives.

ARO.GEN.300 (a) (b) (c) and associated AMC/ GM further guide the competent authority, in particular for the evaluation of the organisation's safety risk assessment⁴. A hook to the management system and the management of change⁵ for the organisation is also relevant. Eventually the overall performance assessment will nurture the oversight cycle as described in ARO.GEN.305(c).⁶

The outcome of the oversight is considered: for quick response to safety performance issues in the short term (planning and content), if needed; and for adjusting the risk profile in the longer term.

*Note : in line with the above conceptual model, **recently published NPA 2015-03 (now Opinion 07/2016)** about the level of EASA oversight involvement in certification projects for products, parts and appliances and their changes/repairs related to Design organisation (Part-21) proposes:*

³ See footnote No.2 - For simplicity's reason, the document only refer to the EASA Aircrew and Air Operations rules but it equally applies to any other aviation domain. Similarly ATM, ATCO or Aerodrome rules also refer to the obligation to adopt the RBO approach when planning and executing the audits. In the future EASA initial and continuing airworthiness rules will adopt the same approach.

⁴ As required by AMC 1 ORO.GEN.200(a)3.

⁵ ORO.GEN.200 and its associated AMC/GM refer.

⁶ The overall performance assessment constitutes the feedback loop for the overall determination of the oversight cycle as required in ARO.GEN.305(c).

- *organisation's performance and experience measurement system, e.g. an initial assessment of the functioning and experience of the organisation and its continuous monitoring and measurement;*
- *an assessment of the safety risks in certification projects to identify areas where the probability and/or severity of the risks is estimated to be higher than in other areas and where a higher level of involvement is required;*
- *Some lighter oversight system in areas with a lower risk to safety when the organisation has demonstrated capabilities or experience and reached a certain level of performance in their core processes (e.g. design and compliance demonstration processes, management of project(s), management of subcontractors or management of organisational changes);*
- *The exchange of information regarding the performance of the organisation and the need to report to the agency any difficulty or event encountered during its compliance demonstration process that may have a significant effect on safety or that may appreciably change the assessed risks.*

It should be noted that RBO focuses more on the organisation whereas the level of involvement as per NPA 2015-03 (now Opinion 07/2016) does more on the products and its certification.

Recommendation 1:	The oversight planning and determination of oversight cycle for each organisation should take into consideration the risk profile and the assessment of the safety performance. When the risk profile relies on expert judgment, the decision making should be made by consensus by a team of experts.
Recommendation 2:	For each organisation, RBO parameters should be continuously monitored at an appropriate frequency in order to identify any trend and to review the oversight programme, its cycle and the safety objectives. The competent authority should continuously follow-up and improve the overall RBO system

2.3 EPAS, SSP and management system as drivers to RBO

SSP is the ICAO tool for a State to define and achieve its safety objectives, including the collection of data and identification of areas of greater risk, concern or need. A State should establish mechanisms to ensure the capture and storage of data on hazards and safety risks for each overseen organisation, as well as at aggregated State level. Mechanisms to develop information from the stored data, and to actively exchange safety information with service providers and/or other States as appropriate should also be considered.

In the European legal framework, a significant number of the ICAO SSP elements are covered by the management system as required by ARO.GEN.200, calling for a safety risk management process, a compliance monitoring function and the mutual exchange of all necessary information.

The oversight programme(s) should therefore:

- take into consideration the risk profile of the organisations, their specific nature and their types of operations, the assessment of associated risks, the SPIs at State aggregate level and organisation level;

- include a mechanism for adapting the scope or frequency of surveillance according to the collected safety information, the actual safety performance and the management of changes for the organisations;
- plan the availability of NAA staff in order to ensure the proper completion of oversight activities; and
- input to the State safety assurance element and to the State safety promotion activities.

To illustrate, Section 4 of Appendix I depicts how FOCA (Switzerland) has defined a simple risk profiling process, further linked to the hazard identification process in place at State level and supporting their ICAO SSP.

Such a risk-based approach to surveillance prioritization will also facilitate the allocation of resources to areas of greater risk, concern, need or emerging risks; in other words it will enable a more efficient use of resources.

In addition, at the European level, managing safety risks is also carried out in coordination with States and industry, which are part of one aviation system, as documented in the European Aviation Safety Programme (EASP) and the European Plan for Aviation Safety (EPAS) The Commissions proposal in the new Basic Regulation⁷ recommends the EPAS be given a more robust legal basis through a possible revision of Regulation (EC) No.216/2008.

The EPAS starts by identifying those areas in which coordinated action will make a difference in avoiding accidents and serious incidents, which is the ultimate goal that links all the activities together. The planning activity is followed up by a reporting activity, in which progress on the actions is evaluated and also documented. This feedback loop ensures that the process to manage risks at European level continuously improves.

Recommendation 3:

The ICAO state safety programme (SSP) should be established and used as a background framework for RBO and the competent authority should have a functioning management system, as required by the rules.

2.4 Limits of RBO

The traditional way of performing oversight has achieved such tremendous safety records that this should continue to serve as the basis on which RBO complements. RBO is not a revolution but an evolution of the current system, bringing alternatives, benefits but also drawbacks.

In fact, in the early time of SMS implementation, some aviation regulators started to significantly replace the existing “prescriptive” system by a full Performance Based Environment (PBE) and experienced serious setback in term of safety records. Compliance to the rules remains the foundation on which the Performance-Based Environment and RBO can be built. As an example, Canadian aviation investigation report A13W0120 highlights that –“If Transport Canada does not adopt a balanced approach that combines inspections for

⁷ http://eur-lex.europa.eu/procedure/EN/2015_277?qid=1475134779627&rid=1

compliance with audits of safety management processes, unsafe operating practices may not be identified, thereby increasing the risk of accidents”.

Although this document proposes methods to implement RBO, a critical mind set is always recommended, as RBO may not be the solution to all problems in oversight. An outcome-based approach focusing on the measurement of safety performance is essential for RBO. However, too much emphasis on Safety performance indicators (SPI) can be counterproductive. The NAA can be blinded or fascinated by the brilliance of SPIs, forgetting some important other parameters essential to the safe operations, such as compliance with prescriptive or safe behaviour.

Other possible RBO drawbacks are that risk-based frameworks may be based on models not capturing all the relevant risks; or risk assessment may not be adequate, thus delivering misleading indication⁸.

In addition, RBO may err on the side of assuming that a regulated entity poses a risk when it does not (either according to the model or in terms of risk assessment) or err on the side of assuming that a regulated entity does not pose a risk when in fact it does. Moreover, capturing new or emerging risks can be challenging and too late in time. For instance the risks posed by the increasing automation of aircraft became evident only after the first safety occurrences.

In any case, the competent authorities should always critically review the adequacy and efficiency of its oversight system, in the context of its own management system and taking into account the State Safety Programme. Ultimately the authority’s management system includes data from organisations and from past oversight activities. The authority’s management system also includes information on past oversight, input from external sources (e.g. sub-contracting of oversight activities by third parties, audit of the oversight system, conformity to international standards such as ISO 31000, exchange of safety data with other authorities in the context of cooperative oversight or agreements)⁹.

However RBO is an essential building block of oversight as regards to the cross-domain assessment of safety risks.

Last but not least, a well-established oversight system as well as the availability of data constitutes pre-requisites to RBO implementation. This is further supported by the recommendation in the ICAO GASP that a 60% Level of Effective implementation should be achieved, before safety management practices are put in place. In other words, the Authority and its regulated entities should have all enablers in place to effectively move towards RBO. These enablers are further described in section 4.

Recommendation 4:

The state oversight system should be mature enough before it can be complemented by RBO. This oversight approach should be linked to the objectives of the SSP and of the management system of the competent authority. EPAS4 actions should also be taken into consideration.

⁸ The Finnish CAA website refers to “[From Safety indicators to measuring risks](#)”, which further highlights the danger of misleading interpretation of SPIs.

⁹ The [U.S. Food and Drug Administration](#) also came to that conclusion incrementing a combination of randomized controlled trials, epidemiological studies and post surveillance.

3. Risk Profile and oversight planning

When determining the oversight programme and planning, the competent authority should assess the risks related to the activity of each organisation and adapt the oversight to the level of risk identified and to the organisation's ability to effectively manage safety risks.

Therefore, as described in section 2.2, the first step towards RBO is the definition of risk profile for each regulated entity, which will support the prioritisation in the content and planning of the oversight. By doing so a competent authority starts looking at the organisations under its oversight in terms of risk and no more in administrative terms of approval holder, where the continued validity of the approval is ensured by a set of predefined steps prescribed by the regulation. The logical consequence is the differentiation of the oversight activity based on the outcome of the risk profiling.

This is why many authorities, not to say "all", have developed their own approaches to risk profiling, which was the main outcome of the interviews carried out. A selection of these approaches are presented in Appendix I, in increasing order of complexity.

The definition of the risk profile is a multifaceted process, based on an evaluation of the organisation's management system, reflecting the culture of an authority and the way it is addressing the challenges of regulating the national aviation industry, including the output of the authority's management system. Size, scope and complexity of operations, including the risk exposure are always at the heart of the analysis.

The majority of the competent authorities adopted a progressive approach, which can be summarised as:

1. Start with one domain;
2. Gain experience; and
3. Then expand the practices to other domains.

In ATM this need stemmed from the early regulatory obligations of ensuring that audits are conducted in a manner commensurate to the level of the risk posed by the organisation's activities. Although only few authorities adopted this risk based oversight approach since the beginning, this concept is being gradually implemented in the rest of the ATM/ANS community. Current practices and ideas have been compiled and elaborated by ATM/ANS authorities and can be found at Appendix IV. On the contrary, in most cases "air operations" have been chosen as the starting point, due to their nature of 'risk integrators' as the aircraft concentrates all the risks in flight where safety data are often available (e.g. FDM, identified top 5 risks in terms of accidents...).

The annual safety reviews produced by some authorities include the analysis and aggregation of the outcome of oversight and some safety events; sometimes with the attempt to find correlations or identify patterns or trends. The Swiss authorities even deliver a quarterly safety performance and surveillance summary.

A common element in all practices is the use of data combined with expert judgement during the risk profile definition. This appears to be a logical choice, as the available data sources are, at this point in time, not very consistent and considering that an algorithm combining safety and background data to deliver a risk indication would be easily challenged in its theoretical basis.

To ensure that expert judgement supports a consistent risk profiling, the related decision-making is made by consensus by a team of subject matter experts, that is to say teams of inspectors of the same competent authority, normally within the same technical domain, sometimes supported by safety analysts. This allows to evaluate and continuously review the risk profile as well as the performance assessment in a consistent

manner, with individual biases or single opinions being blended in the consensus process, and to standardise the approach among the inspectors. In this way is also possible to benefit from the experience gained and to further train inspectors to achieve a common approach.

In addition, during the collection of the practices, guidelines developed by a working group of ATM competent authorities¹⁰ were received and are twofold:

1. The parameters to take into account when producing a RBO audit plan. These parameters are grouped in 5 categories: results from previous audits, occurrence, changes of the functional system, operations (physical locations), safety indicators and others (mainly good practices and examples).
2. The processes in the authority and its external/internal interfaces: safety data collection, safety data analysis and oversight programme and appropriate measures.

Although specific to the ATM domain, Appendix 4.3 contains some valuable ideas, which can be of use while deploying RBO in any other domain.

Further experience gained from the Competent Authorities during RBO implementation indicates that expert judgement remains essential in determining the risk profile, however this evaluation should be conducted (i) by a team of experts, so that no judgement is made only by one person and (ii) by working by comparison (e.g. using the average in a same category) in order to better determine what, why and when to oversee. Conversely, when a model or scoring system for risk profiling or risk evaluation is used:

- The variation of the indicators is often more important than the indicators themselves; therefore too much attention to absolute figures is not recommended;
- It is important to regularly monitor trends of these indicators over time;
- Calibration and weighting of indicators are fundamental to support proper profiling (e.g. excessive weight of one single factor could alter the outcome of calculations);
- Avoid not to get bogged down by the scoring system, it's more important to assess the relevance of the outcome;
- Adequate attention should be given to border situations to avoid inaccurate decision. For instance, a traffic light system where red = 24 months cycle and green = 48 might prove to be inadequate.

Recommendation 5:	The management system of the competent authority should capture the different risk profiles of the regulated entities according to a model. When determination of a risk profile relies on expert judgment, decision making should be made by consensus by a team of experts.
Recommendation 6:	RBO should be progressively deployed and the extension of RBO to additional domains should be consistent and appropriate. Initial introduction of RBO could be facilitated by a dedicated team of "champions".

¹⁰ Safety oversight working group of the NSA Coordination Platform (NCP)

4. Enablers and tools

In 2014, the EASA developed [A harmonised European Approach to a Performance-Based Environment](#) where categories of enablers and tools needed for a RBO are identified. They are, but not limited to:

- Mature Safety Management;
- Management of safety information;
- Information sharing;
- Just/Safety culture;
- Data Driven Decision making;
- Training and qualification of inspectors.

It is not possible to exhaustively mention all the enablers or tools available. For instance, in some domains such as helicopter operations, [oil and gas industry transport](#) or GA, the work delivered by the International Helicopter Safety Team (IHST), European Helicopter Safety Team (EHST), European General Aviation Safety Team (EGAST) or European Authorities Coordination Group for Flight Data Monitoring ([EAFDM](#)) including good practices on the oversight has not been reviewed and included in this document. Some items developed by SMICG, ICAO and EASA are available in Appendix II.

The next paragraphs below in this section are limited to the items, practices or sources of information most quoted by the NAAs during the RBO interviews.

4.1 Management of safety information

Data is essential to support the RBO process; the sources of information must be carefully identified in order to obtain the right information. Data sharing is also important, as it allows to widen the available set of data. Finally, data quality is crucial to support proper decision making, otherwise outcomes can be misleading.

This is further emphasized by ICAO Annex 19, which requires that information is systematically collected, analysed and monitored to identify risks and measure progress against outcomes.

RBO relies on data collection and safety modelling as part of an effective Management System of the authority and mature Management System within regulated entities. Initiatives like the European Data Exchange Programme for Aviation Safety will properly feed RBO and allow the identification of Safety Performance Indicators (SPI), as well as the set-up associated targets. In this way it becomes possible to measure and monitor the level of safety performance. In addition information on the effectiveness of the safety barriers (mitigation strategies for risks) can be continuously gathered.

The Norwegian case in section 6.4 clearly stipulates the benefit of exchange of information between authorities and industry/operators as well as a common understanding how to improve safety altogether.

Recommendation 7:

A system for the collection, analysis, and exchange of safety data at the level of State and regulated entity is a prerequisite for RBO, as well as safety management principles and a just culture environment.

Exchange of information on safety risks between competent authority and regulated entities should be established.

Development of an integrated risk picture in and across different domains should be done in partnership with involved stakeholders.

4.2 Information sharing with other Competent Authorities

In general all interviewed Authorities are exchanging information with other Authorities only on an ad-hoc, case by case basis, without being supported by a framework arrangement. One State has an agreement in place with another one in order to obtain occurrences reported to that state by national operators and vice versa.

