

Report

A Harmonised European Approach to a Performance-Based Environment (PBE)

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1. Introduction

Whilst both technical advancements and development of detailed regulations have helped to establish the safe system and good safety record we have today, it is vital that a harmonised European approach to a Performance-Based Environment (PBE) is further developed in order to maintain and continuously improve this safety record. This paper describes the key concepts of how PBE can enable more effective management of safety and its associated risks and will outline the key definitions that need to be agreed at European level. It will also outline the enablers required to implement PBE at a total system level and highlight the advantages, challenges and options of introducing a more risk-based approach into the existing regulatory system. Finally, the paper is provided to support the discussion on future aviation EU regulation and also to contribute to a common European understanding on such concepts as Performance-based Rules (PBR), Risk-based Oversight (RBO) and Performance-based Oversight (PBO).

Note 1: Although this paper is focussed on safety, similar principles can be applied to other areas, like environmental protection.

Note 2: Annex 19 revolves around a PBE; however neither PBR nor RBO nor PBO are clearly mentioned (only SMM edition 3 – ICAO doc 9859 – Safety management gives some hints). RBO and “safety performance” is being progressively introduced in a different set of EU rules, which focuses more on “management system”.

2. Proposal for the key definitions

Prescriptive Regulation: A regulation that specifies requirements for mandatory methods of compliance.

Safety Performance Indicator (SPI): A data-based¹ parameter used for monitoring and assessing safety performance. (Sources: ICAO)

Performance-Based Regulation (PBR): A regulatory approach that focuses on desired, measurable outcomes.

Performance-Based Environment (PBE): An environment based on safety performance indicators (SPIs) on which safety assurance and promotion as well as performance based regulation and performance based oversight can be built.

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

Risk-based Oversight (RBO): A way of performing oversight, where planning is driven by the risk profile and execution, besides ensuring compliance, focuses on the management of operational risks.

Risk profile (of the organisation): Includes: the specific nature of the organisation; the complexity of its activities; the results of past certification and/or oversight; and the operational risks.

¹ This is considered to include evidence-based

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Note: Safety performance does not impact the risk profile but the planning of oversight

3. Key concepts related to a PBE

PBE introduces a clear set of goals against which indicators are used to measure the effectiveness of the aviation regulatory system. Performance indicators allow for an assessment of the observed situation, measuring trends, providing feedback and helping to identify the means to achieve these goals. In the field of aviation safety, such indicators are called Safety Performance Indicators (SPIs) and enable the system to focus on the desired or required performance results when targets are associated.

SPIs can be qualitative, quantitative, absolute or relative and they must be supported by the systematic collection and analysis of data. In relation to safety, this data can be obtained from sources such as questionnaires/surveys, occurrence reports, technical reports (reliability, observation and data capturing systems such as Flight Data Monitoring), operational performance monitoring systems, oversight and inspection activities, and more generally, data on areas such as economics, social and organisational information. When focussing on hazards, turning data into meaningful safety intelligence will help to deliver a safety risk assessment by addressing the likelihood and severity of the consequences. Data-driven decision making, through the implementation of SPIs at a total system level, is a key facet of any safety management system that supports the development of pragmatic solutions based on solid evidence. A PBE improves the overall quality of rules and safety oversight. Instead of establishing prescriptive regulations telling individuals and businesses what they can and cannot do, PBR sets goals for the desired outcomes (safety objectives) and measures performance against them.

Safety management recognises the interactions, interdependencies and interconnections of the aviation system. Therefore, it is beneficial that interfaces and influences between the different parts of the system are controlled effectively. Safety performance measurement and risk assessment need to be developed at a total system level to correctly ascertain the interfaces between all the domains of aviation. Safety performance and risk management applies not just to any organisation, State or regional agency but also to any domain. This is also appropriate to any process related to certification and oversight by addressing all the interactions and streamlining the collection and analysis of data.

4. Necessary key enablers for PBE

There are a number of key enablers that are required to ensure the successful implementation of PBE:

4.1. Mature Safety Management

Effective implementation of SMSs and SSPs is the most important driver for identifying risks, establishing and using SPIs with the right level of granularity. The following issues will need to be

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addressed in the development of a performance based environment:

- **Organisational Requirements.** Regulatory and oversight bodies, stakeholders and their internal processes should be organised in a way that enables them to more effectively coordinate the collection, analysis and protection of safety information to provide for the best possible safety-related decisions (performance management) of the total aviation system. Human and financial resources will have to be invested to get the necessary competence, training and understanding to establish the new processes. Associated costs to this paradigm shift are expected, in particular at the beginning of its implementation. One of the most critical areas that will require resource is the collection, analysis and reporting of the right information with which to judge performance.
- **Management of Safety Information.** Systematic collection, analysis and protection of safety information are an important first step in PBE. EU, EASA, competent authorities of the Member States, Industry and any other appropriate entities should have a robust mechanism for the management of safety information. New Regulation (EU) No 376/2014 (repealing Directive 2003/42/EC) provides an additional building block for better reporting, analysing and following-up occurrences in Civil Aviation. In addition, common taxonomy-built databases need to be brought into line with the concepts of SMS, whilst an improved central data repository would need to contain data of sufficient quality to support decision making processes.