On top of article 15 in the EASA basic regulation (EC) No.216-2008, exchange of data and safety information is already an obligation in some domains:

- In OPS and Aircrews ARx.GEN.300 requires Authorities to cooperate in the oversight of organisations operating in more than one Member state and to exchange the relevant information.
- These aspects in ATM are explicitly addressed when an agreement on the supervision of organisations active in Functional Blocks of Airspace (FABs) or in cases of cross-border provisions is concluded between the competent authorities concerned with a clear identification and allocation of responsibilities.

Most of the interviewed countries recognized that the participation to the Network of Analysts established by EASA in the framework of Regulation (EU) No 376/2014 has proved to be useful in the effort of sharing data and safety information among NAAs.

In addition UK CAA recognizes the increasing need of sharing not only data but also audit techniques and implementation processes.

Finally some new experiences show that cooperative oversight or sharing of safety objectives in a given domain such as “off-shore helicopter operations” between England and Norway have been very fruitful. Exchange of information related to the European [SSPs](#) or the SSP of any other country can constitute another source of practices for RBO. It is worth noting that, for the preparation of RBO:

- Several NAA websites propose some safety information (e.g. [SPIs and accident categories with data, lessons learned from transport airplane accidents](#); [ICAO runway safety site](#) etc.);
- The EU aviation system relies on cooperation and information sharing;
- Some international organisations like IATA, ACI... can constitute other sources of information.

As to conclude, it can be stated that little has been achieved in the direction of “cooperation” and “information sharing” between States; however this has already proven beneficial and useful. EASA and EU could also play a leading role in that achievement.

Recommendation 8:

Competent Authorities should develop arrangements for cooperation on oversight, exchange of collected safety information, sharing of RBO experience, feedback on experience with the SSP etc....

4.3 Training and qualification of inspectors¹¹

The breadth and depth of a risk focussed audit will be dependent on the qualification of the staff. In order to perform risk based oversight, some supplementary competence is required, in addition to the required domain-specific technical expertise.

In particular, a more proportionate approach requiring constant dialogue with the organisation enables inspectors to better understand how risks are mitigated and to assess the effectiveness of the mitigation process and the level of maturity of the organisation's safety management system. Authority inspectors need to acquire the ability to assess safety management systems.

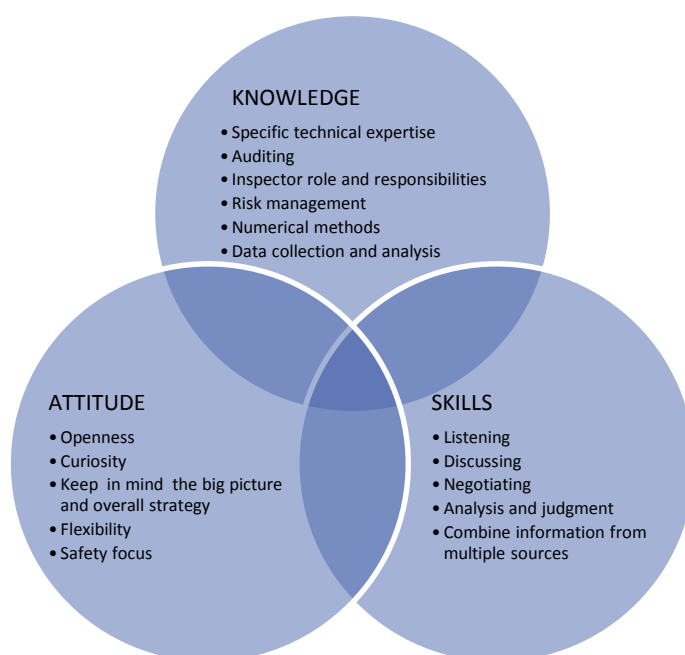
Moreover, as oversight will be mainly based on performance, the ability to measure safety performance should also become part of the inspectors' knowledge base. This means a basic understanding of

- safety analysis techniques and root cause determination;
- how to work with safety indicators.

Duration of the training should be adequate to allow the achievement of the objectives set out above. In other words it is not possible to recommend a standard training duration, as the starting point may vary depending on the background and the knowledge of every individual to be trained.

An organisational cultural analysis needs to take place to identify the competence elements needed to enable inspectors to implement RBO to identify the needs of new joiners to the Competent Authority.

Following the KSA model the competence required for RBO can be summarized as follows:



¹¹ A Working Group tasked to define a Competency Framework for Competent Authorities' Inspectors was established by EASA Management Board and is expected to deliver its outcome by end 2016.

In addition, the [SMS Inspector Competency Guidance](#) issued by SMICG should be considered.

Recommendation 9:

Initial and continuous training should be given to inspectors implementing RBO, to cover:

- development of proper culture when interacting with industry
- use of expert judgment, especially when safety performance and “gut feeling” are blended
- use of RBO-specific tools available at the competent authority.

Support and coaching should be available during the initial phase of RBO deployment.

5. Conduct of Risk-Based Audits

The execution of RBO shows that the direct interaction with the regulated entities goes beyond the mere verification of compliance with all applicable regulatory requirements. The communication is now taking place at different levels, not only at the technical one. In particular, when a (safety) management system is established, the organisation's senior management needs to be involved when assessing and discussing the safety performance. All this requires ability to move away from the traditional checklist, to understand how an organisation is managing its own risks and whether the (safety) management system is effective and delivering the expected results.

Only one authority, the CAA-UK was able to share some experience gained in performing RBO audits; this experience is reported below, as it constitutes, for the time being the only available practice to share.

5.1 UK experience: transforming the CAA and strengthening the people capability to operate in a RBO environment

"The action of transforming the CAA to a performance based regulator has been challenging. The UKCAA has traditionally worked within inspectorates (e.g. flight operations, airworthiness, air traffic, aerodromes, licensing, medical) with limited crossover of information other than at the senior management level. Consequently, it became clear that the UKCAA needed to work as a single organisation with a common vision, adopting standardised processes, procedures and terminology. However, the variance in requirements associated with EASA Implementing Rules has proven to be challenging and to a degree has fuelled resistance to adoption of change. Also, the UKCAA recognised the need to build in additional capacity, thus allowing what has been termed the "day job" to continue whilst building the new system. Early evidence of embedding the new way of working has proven to be essential in achieving momentum in the deployment and the UKCAA culture change. Also, moving to an outcome focus (as opposed to being action driven) has also proven to be challenging, particularly when individual and team judgments are called for.

People have been a key enabler to the roll out of RBO. In meeting their development needs, it has been essential to recognise the time and cost associated with [the] training [of] the staff. A detailed training needs analysis was necessary in order to move to the new working environment along with the associated changes in working methodology/environment. Also, the need to move our staff from a prescriptive compliance focus to an approach where use of judgment informed by hard evidence as a fundamental tool in their oversight, has proven to be challenging. Of critical importance has been the role of the Sector Manager and their understanding and appreciation of the risks at the Entity, Sector and Total Aviation System levels.

Delivering standardised systems and processes across the UKCAA has been challenging. In addition, provision of accurate and timely management information has been essential to the delivery of the necessary efficiency improvements. System investments have proven to be essential for the achievement of the desired outcomes. Finally, industry expectations, particularly in respect of our own internal management system have needed to be managed with suitable clarification, particularly around terminology so as to differentiate our internal SMS focus from that of a service provider such as clarifying that PBR is about delivery of safety improvements as opposed to making efficiency cuts.

As an overall approach, it is recommended to take a proportionate approach to the deployment of RBO and address it by capability, starting with the most-advanced, more mature or more-prone sectors to RBO in terms of deployment.

The UKCAA privileged AOC Holders (which included airworthiness and training approvals), then aerodromes/ANSPs and finally airworthiness and production organisations. To achieve RBO, groups of representatives from AOC Holders, aerodromes, ANSPs ground handlers, manufacturing and maintenance organisations have been established and will work with the UKCAA on an engaged partnership basis to maximise and review the opportunities and challenges that arise.

Risk pictures for entities¹², sectors and ‘total’ risk pictures should be worked on with recognition that the development of a standardised management system in the NAA is a key enabler. In moving to a more evidence focused oversight regime, the UK CAA recognises the need to allow time for the data to grow and mature in order to add the necessary value – UKCAA expects this will take about 3 years”.

The UKCAA indicates that, while delivering the change throughout the CAA, a small change team was established 3 years ago, supplemented at the start of the RBO rollout with a number of seconded staff from across the other business areas. This was done primarily to prepare for transferring some of the ownership of change to the business. Active and effective leadership top to bottom and across the UKCAA has been essential. Positive success has been measurable based on the level of engagement, particularly from senior management. UKCAA also recognised the importance of working within a larger European and global aviation domain and hence has facilitated regular engagement with ICAO, EASA, European NAAs or any other major players.

Recommendation 6:

RBO should be progressively deployed and the extension of RBO to additional domains should be consistent and appropriate. Initial introduction of RBO could be facilitated by a dedicated team of “champions”.

5.2 Risk based audit: issues for discussion

The items listed in this section aim at providing some basic ideas on how to prepare a risk-based audit.

For ATM, specific guidelines have been developed by the NSA cooperation platform-working group:

- A list of elements for consideration when establishing an RBO audit plan is available at Appendix IV-1
- A questionnaire to conduct a risk-based audit is available at Appendix IV-2.

Note 1: Some redundancy may exist.

Note 2: A risk-based audit, when addressing cross-domain issues, may need to be conducted in several organisations. This is typically the case for “runway excursion” as it may address the airport (e.g. runway surface friction), the airport equipment, the weather service equipment (e.g. wind shear detector), the operations of aircraft, the training of pilots, the maintenance of the aircraft (e.g. braking systems), sub-contracted ground handling services etc.

Note 3: References to the rules are inserted as footnotes for each main topic.

- Build your own data for the whole sector for comparison, objectives specific to the sector (e.g. SSP or management system’s objectives) as well as data specific to the audited organisation such as:
 - Risk profile of the organisation including data serving as justifications – compared with a group of similar organisations;
 - Risk picture for the type of operations;

¹² As example, the Australian CAA proposes the sector [risk profile for the aerial application sector](#).

- Incidents / serious incidents / accidents – investigation reports appropriate to the domain - any other occurrence data (and/or trends) as well as report(s) from previous risk-based audits (recommendations or findings - was there any promise of action?).
 - Functioning of the organisation's safety review board¹³ - safety reporting or studies under review¹⁴
 - Organisation's objectives and associated means (e.g. SPIs, dashboard etc.);
- Have an introductory questionnaire such as:
 1. What is most likely to be the cause of your next accident, serious incident or safety occurrence?
 2. How do you know that?
 3. What are you doing about it?
 4. Is it working?
 5. What are the top 5 risks or most "significant" hazard in terms of severity / probability in this organisation? How did the organisation identify and quantify it? Trends?
 6. Do you have a list of hazards? Does the organisation maintain a risk picture?
 7. Do you know why your staff don't follow procedures?
 8. What are your safety objectives? (at department level or organisation level)
 9. How do you ensure you do the right thing? [What does "right thing" mean?] How do you measure it?
- If you could invest in (more) safety, what would you do first?
- Hazard identification and risk assessment as well as safety performance¹⁵:
 - How is the data collection described? Why these data?
 - Study the data (frequency, likelihood and severity) supporting the hazard –What kind of tools does the organisation use? How is the risk measured? What is the risk tolerability?
 - Compare the data with yours, discuss it and set-up objectives (if needed).
 - What are the controls for the high / medium risks?
 - Root causes or impounding factors: Analyse the (safety) barriers, mitigating factors etc. Are the different factors weighted?
 - Does the organisation have indicators? How were they identified?
 - Do these indicators, targets and trends appropriately reflect the level and controls of safety?
 - What are the main difficulties or challenges in designing the SPIs?
 - Is there a dashboard of SPIs? Does the senior management have visibility of these indicators, targets and trends? Is there a communication within the organisation? What do the risk scores mean?
 - How is the (overall) safety performance measured? Which tools and processes?
 - Safety culture, occurrences reporting culture and just culture within the organisation or department¹⁶:
 - How is it evaluated? How often? How many occurrences are recorded? (in total, yearly, monthly) Indicators?
 - How are occurrences analysed?
 - Take example(s) – how was the analysis and identification of root causes performed? Follow-up? Information to the reporter? Set-up of indicators to follow the efficiency of the corrective actions?
 - Report of events to the competent authority in ECCAIRS
 - HF policy and implementation – human performance (Planning, fatigue, absenteeism etc.)
 - How do you communicate with your staff? What type of safety information do you promote? Why? How do you collect their potential concerns, loopholes or potential holes in defences that they may

¹³ AMC 1 ORO.GEN.200 (a)(1) and GM2 ORO.GEN.200(a)(1) refer.

¹⁴ AMC 1 ORO.GEN.200(a)(3) refers.

¹⁵ ORO.GEN.200 and its associated AMC/GM refer.

¹⁶ AMC 1 ORO.GEN.200(a)(3) and GM1 ORO.GEN.200(a)(3) refer.

have identified? Have you ever interviewed the organisation's staff to determine if they see gaps in the system?

- Do you have a "just culture" policy in place? How do you promote it?
- Do you think that some safety events may go unreported in your organisation? Why?
- Procedure / manuals and safety assurance system to risk-based environment (RBE)¹⁷
 - Do you have RBE –related procedures?
 - What are the main drivers or influencers or showstoppers for moving toward RBE?
 - How are the risks identified?
 - Are organisation's internal inspectors challenged internally on their risk assessments?
 - Has implementation entailed changes in the structure and mind- set of the organisation / sector?
 - How useful is a RBE as an internal management tool?
 - To what extent has it been possible to adapt the allocation of resources so that they are in line with the risk assessments?
 - How is the effectiveness of the RBE? What is your evaluation?
 - How are interfaces addressed?
 - How are subcontracted activities included in the RBE?
- Management of change(s)^{18 19}
 - How do you implement new safety objectives, new corporate vision, emerging market, major corrective actions? How are these changes led within the organisation?
 - How do you capture emerging risks and define mitigating strategies?
 - Do you have a procedure?
 - Do you systematically review the risks associated with the changes and appropriate procedures or documentation?
 - How do you identify, evaluate, mitigate and record new hazards induced by the changes?
 - Do you classify these changes as "minor" or "major"? According to which criteria? How are the criticality of affected systems and activities assessed?
 - How do you keep the stability of systems and operational environments under control during these changes?
 - How do you take into consideration the past performance of critical systems as an indicator of future performance?
 - How do you plan these changes and lead them?
 - Do you measure the resistance to change?
 - How do you communicate about these changes?
 - Do you have examples?
 - Have new hazards inadvertently been introduced?
 - Have you monitored these management changes through SPIs?

¹⁷ ORO.GEN.200 and its associated AMC refer.

¹⁸ AMC1 ORO.GEN.200(a)(3) refers.

¹⁹ For ATM/ANS, the following **draft** documents are available:

- <http://easa.europa.eu/system/files/dfu/Assessment%20of%20changes%20to%20functional%20systems.pdf> –AMC/GM on assessment of changes to the functional system
- <https://easa.europa.eu/document-library/opinions/opinion-032014> - **opinion** on the ATM/ANS rule, which addresses the changes (i.e. general changes and changes to the functional system)

- Have you recorded any impact on the existing SPIs over time (feedback or experience)?
 - How would you score these management changes? Why?
 - How were deviations controlled, if any?
 - Have the processes and procedures been updated?
- Have you experienced any crisis or contingency situations? How did you manage the continuity of operations and the return to normal operations?
- Oversight cycle (planning), fees and charges, enforcement actions²⁰
 - How to you assess the overall safety performance of the organisation?
 - (at regulated entity level) Would you consider an extension or decrease of the 2 year period? What are the criteria?
 - (at NAA level) Would you consider oversight fees and charges based on a RBE? What are the criteria?
 - (at NAA level) Do you need to revise your “enforcement action” model?

5.3 Attitude during the conduct of risk-based audits

Very few papers or guidance do exist on the attitude needed for the conduct of risk-based audit.

The items listed below aim at providing some basic ideas on how to behave during a risk-based audit.

Source: OECD – “Risk and regulatory policy – improving the governance of risks”

- Be prepared - It is worth it – “if you fail to plan, plan to fail”
 - Take the risks but mitigate your approach so that you don’t crash;
 - The more prepared you are, the more you can feed the discussion, compare data, negotiate, learn from each other...
 - Define and stick to the objective(s) of your audit;
 - Be sure your statistics support your argument(s) very thoroughly;
 - Be in a position to justify why you focus your RBO on that particular item;
 - Think of how bridging the SMS of the audited organisation with the SSP or management system
 - Ask yourself how would you react against “high risk” items that are not properly addressed or would you take any action against risks classified as “low” by the organisation that appear to be “high”?
 - Be flexible and open-minded, ready to listen and think outside of the box – collect evidence by asking, observing, comparing...
- Inform the organisation that “this is a new approach”:
 - (At high-level management) Plan a kick-off meeting:
 - get the organisation ready for that new approach;
 - set up an audit programme with timelines;
 - According to the “Plan, Do, Check, Act” conceptual model, ask for the details of the safety assurance system (or management system), including;
 - Safety objectives;
 - Training;
 - Qualification;
 - Nomination and resources (who does what);
 - Planning;
 - Risk picture and measurement tools;

²⁰ ARO.GEN.200 and 201 as well as its associated AMC/GM refer.

- Management of changes;
 - Feedback and comparison with the objectives.
- (At local-level management) Ask for the organization's procedures or documentation relevant to the scope of your audit ahead of the audit itself.
- Start with risks and not with rules:
 - RBO differs with the traditional approach to "compliance to the rules" because the focus is on the "risk(s)".
- Speak with the right people at the right time:
 - Start at the level of the Accountable Manager or Safety Officer – meet the managers:
 - Assess / raise their willingness to move towards RBE;
 - Do they have an SMS implementation phase process? What is its status? What is the progress made?
 - Agree with an audit program.
 - Proceed when and where they are ready per sectors and across sectors.
 - Start with a defined domain, a specific issue, a hazard, an incident report, even with an external accident investigation report...
 - Could this event happen in your organisation?
 - How do you mitigate these risks in your own organisation?
 - Do you measure the efficiency of the (safety) barriers?
 - Expand the scope of audit once everyone has gained experience.
 - Encourage frankness, openness, occurrences reporting culture, progress;
 - Watch your communication skills at every level and every time, including your body language;
 - Ensure that the organisation has sufficient resources to implement the approach.
- Designing and implementing a risk-based environment will take time:
 - Be patient – "Don't expect it to be right first time" -this is a learning experience for all:
 - Some steps are quite long to implement such as collection of data, sufficient volume of data for analysis, identification of the root causes, controls and measurement, occurrences reporting culture, just culture...
 - Often built in the "lab", a risk-based framework needs continuous refinement and adjustment when put into practice and is dynamic by definition before being "realistic" and "target-efficient";
 - Don't expect spectacular progress in a short time.
 - Plan several audits (from "light" to "deep") to measure and encourage progress (identification of hazard, risk assessment, root cause analysis, set up of SPIs and targets; tolerability level, development of procedures etc.):
 - Digging deeper to better identify the root cause(s) and measure the efficiency of barriers is a long-term process, needing continuous refinement.
 - Re-in force communication, exchange and trust.
- Demonstrate a co-operative approach without impairing your independence and ability to question and challenge – consider the relationship as a "partnership" but remain on the independent side:
 - Learn from others, but don't just adopt someone else's model. Observe and be assertive;
 - Be positive- this is not because something goes wrong that the whole system goes wrong;
 - Surprises are generally not very well received by the auditees and upset difficult people.

- Don't raise findings at the beginning until the system reaches a certain level of maturity or until both parties reach a certain level of common understanding – build confidence and trust with the auditees:
 - Turn findings and evidences into system improvements;
 - Focus your report on the current situation and recommendations;
 - Focus more on the “trends” rather than on data or absolute figures.
- Don't underestimate the organizational challenges or constraints that the management of change can pose as well as the change of mindset:
 - It may take a considerable amount of time for section managers and senior management to understand the implications and limitations of a risk-based approach;
 - Think beyond the risk assessment of how the organisation will respond.
- Think in terms of achievability and appropriateness:
 - Adapt the approach to the type, size and volume of activities of the organisation;
 - Make sure it can work for the organisation and the state;
 - “Risk assessment” is only a tool and is inherently judgmental; it cannot be purely objective and quantitative even though many expect it to be.
- What lessons, if any, would you offer for the next RBO audit or for your fellow-inspectors boarding the RBO journey?

5.4 Accountabilities and enforcement²¹

Our traditional enforcement systems are all based on compliance. However, risks still exist even in the most compliant system; moreover a system can be compliant but poorly performs.

None of the interviewed States mentioned the need to adjust their established enforcement policy to RBO, likely due to the fact we are at the early stage of the RBO implementation. As earlier mentioned in this document, the UK CAA indicated that establishing a common understanding of a risk-based environment takes a minimum of three years. In addition, a pre-requisite to successful RBO execution is the maturity of a (safety) management system at both organisational and state level. Any “hard” attitude - supported or not by a legal penalty framework - should be avoided in the short term: a proportionate and long-term blaming scenario is wiser.

Some organisations may not want to move to a full or partial PBE for good reasons such as “absence of data”, “low volume” of activities or limited resources. Some organisations may also wish to continue working in a “prescriptive” environment.

However, irrespective of the size, complexity or volume of activities, some SMS elements can always be implemented, such as establishment of a positive safety culture or efficient reporting system, investigation of a safety event with the implementation of more efficient safety barriers, coordination with the State and its SSP objectives per sector. Indeed no willingness of the organisation to partially or fully implement a management system, when appropriate, should lead to progressive actions by the state.

²¹ The [European approach to PBE](#) in section 4.5 set the scenes. See also ARO.GEN.360.

The first leverage is the oversight cycle, which may remain at 24 months or can be lowered in case of safety concern(s) in accordance with ARO.GEN.305. The fees and charges of the state may be adapted to reflect the level of oversight, in particular in case of reinforced oversight²².

[NPA 2015-03 \(now Opinion 07/2016\)](#) in the field of DOA proposes a lighter oversight system and the granting of more privileges when the safety performance and the risk management of the organisation has reached a certain level of maturity and satisfaction

Conversely, the granting of “privileges” (e.g. approval of minor changes, “examination” privileges) can be lowered to the minimum or even cancelled.

A management system is primarily intended to give more accountability and responsibility to regulated entities to manage their risks. Another leverage could be the request of additional staff training or the need to involve more dedicated staff for the management system. Finally, disciplinary actions such as the change of managers or even the suspension of the accountable manager can be envisaged before the potential recourse to financial fines.

Ultimately, temporary suspension or permanent revocation of the certificate may be considered in the following cases:

- (i) gross negligence
- (ii) demonstrated deliberate unwillingness to act in case of evident safety concerns or significant decrease of the overall safety performance of the organisation
- (iii) continuously inadequate management system

To conclude, adapting the national enforcement provisions to the oversight policy may be legally necessary as the RBO offers new means for the assessment of the organisation performance beyond compliance; however, any use of such should be exercised with care and be progressive over time because maturity, common understanding and mutual trust might be confronted, in particular in the early days of implementation. These potential enforcement measures should be dissuasive enough to encourage the appropriate corrective actions to be identified and taken as early as possible to prevent unwanted events.

²² Some national systems have provisions for higher oversight fees when a safety concern is not solved in due time

6. Experiences – success stories

RBO does not necessarily imply less oversight. It does not mean that the focus is on the poorest performers, nor that the oversight cycles are extended systematically to all organisations. It just allows to identify safety performance or trends, to adapt the oversight cycles or to implement targeted actions. It also helps to capture loopholes where “traditional” oversight fails or measures risks for cross-domain activities.

Regulators should carefully govern the use of data to match the scope and the nature of their role, tailoring their data feeds according to the size, maturity and complexity of the aviation system they regulate. It is unlikely that a small aviation authority would have the same data volume, granularity, resource, capacity or IT system sophistication as a large one.

Breaking the routine and bringing a new look at how aviation operates allows oversight to be delivered in a consistent and proportionate way. Here are a few success stories during the implementation of RBO.

6.1 RBO in practice by Switzerland

Issue 1: SAMEDAN airport



Review of incident/accident data identifies latent hazards to business jet type operations.

Measures taken:

- Impose new MET restrictions
- Mandatory pilot briefings
- Increased surveillance

Result:

Significant decrease in number of high risk bearing incident reports.

Issue 2: Loss of Control Inflight (LOC-I)

Review of Occurrence Reports identifies unacceptable number of flight control anomalies on a specific fleet.

Root Cause: de-icing procedures.

Measures taken:

- Additional training of ground service staff
- Maintenance procedures inspected / corrected
- Surveillance on OPR awareness

Result:

Significant decrease in number of flight control anomalies.

6.2 Success stories from UK-CAA

6.2.1 At the level of the Competent Authority

Note: the UK-CAA often uses terms “performance-based oversight” (PBO) or “performance-based rules” (PBR) to refer to what in this document is called RBO. Within the context of this section, the terms PBO, PBR and RBO can be considered to be identical.

"Delivery of PBO needed to be managed [and have a properly structured/designed organisation in order to deliver effective PBR]. This has been achieved by taking a 2 year phased approach with clear anticipated outcomes. Also, by looking at risk in three layers (entity-sector-total) we have been able to build up our knowledge/assessment in a sustainable graduated manner with the CAA remaining focused on the desired multi-layered strategic outcome. A suitable internal management system has become a recognised essential requirement to the CAA being able to identify the safety benefits associated with PBR. Effective and timely stakeholder management is essential and the establishment of the PBR Internal Group (PBRIG) adopting innovative working methods provides a platform to deliver successful PBR across the UK aviation industry.

In respect of the UK CAA's transformation to a PBO focused regulator, our experience so far indicates that the transition to PBO is a lengthy but worthwhile journey given the change, the investment and the commitment required by the business. Hence, we expect that our methods and culture will improve as we move forwards."

Recommendation 6:

RBO should be progressively deployed and the extension of RBO to additional domains should be consistent and appropriate. Initial introduction of RBO could be facilitated by a dedicated team of “champions”.

6.2.2 From the CAA blog - a personal view on the front line

“For a disparate group of helicopter AOC entities, I could write a few lines .../... on my experience of the PBO process thus far...

I experienced the inevitable feeling of scepticism, swiftly followed in my case by the obligatory shrug of resignation (or was it indifference?) and finally my normal ‘Ok, let’s give it a go and see how we get on with it, then’ approach...

Well, the short answer is (drum roll...) – it works for me.



After four internal meetings, three here at Gatwick and one at the Manchester Regional Office, discussing in detail the views and risk picture for four very different entities and with lots of help and guidance, where needed, from the Business Change Managers of the ESP team (my grateful thanks to all), I have been very impressed with how this joined-up, big picture approach is working out.

For example - no names and no pack-drill of course - I have an operator who is not unsafe nor non-compliant and who generally gets a clean bill-of-health following the annual audit, but I still do not have the feeling of comfort that the safety performance of the entire operation isn't balanced on a knife-edge of good fortune - or worse, just plain old luck.

So to have the opportunity to sit down in a room with assigned airworthiness surveyor and licensing standards officer for this operator and to discover that they have the same impression from their own perspective, to be able to quantify the risks and to agree a joint strategy to address the issues and then to take that strategy forward to a meeting with the Accountable Manager and to achieve the results we were looking for was, I believe, something of a revelation to all concerned – including the Operator!

Just one real-life example – the other meetings have been less dramatic, but equally enlightening – and we've had some good laughs to boot!

Am I just following orders and grudgingly accepting the new way of working or is there actually something in this PBO thing?

Well, we're breaking down the walls of the silos as planned and sharing (and caring) and collaborating with our colleagues to address the Total Aviation System in line with our Target Operating Model, just as we have been told we should – BUT - I, for one, am better informed about 'my' operators and have a stronger (working!) relationship with my colleagues in other departments; our oversight is stronger and more focussed as a result and in my experience, at least, the Operators are supportive of this joined-up approach to our relationship with them – who would have thought it?

So that's it - for me, as the assigned inspector to a number of small/medium size helicopter AOC holders, the PBO process is a good thing, the team are helping me get to grips with it and they are acting on my feedback to smooth out the inevitable wrinkles and glitches – what's not to like, as they say?"

Recommendation 9:

Initial and continuous training should be given to inspectors implementing RBO, to cover:

- development of proper culture when interacting with industry
- use of expert judgment, especially when safety performance and "gut feeling" are blended
- use of RBO-specific tools available at the competent authority.

Support and coaching should be available during the initial phase of RBO deployment.

6.3 Success story from Ireland (IAA)

“We recently invited the post holders of the six main AOC holders to a safety review presentation by IAA. This presentation provided a detailed analysis of accidents and serious incidents involving Irish AOC holders over the past 7 years and provided an overview of the State Safety Plan for Ireland focusing on RBO and sharing of SMS/FDM data.

The meeting was attended by 29 industry personnel (i.e. all available post holders plus two Accountable Managers) and the discussions were quite open, convivial and informative.

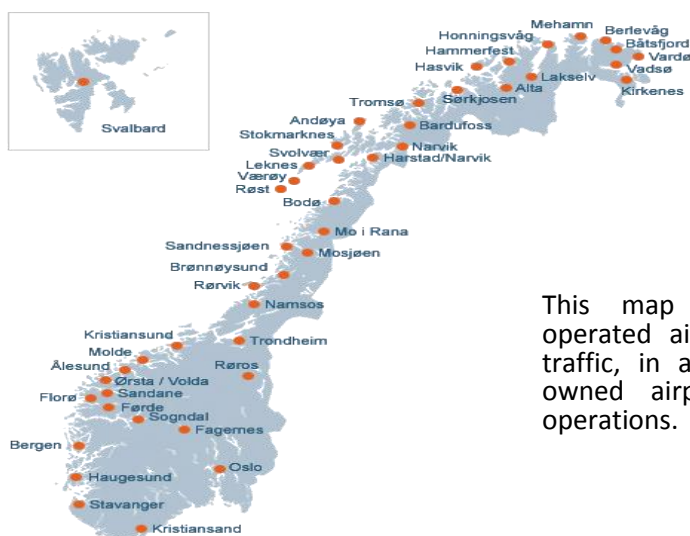
At this time we see good benefit in the education of both regulator and industry on the RBO process. Over the past few years we have seen marked improvement in our ability to communicate with the regulated entities on the RBO process in general and in particular in the communication of the results of the risk profiles with them (particularly in the air operations domain).

We feel that we can collaborate a lot more with our industry (in some domains) on the identification of key risks (e.g. via SMS/FDM data) and agreement on safety targets.

Internally we are beginning to see a growing awareness in many domains of the concept of RBO. Inspectors are beginning to understand the need to focus their oversight efforts on key safety risks and prioritise follow-up of non-compliance items with higher risk to aviation safety.”

6.4 An approach scaled to one specific sector – helicopter safety in Norway

Norway is a relatively small country with a population of only 5 million, having a total of 119 airports and airfields and some 50 approved heliports on and offshore, located all over the mainland, South Pole and Spitsbergen in the north. The coastline is so jagged and the geography so unfit for a developed road network that aviation is the most used and important way of travel. This was made clear during the ash crises in 2010 when the airspace had to be closed. The third busiest air route in Europe is also the routing between Oslo and Bergen.



This map shows the government operated airports running commercial traffic, in addition there is 5 private owned airports running commercial operations.

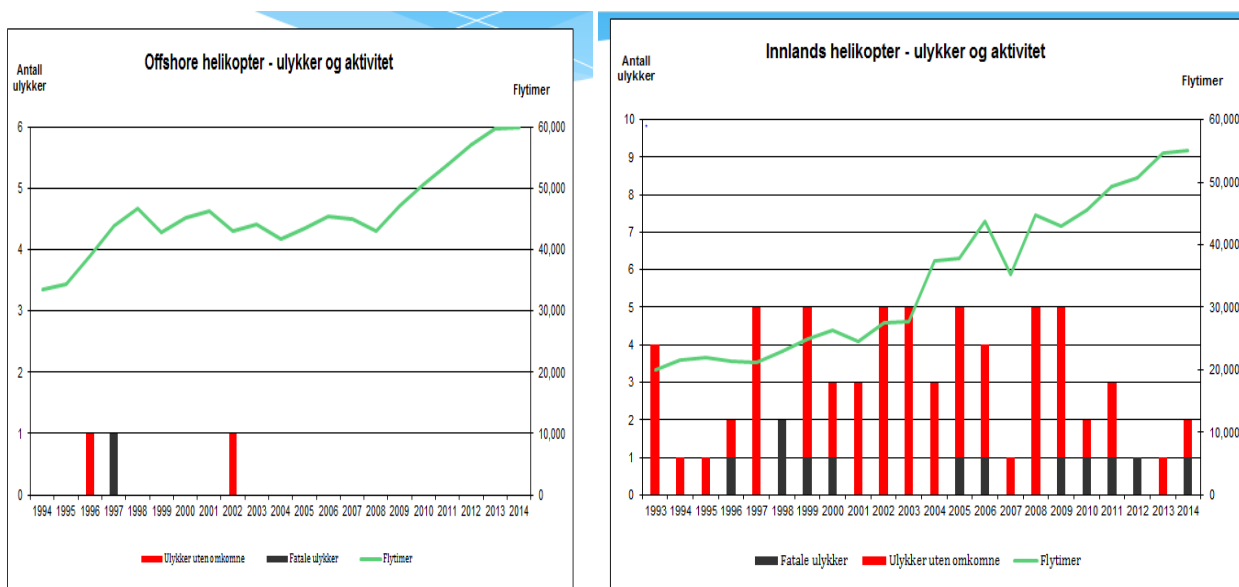
During period “1994/2003”, statistics showed:

	Offshore operations	Inland operations
No. accidents	3 including one fatal	31 accidents, 5 fatal
Flight hours produced	420.000	240.000
Accident rate:	0,72	12,9
Fatalities per million hours flown with pax	1,8	

By 2000, the Norwegian Government decided to target “no accident” resulting in fatalities or seriously injuries in commercial aviation and thus formed two Safety Committees in Helicopter Operations:

- the Safety Committee Offshore, chaired by the CAA, involving all operators, customers, ATM/ANS providers and unions and financially supported by all stakeholders;
- the Safety Committee Inland, financially supported by the CAA and working with the AOC operators.

In order to improve safety, the government in full cooperation and coordination with their stakeholders launched a package of actions, including studies, analysing root causes of accidents or serious incidents, working findings and recommendations, prioritizing actions, targeting and monitoring new objectives, re-adjusting their objectives based on new events, financing new projects with other NAAs (i.e. UK-CAA) such as GPS-guided offshore approaches, drafting better rules with EASA etc.



The outcome showed a significant improvement for offshore operations (no accidents or fatalities for period 2004-2014 with the same volume of activities – no fatal accidents for the last 17 years) although the FH produced have more than doubled between 1994 /2014.

More efforts was needed to be pursued for the inland operations.

Further root cause analysis showed that:

- The respect for rules and regulations is in general undermined;

- Missing understanding of the effect and importance of safety work amongst operators, pilots and users;
- Weak reporting culture related to incidents and serious incidents;
- Experience of the crew is limited as most of the pilots start their career in this segment;
- Bad attitudes and inadequate self-image of the crew;
- Other considerations" (profits) at the expense of safety;
- Rules are sometimes neglected ... for economic reasons (both commercial and private), in order to please the customer (customer pressure);
- Risk and adrenaline kick has become an industry feature.

A clear mandate was given to the Inland committee with focus actions and main priorities such as intensive safety promotion, creation of informative and lively websites (www.helikoptersikkerhet.no), further studies with other CAAs and implementation of recommendations, changes to the rules (simplification and adaptation), review of the educational and training requirements, awareness and safety culture raising, increased culture of reporting, exchange of experience between the operators or with other international working groups (e.g. EHEST, IHST). In addition, commitment from all stakeholders was continuously sought.

The results have showed significant improvement since November 2009, considering that the FH produced have doubled since 1994 and significantly increased during the last 10 years.

Finally the work performed was transferred in a workable SSP / SMS, including:

- A risk-based oversight system (guidelines for prioritization of oversight activities) on top of the compliance-based oversight;
- The establishment of a system analyzing the root causes (e.g. competence, procedures, attitude, resources, HF error etc.);
- Objectives and lively indicators and coordinated with the EPAS (e.g. 33 SPIs were established by Nov 2014);
- Potential extension to other aviation segment (broader picture) such as identification of critical elements, pre-defined root causes and key risk elements, classification of severity.

Following that implementation of the SMS/SSP work with the benefit of the inland safety committee, the accident rate fell from 1 per 8000 hours to 1 per 40000 hours for inland helicopter operations.

6.5 Experience from Sweden

During the interview the representatives from Sweden reported that implementation of RBO, in terms of differentiated, tailored oversight took some time to be implemented, but it delivered significant benefits:

- the better targeted oversight allowed an optimisation of "resources" usage, with reduction in the overall number of hours spent on performing oversight of approved organisations, with more time dedicated to the less-compliant ones and less audits performed at the better-compliant ones. The key element is the differentiated audit frequency, varying from 1 to 4 years, depending on the performance;
- The output of the risk profile could be used :
 - for the purpose of planning oversight, as the risk perspective becomes an input to the safety promotion process for more targeted actions and deliverable, such as flyers, workshops; and

- shared information with undertakings, enabling priority in the authority management, internal training activities (within the authority), interpretation or update of existing rules, initiation of new rules.

Recommendation 2:

For each organisation, RBO parameters should be continuously monitored at an appropriate frequency in order to identify any trend and to review the oversight programme, its cycle and the safety objectives.
The competent authority should continuously follow-up and improve the overall RBO system.

Appendices



I Risk profiling – Some examples

I - 1 The Austrian example of risk profiling

For Austrocontrol (Austria) the objectives of the use of a risk profile are:

- Identify potential operational hazards;
- Optimise inspection intervals and depth of the inspection;
- Optimise the resources efficiency; and
- Optimise oversight cost.

The risk profile of an AOC Holder takes 13 parameters into consideration: approximately half of these parameters are assessed during the respective audit / inspection, the remainder are rated automatically based on information recorded in the Austro Control's electronic audit tool database. As a result a dynamic risk profile is created.

The risk profile is then transformed into a rating system using a scale of 0 to 3, with 0 representing a very low risk and 3 a high risk. This approach requires:

- (i) careful selection of personnel,
- (ii) qualitative evidence-based evaluation by the Flight Operations Inspector(s) and
- (iii) Interaction with the AOC holder. Individual parameters are "weighted" according to the Authority assessment taking into account potential risks.
- (iv) The responsibility for completion of the risk profile rests with the responsible Flight Operations Inspector, who considers all aspects in association with detected findings by the Authority, e.g.: Level of findings, Operator's handling of Findings, Interaction FOI – AOC holder.

The considered risk parameters are:

- 1) Safety, risk and quality management system;
- 2) Fleet size;
- 3) Operation of different aircraft types;
- 4) Special operational requirements - Type(s) of operation;
- 5) Facilities and equipment;
- 6) Management personnel - management structure;
- 7) Staff turnover esp. in regard to post holders;
- 8) Part-time / fulltime employment of post holders;
- 9) Training;
- 10) Duty and rest time management;
- 11) Operators attitude to the authority (e.g. planning and agreements of audits; resolution of findings);
- 12) Company experience; and
- 13) Change in company organisation, scope or size.


The calculation of the risk factor is based on these parameters. Each parameter is rated with a maximum of 3 points (0=very low risk, 3=high risk). Consequently the maximum score is 39 (equals 100%). The actual achieved points must be deducted from the maximum possible score (39 points) resulting in the risk factor in percent.

The resulting assessment is described in the following table:

Risk calculation %	Conditions	Audit/inspection interval	Risk assessment
>75%	No level 2 or level 3 entries	Risk is very low, Audit/Inspection interval can therefore be 24 months	Very low
65-75%	No level 3 entries	Risk is low. Main interval for audits inspections is set to 24 months, however every 12 months targeted audits are performed on the risk areas underlining risk parameters ranked as level 2	Low
55-65%	Level 2 and level 3 entries	interval for audits inspections is set to 12 months	Medium
<50%	Level 2 and level 3 entries	interval for audits inspections is set to 6 months, however the higher risk parameters are given more attention during the audit interval	High

The tool is creating a report providing information on risk level, trend with regard to the last inspection or change of some of the operator's basic data and recommendation in regard to an inspection interval.

Risiko Analyse



Unternehmen

ABCD Flug

AOC Nummer

A-12345

Date

03.01.2012

Risiko Beurteilung	%	Trend
hoch	49%	↑

Empfohlener Audit / Inspektion Intervall

Das Audit / Inspektion Intervall wird mit 6 Monaten festgelegt, jedoch werden die Risikofaktoren verstärkt innerhalb der Auditperiode observiert

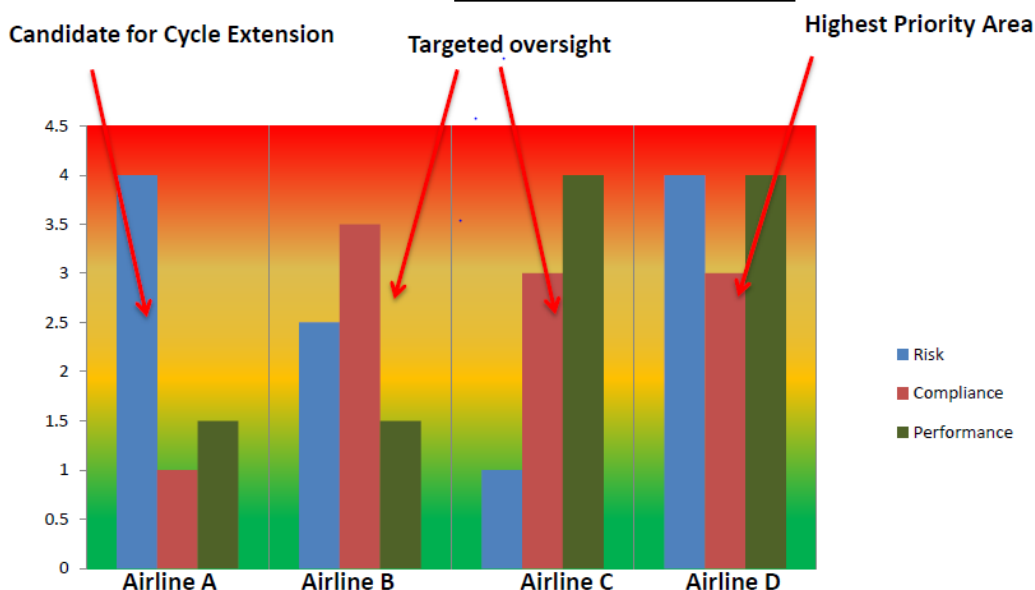
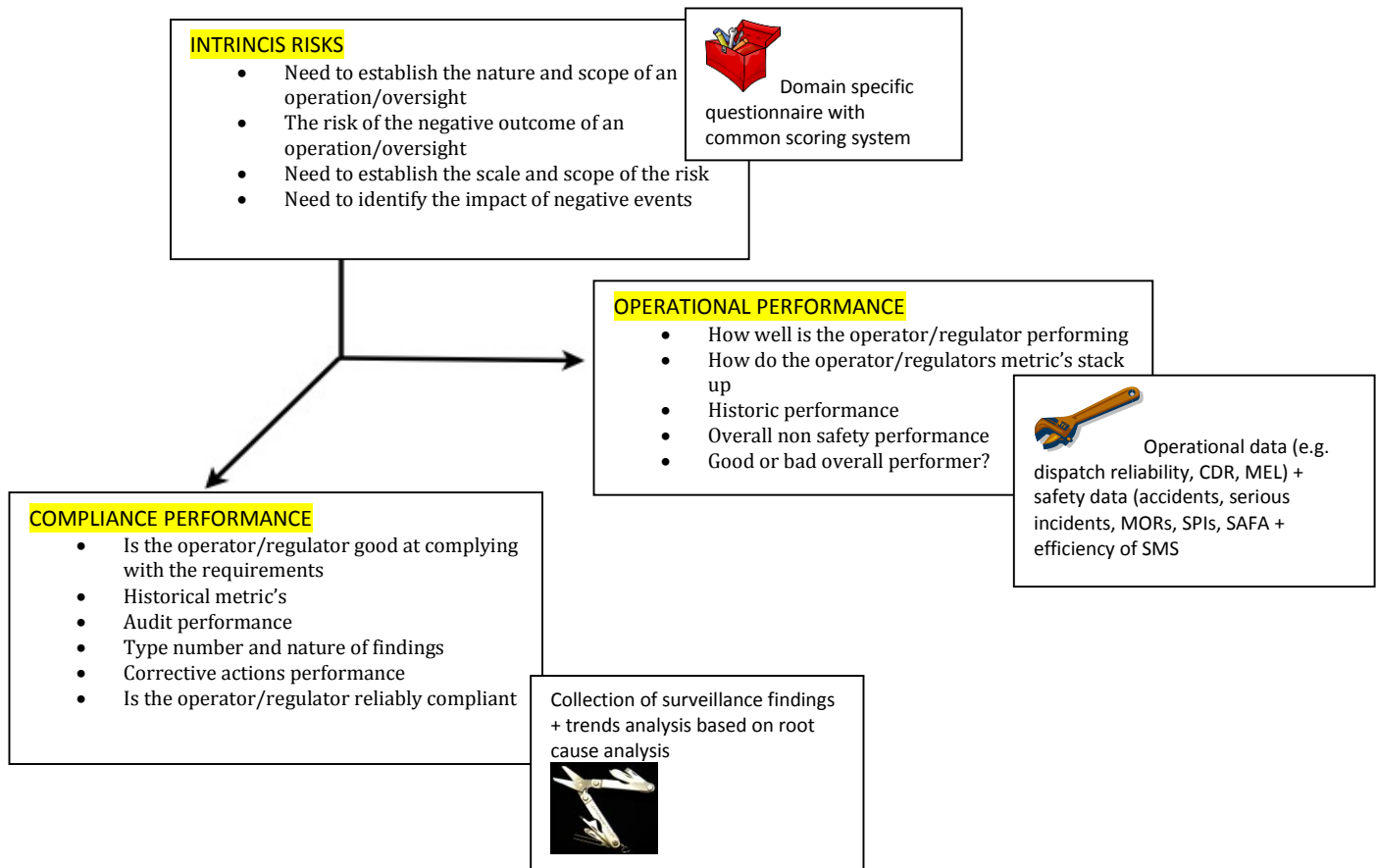
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Example of output

I - 2 The Irish method – another simple model

The Irish competent authorities see RBO as a way to manage the risk with limited resources, establish priorities, direct the resources, making the best possible use and focus on the desired outcomes in order to maintain and improve safety levels.

The overall risk profile relies on a three axis model and the use of bespoke tools for each axis, both at the level of the regulated organisation and the competent authority:



I - 3 The Spanish risk profile - the integration of different CAA components

AESA (Spain) uses a more comprehensive approach to define the risk profile of a regulated entity. So far only AOC holders in Commercial Air Transport (CAT) and Aerial-Work operators are being analysed.

The following process is based on the following elements:

- Establish numerical indicators to identify and measure parameters, values and safety-related attitudes, based on the results of the monitoring activity CAT operators;
- Get a regular picture of the level of safety in the activity of each operator;
- Monitor the evolution of certain parameters and their evolution;
- Determine the trend of the sector;
- Identify areas and operators where appropriate approach to monitoring activity, could drive an improvement of operational safety;
- Adapt the Annual Inspection Plan to the results of this analysis; and
- Present the analysis results in graphical, easy and intuitive way.

The sources of information used are derived from:

- Results of inspection and monitoring activities conducted by AESA;
- The operators themselves;
- Air navigation services providers and national airports; and
- The ECCAIRS database (European Coordination Centre for Accident and Incident Reporting Systems).

The information used is:

- List of Operating Licenses for category A (airplanes>10 tons or 20 seats) and category B (airplanes<10 tons or 20 seats ; helicopters) operators;
- Number of flights and carried passengers;
- Data reported in the AOC;
- Aircraft Register;
- Operators' Performances monitoring carried out by the responsible oversight structure;
- Periodic reports on ramp inspections (SANA ,SAFA) and SAFA reports;
- Occurrences reported through the national reporting system;
- Analysis of reported occurrences: severity and reporting;
- Events specific to the operator;
- Economic and financial reports from operators.

The operators are split in three different categories as explained below, due to the different types of aircraft used and because of the different regulations applicable (operation, maintenance types and characteristics of the inspection) that affect the behavior and distribution of dispersion indicator values. This separation also occurs in response to exposure to the risk factor, which is greater, in terms of potential loss of life and property damage in CAT operators with larger aircraft. Category B operator, whose fleet consists of airplanes and helicopters and some of these are used either for CAT or other types of operations are considered, for evaluation purposes, under the predominant activity and classified under two categories:

- Category B-airplanes; or
- Category B-helicopters.

Technical and financial indicators are also used, as follows:

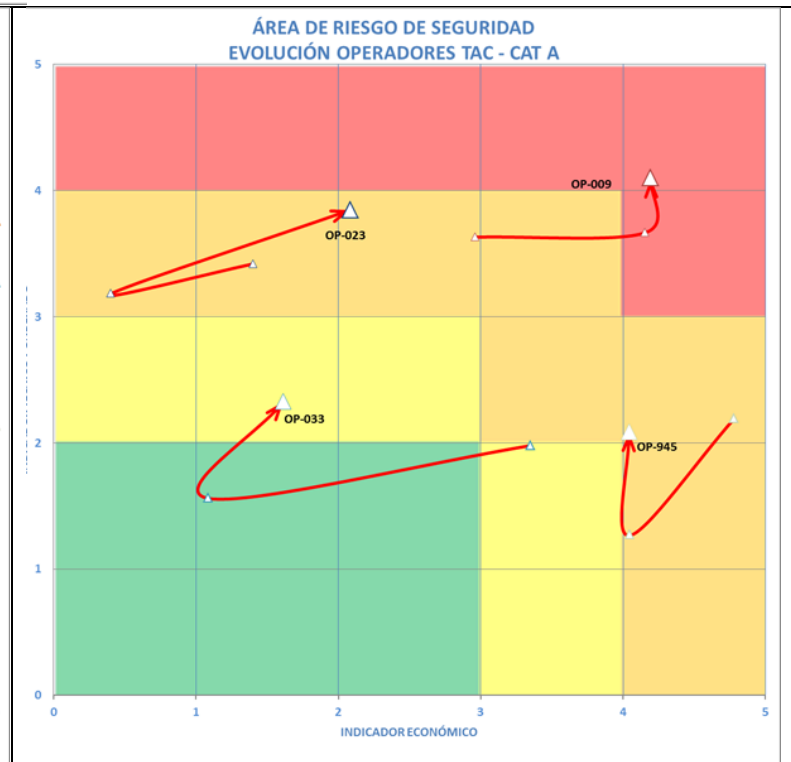
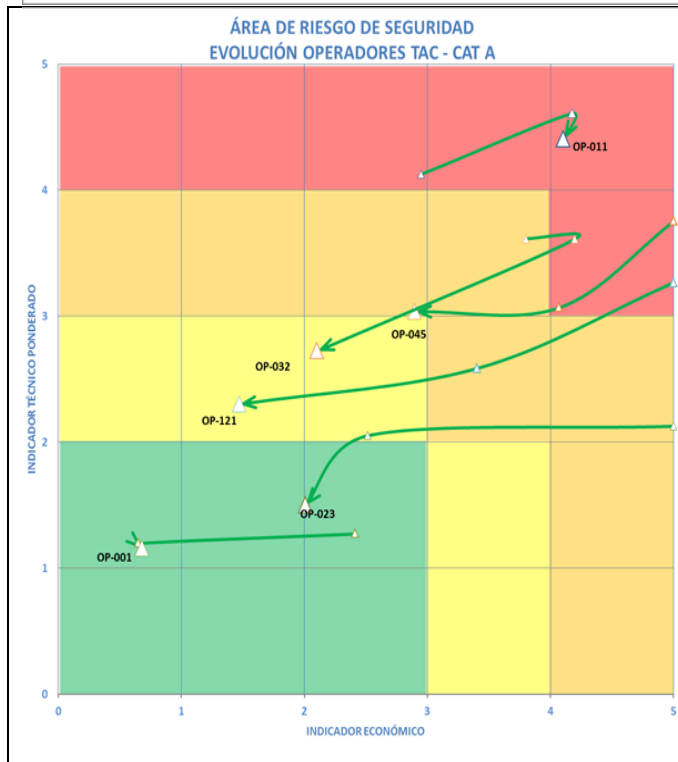
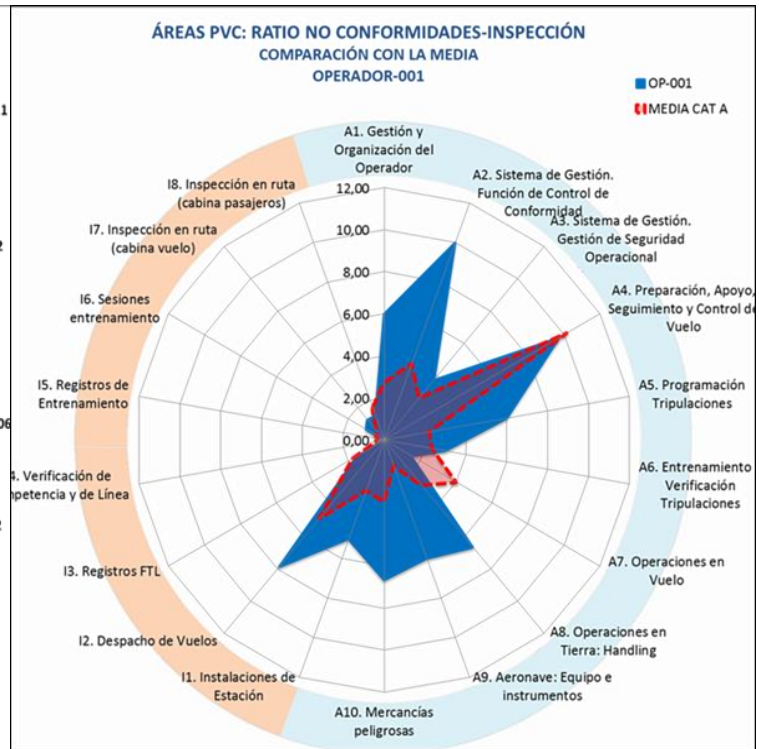
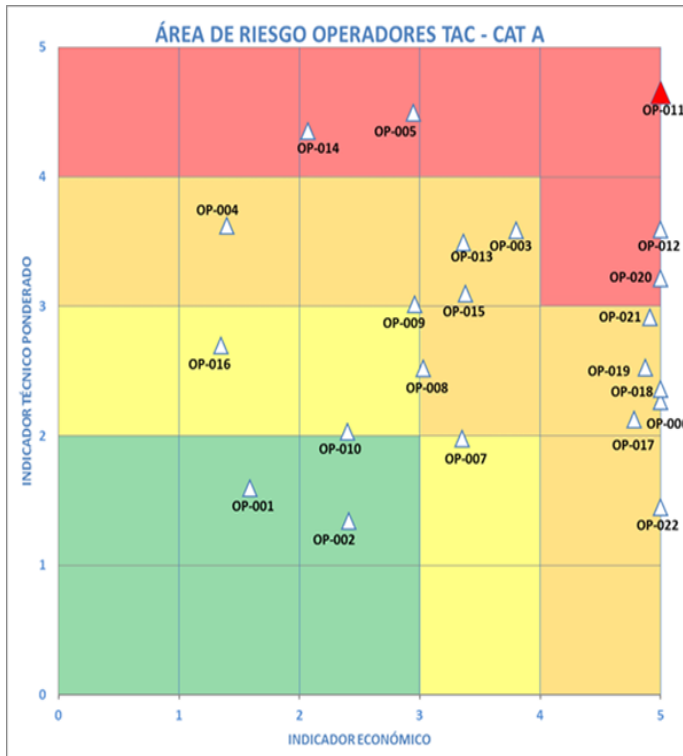


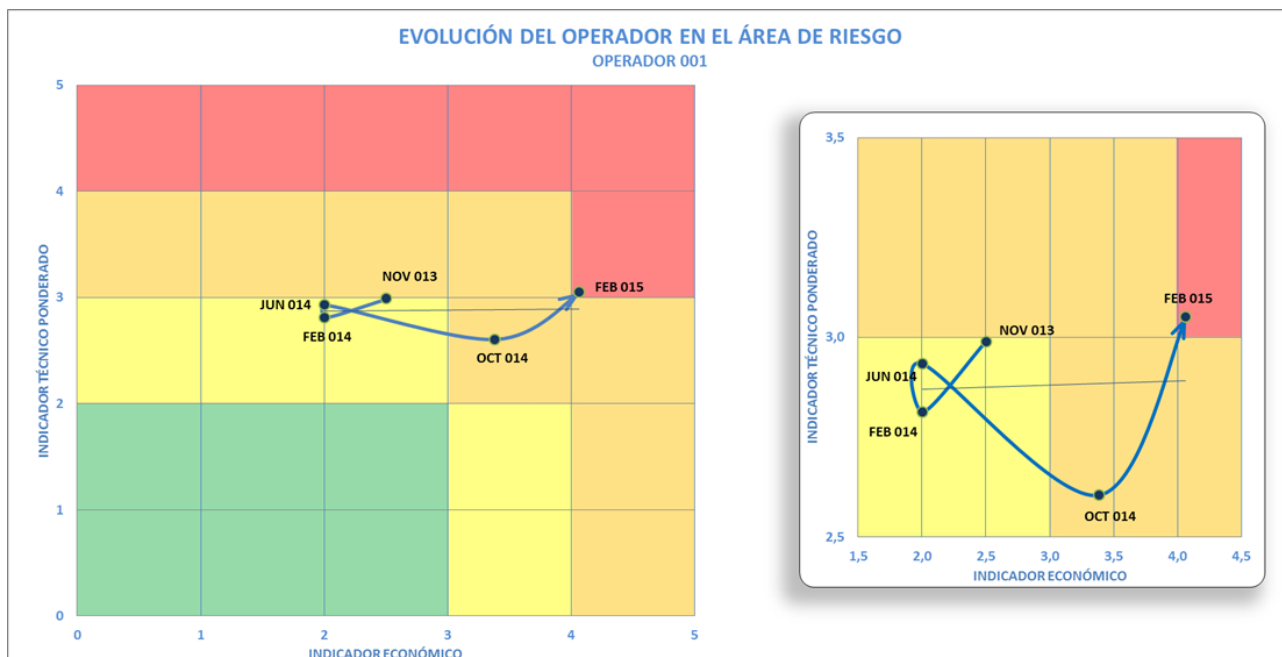
Type	Indicator	Sub-indicator	Risk area
Technical indicators	Airworthiness	Fleet age	Airworthiness Operational safety
		Age of design	Airworthiness Operational safety
		Fleet composition	Airworthiness Operational safety
		Airworthiness monitoring (ACAM)	Airworthiness Operational safety
		CAMO oversight	Continuing airworthiness
		Extension of deferrals (MEL)	Continuing airworthiness
		Extension of Maintenance programmes	Continuing airworthiness
	Operations		AOC Operational safety
	SAFA ramp inspections		Airworthiness Operational safety Crew
	SANA ramp inspections		Airworthiness Operational safety Crew
	Severity of occurrences		Operational safety
	Reporting culture		Operational safety
Financial	Total value of the airline		

All the above indicators are calculated through formulas where the sub-indicators are combined using weighing factors.

The outcome of the analysis is a monitoring and plotting of indicators, including trend analysis.

These indicators are analysed within a safety committee, where all operational functions of AESA are represented, in order to target the oversight activity, within the 24 months audit interval prescribed by the regulation. Some of the outcomes are also shared with the operators in order to let them understand what the driver behind the authorities' oversight is.





The ratios and numbers are only used as informative data. Before any decision, the experts or inspectors, which are part of the Committee, should further evaluate the following:

- Standardization key Issue, when comparing Inspections information;
- Evaluation of worst ranked operators with specific and focused information;
- Any additional concern not visible in the ranking. e.g. complaints, enforcement procedures;
- Results of the Safety Committee-Operators meeting;
- Prioritization of inspections or need for additional inspections;
- Information stemming from other sources e.g. organisational change(s), follow-up of findings, on-going actions.

I - 4 The Swiss risk profile linked with the SSP

FOCA (Switzerland) has defined a simple risk profiling process, which is linked to the hazard identification process in place at State level and supports the State Safety Programme (SSP).

-- QUOTE from the SSP --

3.1.2 Steering of oversight activity on the basis of safety data

Switzerland has for many years been carrying out integral oversight in the civil aviation sector encompassing airports and airfields, air traffic control, aviation companies, development companies, manufacturers, maintenance providers, training organisations and all flight personnel (cf. table in Appendix 2). Within the scope of its oversight of Swiss companies, the FOCA carries out audits and inspections to verify compliance with national and international legal provisions and standards. As far as foreign airlines are concerned, which are subject to oversight in their country of origin, the FOCA carries out random inspections of aircraft and flight crews.

The planning of audits and inspections is carried out in accordance with a risk-based approach. In addition to carrying out audits and inspections of all companies, the FOCA focuses on companies or areas in which weak points have been identified. In the FOCA safety management system, the planning of these activities is described in the processes of the safety divisions. Generally speaking, the planning of oversight activities is based on the following criteria:

- *Compliance with the relevant legal provisions;*
- *Prioritisation of safety areas based on the safety risk portfolio;*
- *Need for action according to safety recommendations resulting from investigations by the SAIB;*
- *Safety-related topics specified internally (by divisions / sections) ;*
- *Recommendations of the Safety Risk Management division*
[using the Hazard identification process to collate the The Hazard and Risk Register];
- *Feedback from the SAFA (safety assessment of foreign aircraft) and SASA (safety assessment of Swiss aircraft) random inspection programmes;*
- *International cooperation, e.g. European Strategic Safety Initiative (ESSI) of EASA and its sub-organisations ECAST (European Commercial Aviation Safety Team) and EHEST (European Helicopter Safety Team).*

3.1.4 Oversight on safety management systems

The FOCA safety divisions are responsible for the general oversight on stakeholders. In this connection they also bear responsibility for the assessment and ongoing oversight of their existing or future safety management system. The assessment of stakeholders' safety management systems is carried out as part of audits and inspections based on standardised catalogues of questions. This method permits a qualitative assessment of a safety management system and comparison with the anticipated standard. Within the FOCA, the Safety Risk Management division is responsible for coordinating the further development of safety management systems and making recommendations regarding standardisation.

-- UNQUOTE --

The following goals are:

- To obtain a quantified statement about the performance of the operation;
- Data should be readily available;
- Easy input in the system;
- Various aspects of the operations to be taken into account.

In the flight operational field, oversight activities are planned (oversight cycle) as well as performed (focus on specific topics) using a performance- and risk based approach.

The following two main areas are taken into consideration to steer the oversight activities:

a) Performance of the operators

Area	Activity	Elements considered
Oversight	Audits / Inspections	Implementation of corrective action within due date. Extension requested? Effectiveness of corrective action.
	corrective actions	
Approval	Manual revision / User Approval / Change of Nominated Personnel / Change of Certificate etc.	All supporting documents attached and complete? Contents of the application complete? Completeness of corrective action.
	Any other application	
Reports	ASR / OR (occurrences)	Number of reports, reported by SRM for each organisation (including reports from other sources). Number of aircraft. current week of the year
	SAFA / SASA	
Gut feeling (expert judgment)		No. of inspections No of findings

b) Risk-profile of the operators, where following parameters are presently used to establish a risk-profile:

- Changes in management personnel
- Number of persons holding nominated post holder' posts
- Number of different aircraft types
- Average number of aircraft per type
- Operation of legacy aircraft (orphan types)
- Changes to the operated fleet
- Number of new operations specifications issued
- Financial evaluation
- Number of operational bases
- New operational bases
- Operational bases under special conditions (e.g. outside EU, low infrastructure countries)

Recommendation 1: The oversight planning and determination of oversight cycle for each organisation should take into consideration the risk profile and the assessment of the safety

performance. When the risk profile relies on expert judgment, the decision making should be made by consensus by a team of experts.



I - 5 The Finnish example of risk profiling

Trafi, CAA of Finland, wants to move from a “compliance” to a “safety” authority. Almost all Finnish AOC holders have started implementing SMS.

RBO is seen as a solution offering more efficient working methods and more effective use of resources. The resulting targeted activities are adding values in the communication with regulated entities. Therefore the authority wants to achieve the following objectives:

- Understanding and compliance of the SMS requirements, through cooperation between Authority and Industry and learning from each other. To that extent:
 - o **no** “findings” have been raised during the implementation process; and
 - o guidance material has been developed and made available to regulated organisations.
- A defined set of safety related procedures;
- Practical and functioning system which generates safety benefits;
- An all-embracing way of thinking and a state of mind;
- Facilitates the change to an authority also focused on safety and risk aspects as a complement to an authority checking “compliance”.

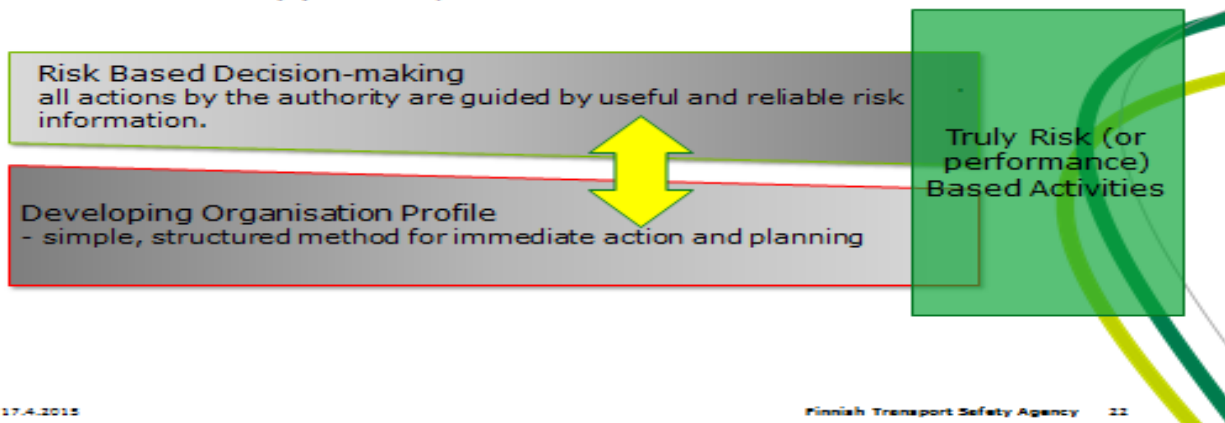
To meet its objectives, Trafi has launched two programmes to support RBO:

- 1) Risk Based Decision-making: a review of what kind of data we get today, try to get better data, with the objective of getting a new kind of data or getting data with a higher quality.
Methods to build the risk pictures need to be defined, as well as the means Trafi has for influencing safety have to be reviewed.
- 2) Development of organisation profile keeping into account that “one size does not fit all” and it must be tailored to fit the needs of each mode of transport. This will allow looking at the big picture, with the support of an easy-to-use IT-tool.

Our Two Programmes



We have launched two parallel programmes aiming at Risk Based Approach;

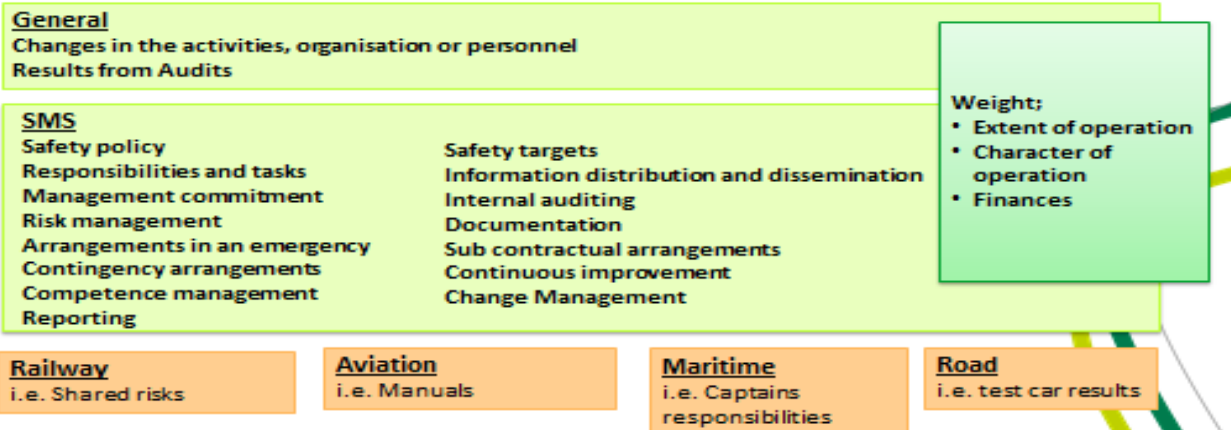


17.4.2015

Finnish Transport Safety Agency 22

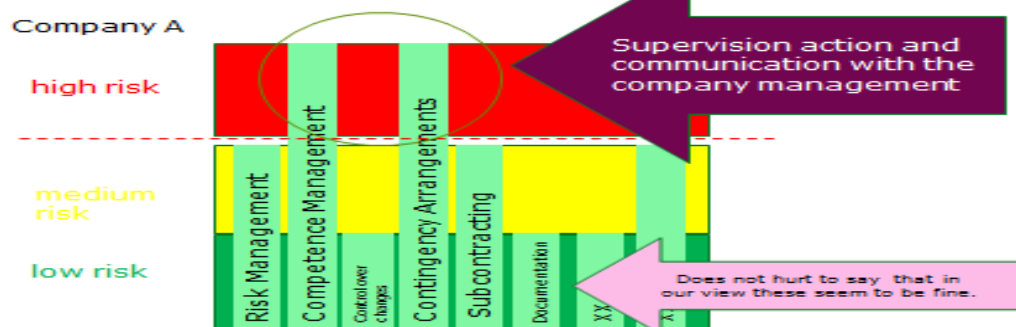


Organisation profile - factors



Finnish Transport Safety Agency

What do we wish to get?



17.4.2015

Finnish Transport Safety Agency 27

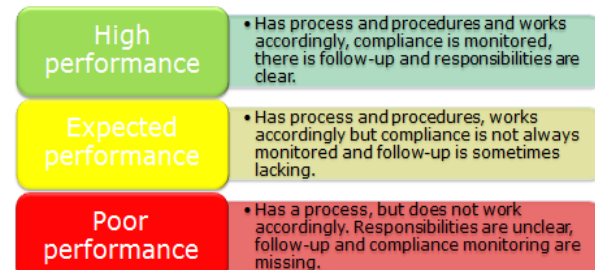
If we know that



Assessing performance



- All items are not equal
- Three descriptive assessment levels for each criteria



- Poor performance indicates a risk might be present
- High performance can indicate maturity and good safety culture

Finnish Transport Safety Agency 9



II Tools supporting RBO

Some of the following tools can be used to support the implementation of RBO by competent authorities. The list presented is not exhaustive or complete and some others are currently under development.

Recommendation 9: Initial and continuous training should be given to inspectors implementing RBO to cover:

Development of proper culture when interacting with industry -.

Use of expert judgement, especially when safety performance and “gut feeling” are blended. Use of RBO-specific tools available at the competent authority.

Support and coaching should be available during the initial phase of RBO deployment...

II - 1 SMICG tools

The Safety Management International Collaboration Group (SMICG) is a worldwide joint cooperation between many regulatory authorities for the purpose of promoting a common understanding of safety management principles and requirements and facilitating their implementation across the international aviation community.

The following documents, that can be adapted for the implementation of a Risk Based Oversight, have been proven of great utility not only for the NAAs but also for the Industry in order to implement a performance-based environment:

- [A Common Approach to Safety Performance Measurement \(SPMA\) Paper](#)
- [A Systems Approach to Measuring Safety Performance – The Regulator Perspective](#)
- [How to Support a Successful SSP and SMS Implementation – Recommendations for Regulators](#)
- [Measuring Safety Performance Guidelines for Service Providers](#)
- [Risk Based Decision Making Principles](#)
- [SM ICG SMS Evaluation Tool](#)
- [SMS for Small Organizations](#)
- [SMS Inspector Competency Guidance](#)

Please note the [SMICG](#) documents are freely available on the Skybrary website, which also proposes [some safety management tools](#), such as [ATM safety culture tool kit and measurement](#).

II - 2 ICAO tools

ICAO is also playing an instrumental role in developing tools needed for the implementation of “safety management”.

The third edition of the Safety Management Manual (Doc 9859) proposes the following:

- An organisation safety culture and risk profile assessment checklist for air operators (Chapter 2, Appendix 1 refers), which can be adapted to other domains;
- An example of safety risk mitigation worksheet (Chapter 2, Appendix 2 refers);
- An illustration of a hazard prioritization procedures (Chapter 2, Appendix 3 refers);
- A list of questions appropriate to a risk-based audit (Chapter 5, Appendix 7 refers);
- some SMS safety performance indicators for use and review (Chapter 5, Appendix 6 refers)



Some of the above documents are available and ready-to-use in editable format through a [SM toolkit](#). The future iterations of the SMM should bring more useful and practical tools. In addition some SSPs and websites offering more resources are also proposed [here](#).

Finally it is worth noting the wealth of safety information to extract from [ICAO SPACE website](#) (ex iSTARS) in order to drive risk-based audits. The ICAO safety intelligence platform automatically goes through gigabytes of data generated each day and related to weather reports, accident notifications, traffic, fleet changes and audit programme findings... to identify its relevance to holistic safety issues. To illustrate, consideration can be given to the following, but not limited to:

- statistics and data on accidents and incidents from ADREP;
- all major airport punctuality on a daily basis;
- scheduled commercial traffic per airports;
- charts and data displaying the route networks and flights between states;
- fleet info per region or state;
- weather statistics (e.g. number of VMC versus IMC days per airport);
- maps surrounding areas of an airport with a terrain index tool;
- approach procedures and PBN implementation;
- level of effective implementation (LEI) per state per domain;
- SSP gap analysis tool;
- safety culture evaluation tool.

When combining these databases with the ones available at national level, it becomes possible to:

- Rank the airports according to a potential risk profile based on the mountainous surroundings (peak and proximity), the volume of traffic as well as peak hours and congestion (commercial, current and expected), the average weather conditions, the bird-strike or bird migration hazard, the availability or the reliability of the navigation equipment, the number and length of runways, the seasonality effect, local wind (shear) or weather effect, volcanic ash hazard etc.;
- Define a governmental strategy regarding the navigation or aerodrome equipment necessary to operate the airports based on the risk profile in order to mitigate the risks as well as the management of the airports (e.g. ground handling activities, airport maintenance; icing de-icing activities);
- Check the adequacy of the navigation equipment or approaches at the airports within the State or for the airspace management or transfer of traffic at the frontiers between states (ATC staffing issues, variation of volume of activities per hour etc. ;
- Identify the CAT operators who frequently fly to the highest profile risk airports and focus the oversight on age, diversity and equipment of the fleet airworthiness status, training and competence assessment of pilots, stable approaches, FDMS and its benefits, MEL and differed items, ground damages, etc.;
- Develop State Emergency Response Plan (ERP) in coordination with the regulated entities.

The above suggestions can be used as a source of useful information in the context of RBO.

III Questionnaire used for the collection of the RBO practices

Note: this questionnaire was used as a basis for the definition of the conceptual model described in section 2.2 and to collect the practices presented in this document.

III - 1 Introduction

As stated in the letter by EASA Executive Director dated 1 July 2014, the purpose of this exercise is to collect and consolidate practices on how to implement RBO to be disseminated under art. 5(3) of Regulation No. 628/2013.

At a later stage the same material could form the basis for the development of Guidance Material, to be published according the EASA Rulemaking Procedure.

As a consequence, the content of the interviews is purely informative and all the answers provided will not be used in the context of Standardisation or of the Continuous Monitoring. The information collected will be kept confidential until the interviewed authority will agree to its dissemination, in full or in part.

Instructions for the interview

The questions below have been formulated to be as generic as possible, the answers can always be adapted to the specific national context and if necessary links to the State Safety Programme (SSP) can be highlighted.

It is expected that, when relevant, the material developed by the Authority (procedures, checklists, etc...) is shared with EASA, in line with the objectives of this exercise. When needed the Agency will translate the material provided into English.

III - 2 Questions on Risk Based Oversight

1. Conceptual model

The Working Group has developed a definition of Risk Based Oversight and a conceptual model to explain the links between the various components that make it possible.

As a first step, we would like to have your views, and possibly, your comments on the following.

1.1. Definitions

OVERSIGHT: the function by means of which a competent authority, ensures that the applicable requirements are met by regulated entities

Keyword: compliance

RISK BASED OVERSIGHT: a way of performing oversight allowing the competent authority to:

- i) prioritise and plan its activities based on compliance, risk profiling and assessment of the safety performance; and
- ii) Verify compliance with a focus on management of operational risks.

RISK PROFILE (of an organisation): the risk profile of an organisation includes:

- the specific nature of the organisation;



- the complexity of its activities;
- the results of past certification and/or oversight;
- the maturity of the (Safety) Management System, including the ability to manage changes; and
- the operational risks.

1.2. Conceptual model

Risk Based Oversight can be seen as the combination of planning and execution phase of oversight.

During planning, the prioritisation of activities takes place on the basis of the information available from the risk profile and from the overall safety performance.

In the execution of oversight, both compliance and management of operational risk have to be verified.

The output of the oversight is considered in the short term planning and quick response, if needed and, in the longer term, for adjusting the risk profile.

To make RBO possible competent inspectors and appropriate tools need to be available.

2. Risk Profile and oversight planning

2.1. Do you make use of risk profile to support your oversight activities?

2.1.1. How is it determined?

2.1.2. Does it apply to individual organisations or to groups of regulated entities?

2.1.3. Which sources of information are used in the determination of the risk profile?

2.1.4. How is the oversight planning cycle and programme determined?

2.1.5. Is the regulated entities' ability to manage changes and the effectiveness of their compliance monitoring taken into consideration?

2.1.6. Do you make use of indicators for compliance and performance for every individual regulated entity?

2.2. What kind of evidence supports your oversight planning, if any?

2.3. How do you identify the safety areas of greater concern or need?

2.4. Have you developed a methodology to periodically review the outcome and the effectiveness of your oversight?

3. Risk Management and assessment of (Safety) Management System

3.1. On top of compliance verification, does your oversight process entail:

3.2. Assessment of safety risk management process and its effectiveness

3.3. Measurement of the safety performance

3.4. Do you have tools available to assess the effectiveness of a (Safety) Management System, safety culture, etc.?

3.5. Are they domain-specific?

3.6. Tools to manage risks:

- 3.7. Are there tools in place to manage risks at State level?
- 3.8. Are there tools in place to manage risks at regulated entity level?
- 3.9. What are the interfaces between these 2 processes?
- 3.10. Are the outcomes of these processes compared?
- 3.11. Have you developed a methodology and/or tools to extend the standard oversight cycle?
- 3.12. What data from other sources are collected and then used to determine the RBO and how?
- 3.13. Have you developed a methodology and/or tools to analyse findings for their safety significance and to consider them in doing RBO?
- 3.14. Is also repetitiveness of findings and timeliness in their closure considered?

4. Cooperation with other NAAs, data collection and sharing

- 4.1. How do you take into account the information stemming from mandatory and voluntary occurrence reports in planning your oversight?
- 4.2. Have you developed a methodology and/or tools to share information?
- 4.3. Do you share information with other Competent Authorities?
- 4.4. Are there any agreements with regional or international organisations or Industry representative bodies or countries to share data?

5. Enablers and tools

- 5.1. Have you developed a strategy to implement RBO?
- 5.2. Have you developed training for your inspectors to support implementation of RBO?
- 5.3. On which topics?
- 5.4. Have you developed a methodology and/or tools to plan your resources for performing RBO?
- 5.5. Which elements are taken into account for that?
- 5.6. Was there a need to adapt your enforcement mechanisms following introduction of RBO?
- 5.7. To what extent?

6. Your experience

- 6.1. Did you experience any benefit from RBO implementation?
- 6.2. Do you have any success stories to share?



IV Guidelines for Risk Based Oversight by NSAs

**NSA COORDINATION PLATFORM
SAFETY OVERSIGHT AND ONGOING COMPLIANCE WORKING
GROUP**

**Guidelines
for
Risk Based Oversight by NSAs**

**Version 1.0
Edition Date: 11.11.2015**

DOCUMENT SUMMARY

Abstract: This document contains the result of the discussions at different NCPSO WG meetings of the practices for risk based oversight used by some of the European NSAs.

The objective of these guidelines is to provide a common understanding of risk based oversight criteria and processes in order to help National Supervisory Authorities (NSAs) to adopt a Risk Based Oversight approach when conducting their oversight tasks.

Originator: NCP WG Safety Oversight

Addressed to: NSAs

Title : NCPSO Guidelines for Risk Based Oversight by NSAs

Reference: NCP WG SO - Guidelines for Risk Based Oversight by NSAs.doc

This reference is the filename.

Version: 1.0

Date: 11.11.2015

Status: ☐ Draft
☒ Released

Classification: ☐ Public
☒ NCP limited
☐ Addressees limited

Explanation version numbers:

V 0.x: draft issue

V 1.0: adopted issue (formal version)

V y.x: draft revised issue

V z.0: adopted revised issue (formal version)

DOCUMENT CHANGE RECORD

Version	Date	Reason for changes	Author of changes
0.1	xx.10.2015	1st draft for discussion during NCP WG#16	Andi Cristian SAVA – Chairman
0.2	10.10.2015	Comments from NSAs	SE NSA and IS NSA
1.0	11.11.2015	Comments during NCPSO#16 meeting and approval	NCPSO WG members

Disclaimer: These guidelines have been produced by the NSA Coordination Platform. The views expressed herein do not necessarily reflect the official opinion or policy of the European Commission.

Document Approval

Action	Name and function	Signature	Date
Coordinated by	Andi Cristian SAVA Romanian NSA		11.11.2015
Elaborated by	NSA Coordination Platform - Working Group on Safety Oversight and On-Going Compliance		11.11.2015
Approved by	NSA Coordination Platform - Working Group on Safety Oversight and On-Going Compliance	< Approved during the 16 th meeting >	11.11.2015

TABLE OF CONTENTS

1	Objective	
2	Scope	3
	RBO Criteria	
4	RBO Related Processes	
4.1	Safety data collection	
4.2.	Safety data analysis	
4.3.	Surveillance programme and appropriate measures	

1 Objective

The objective of these guidelines is to provide a common understanding of risk based oversight criteria and processes in order to help National Supervisory Authorities (NSAs) to adopt a Risk Based Oversight approach when conducting their oversight tasks but providing the necessary flexibility for implementation in a manner commensurate with the complexity of the ATM system being under the supervision of NSA(s).

This document is elaborated based on the answers provided by the NSAs representatives to a questionnaire developed to facilitate the identification of the following aspects:

- RBO criteria;
- RBO specific activities;
- responsibilities related to the RBO activities;
- correlation with other safety related processes implemented within the NSA and/or State;
- internal and external interfaces of the NSA;
- tools used by NSAs.

This document contains the collection of the practices for risk based oversight used by some of the European NSAs. Although, some aspects presented here might not be applicable in

a certain environment, these examples provide valuable principles that could be considered by NSAs.

Early 2014 EASA took the initiative to collect RBO best practices in all domains from competent authorities. EASA has also organised a Workshop on the 22nd of September 2015 and elaborated a document which is yet to be finalised.

The NCP SO and EASA have been working in close coordination along both processes (EASA exercise and discussions at the NCP SO WG) in order to mutually benefit from both parts.

The present document is going to be included in the EASA RBO document as an appendix to show the ATM/ANS RBO practices; in a future update of this deliverable, a reference will be included to link to the EASA RBO document once it is published.

2 Scope

The scope is determined by the following requirements:

1. Commission Implementing Regulation (EU) No 1034/2011 of 17 October 2011 on safety oversight in air traffic management and air navigation services and amending Regulation (EU) No 691/2010, and in particular Article 7 (3) and Article 10 (2);
2. Commission Implementing Regulation (EU) No 1035/2011 of 17 October 2011 laying down common requirements for the provision of air navigation services and amending Regulations (EC) No 482/2008 and (EU) No 691/2010, and in particular Article 8.

Under these provisions the competent authority has to:

- establish and update annually an indicative inspection programme which covers all the providers it has certified and which is based on an assessment of the risks associated with the different operations constituting the air navigation services provided;
- establish and update, at least annually, a programme of safety regulatory audits in order to ensure that audits are conducted in a manner commensurate to the level of risk posed by the organisations activities;
- conduct reviews of the safety arguments in a manner commensurate with the level of risk posed by the new functional systems or by the proposed changes to existing functional systems, including safety regulatory audits.

In correlation with the above mentioned obligations, the identification of safety risks in civil aviation is performed, among others, by analysis and follow-up of occurrences as required by Regulation (EU) No 376/2014. Therefore, the safety information derived from these activities must be included in the process applied for the elaboration of the safety regulatory audit programme and for the determination of the audit scope and criteria.

3 RBO Criteria

Criterion	Factors/parameters
Previous audits	<p>Results of the audits in the previous period with special emphasis on identified issues.</p> <p>Conclusions from previous reports (certification audit and continuous oversight activities).</p> <p>Number of findings and classified per severity.</p> <p>Effectiveness of corrective measures.</p> <p>Percentage of compliance vis a vis common requirements (no weights are allocated).</p> <p>Trend analysis of the findings per domain.</p> <p>Number of unannounced inspections.</p> <p>Open and overdue findings.</p>
Occurrences	<p>The output of safety occurrence monitoring can also be used to orient future on-going oversight activities in relation to safety.</p> <p>Registered occurrence reports and analysis. Investigation performed by the ANSP and recommendations contained in the investigation report.</p> <p>Number and type of occurrence reports relevant for each ANSP in combination with trends (significant decrease or increase of number of reported occurrence and type of them).</p> <p>Reporting culture within an organisation.</p> <p>Severity level of occurrences.</p> <p>Occurrence reporting received through the mandatory and voluntary reporting systems.</p>

Changes to functional system (for all ANSPs/Organisations)	<p>List of the main planned changes to functional systems.</p> <p>Safety requirements contained in Risk Assessment documents related to changes to ATM Functional system.</p> <p>ANSPs' plans regarding to put into service of new systems and new large project having an impact on ANS provision.</p> <p>Safety related changes.</p> <p>Significant changes in the functional system.</p> <p>Results of safety review (possible deficiencies, possible conditions).</p> <p>ANSP ability to manage changes.</p> <p>Significant changes in traffic volumes.</p>
ANSP Organisation	<p>Complexity of the organisation.</p> <p>Maturity of Safety Culture.</p> <p>Number of services (ATS, MET, CNS, AIS, TO...).</p> <p>Number of units.</p> <p>Dependency on subcontractors.</p> <p>Delegation of ATS.</p> <p>ANSP certified by an EU NSA that provides services in another EU State²³.</p>
FAB	<p>Agreements within the FAB regarding oversight – frequency, participation etc...</p>

²³ The NSA should monitor the ANSP certified by them that provides services in another States. For those external ANSPs with an EU certificate that provide services in the national territory there is a regulatory obligation for establishing an agreement between the respective NSAs on the oversight.

Operations (areas and physical locations)	<p>Identification of departments/functions that may affect operational safety.</p> <p>Identification of departments/functions with higher rates of risk that is associated with the activities of ANS providers.</p> <p>Locations (e.g. ATS units, geographical environment (e.g. weather conditions, physical obstacles)) where there are situations that could have a negative impact on safety.</p> <p>Percentage of school/training flights.</p> <p>Traffic complexity.</p> <p>Mixed civil and military traffic.</p> <p>Complexity of infrastructure (TWY's etc.)</p> <p>Airspace structure.</p> <p>Number of movements in combination with trends (where a decrease is to be weighted higher).</p>
Safety Performance Indicators	<p>The overall level of safety performance determined in a certain period.</p> <p>Level of safety based on final audit report.</p> <p>Achieved level of safety in relation to the annual report on the conducted analysis of safety indicators.</p> <p>Safety performance indicators aligned with State Safety program.</p>
Others	<p>Brainstorming sessions of auditors.</p> <p>Conclusions from the Annual safety report in ATM/ANS, related to the previous year.</p> <p>Any entry having an impact on safety (reporting passengers and other reports that are not included in the system of mandatory reporting etc.).</p> <p>The audit planning (because of this process) contains the audit subjects and audit scope based on information from AB (analyse bureau).</p>

	<p>ANSP providers - Annual reports.</p> <p>Organisational changes.</p> <p>Inputs from safety reports from national and international bodies (e.g. AIB, FAB, EASA).</p> <p>Inputs from external organisations (e.g. airports, airlines, labour unions).</p> <p>ANSP and NSA stakeholder's conferences.</p> <p>Example of risk profiling: From the database a risk profile is deducted and specific risks are identified. An IT risk tool is used. In this tool, the ANSPs are scored on SMS subjects and the outcome of this score is used to establish the audit planning.</p>
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4 RBO Related Processes

4.1 Safety data collection

4.1.1 Data sources/ processes used to collect safety data.	4.1.2 Correlation of the NSA's processes with those established by the services providers/ organisations.	4.1.3 Collection of the safety data.	4.1.4 Responsibilities in the NSA related to safety data.	4.1.5 Dissemination of the safety data within the NSA / State?
<p>Audit / inspection process</p> <p>Audits / inspection reports /nonconformities classification and specificities.</p> <p>Audit objective (certification or on-going oversight).</p> <p>Evidences gathered during the on-going oversights audits (audit conclusions, follow-up of the observations, follow-up of the corrective action plans).</p> <p>Monthly updates of ANSPs operational manuals.</p> <p>Occurrence reporting process</p> <ul style="list-style-type: none"> - Number - Severity (new EASA Opinion) - AST - ECAIRS 	<p>Processes in place with ANPSs, list of what/when information exchange will take place between parties.</p> <p>Clear procedures/work instructions for reporting to the CAA;</p> <p>ToR with clear responsibilities identified at both NSA and ANSP sides;</p> <p>Change process at ANSP side with clear instructions in which cases and how changes need to be notified to NSA.</p> <p>NSA approves main processes of service providers/organisations (for example: changes of ATM FS).</p>	<p>All the information collected is stored on a shared drive / database where everybody from the NSA has access to.</p> <p>ANSPs send to NSA safety performance indicators values using NSA website. For this the ANSPs have a login and a password to access the tool and to introduce its values.</p> <p>ANSPs shall provide safety information to Investigation Bodies if so required.</p> <p>Electronic reporting by the ANSP into ECCAIRS database.</p>	<p>Unique NSA-email-address available, access by each NSA-staff.</p> <p>Safety data are collected and stored by the process owners.</p> <p>The change manager is receiving the changes and related information. In future changes might be notified through a request collector;</p> <p>All information gathered during an on-going or a certification audit is collected by the audit team leader.</p> <p>An archive of audit and inspection reports is</p>	<p>NSA-staff is taking their respective information out of the NSA-email-address-folder.</p> <p>Appropriate data are disseminated via e-mail or via an internet platform (OST for example). It is stored on the shared drive.</p> <p>Occurrence reporting is available via ECCAIRS.</p> <p>NSA's website: Different data are published: Statistics, mandatory (and voluntary) occurrence Reporting System reports, all the air traffic incident reports produced incidents investigation body.</p> <p>Safety experts committees, in particular, with the ANSPs.</p>

<ul style="list-style-type: none"> - AIB reports, information, recommendations. <p>Change management process</p> <ul style="list-style-type: none"> - Severity of the change - Maturity of the change management process - Quality of the safety assessment related to the change <p>Safety performance</p> <ul style="list-style-type: none"> - determined safety performance derived from the corresponding safety performance indicators - Evaluation of Safety Management Systems. <p>Organisation/Unit specificity</p> <ul style="list-style-type: none"> - Complexity/traffic - Previous performance <p>Business Plans</p> <p>Information contained in the business plans, mainly related to planned significant changes to the service provider's ATM functional system.</p> <p>Knowledge</p>	<p>Occurrence reporting is discussed with ANSP on AIB meeting.</p> <p>Safety data are discussed on Safety Board.</p> <p>Consultation with affected providers and organizations (to agree the proposed terms and scope of audit activities) is done prior to final approval of the programme of audits.</p> <p>The authority provides statistical safety information derived from the mandatory (and also voluntary) occurrence reporting system through its software tools.</p> <p>The authority and the ANSPs exchange safety information regarding a particular safety risk area.</p> <p>Regular processes are documented in the ANSP SMS.</p> <p>ATM/ANSP processes related to SMS are aligned and accepted by the NSA.</p>	<p>Official registration of the incoming information (either in ECCAIRS or electronic in document management system).</p> <p>Direct input by Inspectorate into Risk Based Oversight Tool.</p> <p>Official notification letters.</p> <p>Using dedicated e-mail address.</p>	<p>common for NSA under supervision of Supervision Section, database of occurrence reporting and reports of final analysis of occurrences is under supervision of Development Manager and database of changes of ATM FS is common for NSA under supervision of Interoperability Section.</p> <p>With the exception of the safety information required by the AIB (Safety Investigation Authority), the NSA is the receiver of the safety data, and within the NSA a Directorate is in charge of collecting all safety data.</p> <p>Safety analysts are responsible for the ECCAIRS database</p> <p>By use of a specific email address for Occurrence Reporting in the Safety Department and for</p>	<p>ANS Division disseminates the safety information to relevant ANS units (ATM, MET, CNS, AIS).</p> <p>With the exception of MORs all other data is disseminated via the Risk Based Oversight Tool (RBOT). MOR. Direct input to Inspectorate from ATS Investigations.</p> <p>Use of intranet of the organisation.</p> <p>Use of software tools for statistical safety information derived from occurrence reporting.</p>
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<p>Information from the inspector that if the audit period was longer, the number of nonconformities would be much higher. The service provision could be better controlled/ managed.</p> <p>Unit and Corporate Audits</p> <p>Inspectorate Knowledge</p> <p>Business and Annual Plans Service Providers perceived top risks.</p>	<p>Close coordination between the NSA's Safety Department and the ANSPs, namely on the review RAT classification and checking of AST data.</p> <p>NSA Handbook should be correlated with the service provider procedures, including process design.</p>		<p>oversight processes in NSA's Air Navigation Directorate.</p> <p>Occurrence Reporting: Safety Directorate.</p> <p>Safety Performance/ Audit / Change Management: ANS Supervision Department / Supervision Directorate.</p> <p>MORs (Safety Data department and ATS Investigations and Inspectorate) Audit reports and SMS evaluation (Regulatory co-ordination section).</p>	
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4.2. Safety data analysis

4.2.1 Methods / processes used for safety data analysis.	4.2.2 Tools used for safety data analysis.	4.2.3 Quality of the collected safety data.	4.2.4 Correlation between the methods used for safety data analysis and the ATM/ANS organisations specificities.	4.2.5 Responsibilities within the NSA/ State for ATM/ANS safety data analysis.	4.2.6 The output of the safety data analysis process.
<p>Monthly and ad-hoc meetings and trend analysis (i.e. accumulation of occurrences,...), yearly safety survey verification.</p> <p>Each process owner develops his own dashboard in order to monitor the data under his responsibilities.</p> <p>The number of several types of occurrences is monitored yearly and included in the NSAs year report.</p> <p>Occurrence reporting: Reactive approach: Focused on monitoring of the</p>	<p>Excel files, tables, Risk Analysis Tool TOKAI, AWB in ECCAIRS System.</p> <p>RBOT which is Excel based.</p> <p>ECCAIRS to manage the mandatory and voluntary occurrence reports, data warehouses to manage the safety performance indicators monthly provided by service providers, and Aerial Safety Strategic Observatory to collect data from different data sources to thereby</p>	<p>Regular inspections/audits at ANSP with check of evidences.</p> <p>Comparison of databases NSA and ANSP, sampling encoded data in ECCAIRS to verify completeness and correctness.</p> <p>Double check by other NSA users of data.</p> <p>Contacts with the service provider if an anomalous data/tendency is detected.</p>	<p>Exchanged of data are organised in collaboration with the ATM/ANS organisations.</p> <p>NSA verifies occurrence data within AIB meeting with participation of ANSP 4 times per year. Each occurrence report is simultaneously the part of Safety Board meeting (take place 4 times per year).</p> <p>Methods are common for all</p>	<p>NSA-Members (ATM, CNS, AIS, MET) during regular meetings.</p> <p>Involvement of several people of the NSA and the CAA.</p> <p>In the NSA, the Directorate responsible for identifying safety hazards and assessing associated safety risks. For decision making regarding the risk mitigation actions, the NSA has established a collaborative procedure with all NSA Directorates.</p>	<p>Request for investigation reports and additional analysis by ANSP.</p> <p>Check of ANSP recommendations during NSA-inspection.</p> <p>Change of scope, content, quantity of next audits, inspections.</p> <p>Output collected in Risk-Based Analysis Excel tool</p> <p>Statistics</p> <p>Meeting minutes and outputs from Safety Board meetings,</p>



<p>process and how events are resolved, on corrective measures and other processes relevant to the Department to ensure safety in the event of emergence and persistence of the dangerous condition. Proactive approach: Focused on analysing log files of events obtained either by air navigation service providers or through ECCAIRS.</p> <p>Trend analysis is used for evaluation of non-conformities; assessment is 2 times per year.</p> <p>Outputs from RAT are used (leadership AIB).</p> <p>The NSA has developed two methods to analyse data: To identify the areas of greater concern or need at national level, used for Safety plan elaboration. For air operators, another methodology has been developed to identify the air</p>	<p>expedite decision-making to improve aviation safety.</p>	<p>Basic QMS requirements approved at specific organization.</p> <p>Quality is assured by cross checking data during safety oversight activities and regular (monthly) meetings with ANSPs.</p> <p>Access is limited only to trained personnel.</p> <p>Competence training and experience of the oversight staff and formalised processes for submitting and assessing MORs.</p>	<p>domains and there are no specificities for the ATM/ANS domain.</p> <p>The methods in place are related to the ATM/ANS unit specificities.</p> <p>This takes into account:</p> <ul style="list-style-type: none"> - previous performance: - traffic level - complexity of activities <p>Related to organisation size, complexity and type of operations and resulting risk levels.</p>	<p>Safety analysis Section.</p> <p>Coordinated activity between the Safety Department and the Air Navigation Department.</p> <p>NSA – Safety Directorate and Supervision Directorate. State – CIAS as AIB (serious incidents and accidents).</p> <p>Safety Data Department, ATS investigations and the Inspectorate.</p>	<p>Decisions concerning changes of ATM FS.</p> <p>Two main outputs of the safety data analysis process: The State Safety Plan that documents the risk areas of greater concern or need, and the risk mitigation actions that are taken in collaboration with all NSA Directorates in internal Safety Committees.</p> <p>Safety Statistics in the Annual Safety Review</p> <p>Safety Performance indicators.</p> <p>Safety reports, Proposal for new inspections, Proposal to focus the audits on certain areas/ requirements, Request for corrective measures, Proposal to review/ improve the NSA processes.</p> <p>Targeted Oversight.</p>
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<p>operators that need more oversight. There are plans to extend this methodology to other domains like air navigation.</p> <p>Exploratory data analysis, descriptive statistics, time series, statistical analysis, expert judgement.</p> <p>By analysing the narratives of the reports and determining short and long term trends.</p> <p>The Risk Based Oversight Tool provides an indication of trend analysis. RBOT display Inspectorate Confidence and Compliance levels and Overall Risk Levels and comparison between service providers.</p>					
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4.3. Surveillance programme and appropriate measures

4.3.1 NSA safety regulatory audits/inspections programme adequacy check.	4.3.2 Planning and prioritisation of the audits and inspections.	4.3.3 Allocation of the inspection/audit resources.	4.3.4 Actions in case of insufficient NSA resources.
<p>Depends on output of safety data analysis (on regular basis).</p> <p>At least biannually and as needed, depending for instance on the outcome of audits or occurrences.</p> <p>At least annually.</p> <p>Several times a year because there is continuing inputs.</p> <p>1 times per month on regular meeting of the NSA director (participants heads of NSA Sections).</p> <p>Annual oversight plan is elaborated based on the result of the last year Annual Inspection Plan. In particular, it shall consider: higher safety risk areas, non-compliances of current legislation and service providers' response times and actions taken in case of non-compliances, the priorities set by the internal Safety Committees, studies and analyses carried out by Aircraft Safety Experts Committee and Air Navigation Safety Experts</p>	<p>Risk-based analysis tool used by NSA in order to prioritise audits/inspections, based on previous audit results and safety data analysis.</p> <p>Through our proper RBO analysis: By evaluating which safety requirements have not been covered yet by audit and by evaluating the safety criticality of certain requirements with respect to certain services within the ANSP.</p> <p>Priority is done based on procedures written in document Guidelines for planning of safety oversight of the safe provision of ANS and compliance with safety regulatory requirements</p> <p>An assessment of the risk inherent or identified within the ANSPs operations affect how the audits are prioritised.</p>	<p>Common NSA-team-planning for resources.</p> <p>It depends on the competence, the availability of the auditors and the scope of the audit.</p> <p>Director of the Department in coordination with the heads of sections checks the status of the resources available for implementation of a program of safety regulatory audits and inspections. In particular, check availability: a) Human resources (particularly with regard to the availability and competence of senior auditors and b) Information sources (updating the normative requirements for the design and specification checklists) c) Financial resources (travel and ensure mobility) d) Communications, IT and logistics resources (ensuring mobility, communication and administration). These activities are initiated prior to</p>	<p>The program is checked for adequacy regularly. In case there are no sufficient resources, prioritisation is made on audits for which an impact on safety is higher (based on our RBO analysis).</p> <p>NSA cooperates with other NSA's within FAB to have enough resources (Pool of Experts) and NSA can ask for expert in the area identified.</p> <p>Other non-critical activities are delayed and inspection teams are focused on any risk issue raised. In addition, overload.</p> <p>Prioritisation, desk-top audit instead of on-site audit, shortens audits.</p> <p>Use the recruitment tools available.</p> <p>Escalate the matter to a higher management level.</p>



<p>Committee. These are our external Safety Committees with service providers, and The results of the analysis of the information available on NSA through the State Safety Program (SSP). In addition to the Annual Inspection Plan, more safety audits/inspection activities can be agreed, as a risk mitigation measure, in the NSA internal Safety Committees.</p> <p>As often as necessary, depending on the outcome of safety data analysis. Unplanned inspections can be used.</p> <p>The audit programme should cover a period of one year. Ad hoc inspections can be performed when necessary.</p> <p>Annually. Ad Hoc audits/inspections are carried as and when required based on information received. I.e. MOR/Changes.</p>	<p>NSA processes stipulate which requirements shall be audited at least annually, which requirements shall be covered within a two year period and which requirements shall be covered within a five year period.</p> <p>This planning takes into account the determined necessities and the requirement to verify all applicable safety regulatory requirements in an interval of two years.</p> <p>Planning can be updated at any time, according to any concerns raised.</p> <p>The planning of the programme aims to be flexible in order to accommodate other inspections/ audits and to be both proactive and predictive.</p> <p>The annual audit programme is produced to cover all 60 providers. For multi-site ANSPs previous audit records held in the RBOT are consulted to ensure all units are given sufficient oversight.</p> <p>The annual audit programme itself is not based on risk levels, it is the content and depth of the audit/inspection that is targeted to</p>	<p>the preparation of the program and must be completed before its approval. A division director is responsible for the implementation of all activities.</p> <p>Inspectors are “allocated” to ANSP service units’ for a two year period, during that time they lead audits conducted on that unit/ANSP and the inspectors themselves decide if more resources are needed on the individual audit.</p> <p>Based on expertise of the CAA/NSA staff.</p> <p>By performing and regularly updating the man/hour plan for each Department.</p> <p>Based on the safety data analysis output and the ATM/ANS unit specificities (traffic, complexity), the Focal Point for Certification, after discussions with the audit team leader, decides on these matters.</p> <p>The Inspectorate allocates individual inspectors with the appropriate skills to specific service providers based on location and type of service provision.</p>	
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	<p>areas of the providers operations that the data analysis indicates weaknesses. However; Ad Hoc targeted inspections are also carried out as required.</p> <p>By using this process sufficient audits are carried to meet the 2 year cycle required by the regulations and encompass the requirements for risk based oversight.</p>	<p>Where Ad Hoc audits are required additional resources are provided dependant on the reason for the audit i.e. Engineering/Operations/Training etc.</p>	
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V Contributors

This paper has been developed by a project team established within the EASA Flight Standards Directorate, with the representation of all technical departments:

- FS.1 Maintenance and Production Department
- FS.2 Air Operations Department
- FS.3 Air Crew & Medical Department
- FS.4 ATM/ANS & Aerodromes Department

The Policy & Planning Department (FS.5) coordinated the project.

The following Authorities accepted to be interviewed and decided to share their practices

- Austrocontrol, AT
- Estonian Civil Aviation Administration
- Finnish Transport Safety Agency (TraFi)
- Direction Générale de l'Aviation Civile, FR
- Luftfahrt-Bundesamt, DE
- Irish Aviation Authority
- Inspectie Leefomgeving en Transport, NL
- Agencia Estatal de Seguridad Aérea, ES
- UK Civil Aviation Authority
- Norwegian Civil Aviation Authority
- Federal Office of Civil Aviation, CH
- Romanian Civil Aeronautical Authority