4.2. Information Sharing

The range of systemic networks under EASA governance should be developed around the new approach of PBE, with a clear focus on supporting the European Aviation Safety Programme / Plan (EASP / EASp) and the SSPs of the EASA Member States (MS). This will help to spread knowledge, encourage interaction between the different aviation domains and support the development of clear strategies to support States or organisations in their management of safety performance. Closer coordination and a clear focus on risk management will also enable organisations or MS with a low volume of aviation activities to compensate for their lack of data, which means they might be unable to rely on information solely gathered within their own organisation or State.

4.3. Culture

The development of a clear framework for the implementation of a “Just Culture” helps in fostering the necessary “Safety culture” in an environment of trust. This is a prerequisite for the collection of safety information and will provide an adequate level of protection to combat cultural and judicial barriers. Implementation of Regulation (EU) No 376/2014 on Occurrence

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Reporting will support this requirement. The confidence to share data openly will need cultural change at all levels (industry and regulators).

Another essential element for a PBE is the capability for professional judgement. Key management staff should have the proper mind-set to build the competences necessary for successful understanding between industry and regulators. Although considered by some to be too subjective, judgement based on training, experience and qualifications would contribute effectively to understanding the risks which are not readily revealed by data alone. ‘Expert witnesses’ can help to identify such risks with an appropriate level of objectivity.

4.4. Structure of the Rules - Authority and Organisations Requirements

Authority and Organisations Requirements should support the concept of SSP and SMS, allowing the State and the organisations to set objectives and to continuously manage the overall safety performance. The rules, with their technical annexes, allow the development of additional objectives supported by SPIs, specific to every domain and appropriate to efficiently target the risks. Moreover, the principle of proposing technical ways of compliance and allowing MS and organisations to establish alternative means to comply, by proposing SPIs, demonstrating an acceptable level of safety performance and sharing these alternatives, constitutes a mechanism towards more PBR.

Consideration should be given to foster necessary commonality in the OR/AR rules across all domains, focussing in particular for:

- large organisations with multiple approvals, which operate as a single entity; and
- risks at the interfaces between the sectors.

At the same time it is important to apply the proportionality principle for small and medium-sized organisations.

4.5. Accountabilities, Responsibilities and Enforcement

In a PBE, and in particular for PBR, organisations or individuals are given objectives and flexibility on how to meet them. Processes would be set up to measure performance and assess whether the given objectives are met. This requires rights and obligations to be clearly identified; a monitoring system including rewards and tailored corrective actions, as well a way to establish an assurance that expected performance can be attained. If such processes are not implemented or do not function properly, or in case of reckless conduct, gross negligence or wilful misconduct, proportionate enforcement should be taken at the right level of accountability. 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. The more self-determination allowed by the PBR environment, the more stringent enforcement will be required by regulators, that need to be aware of the performance of the service providers. This constitutes a profound change among EASA Member States, both at the level of the authorities and the regulated entities.

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5. PBR versus prescriptive rules

Prescriptive rules and the associated oversight have achieved tremendous results in the past, reducing the rate of passenger fatalities per 100 million passenger miles by a factor of 50 in the last 50 years and recently hitting an historical record of 0.1 or less (ICAO sources). However, risks still exist even in the most compliant systems. Moreover, in reality, it is impossible to develop rules for every possible situation. Both of these issues can be better addressed in a performance-based regulatory environment, especially as modern aviation systems become more and more complex in a dynamic marketplace. Emergence of new industry standards or new technology illustrates the mounting challenges.

Experience has shown that simple compliance with prescriptive regulations does not guarantee safety alone. PBR offers improvements by proposing SPIs, targeting safety objectives and efficiently mitigating risks through a better focus on the outcome rather than only the way something has to be done. It provides flexibility in the implementation rather than just trying to develop prescriptive rules for every eventuality.

The key advantages of PBR are:

- Better focus on achieving the desired performance.
- Improved understanding of risks and clearer identification of the required mitigations.
- More tailored oversight activities that focus activities on the areas of greater concern or need.
- Efficiency through a better targeting of resources.
- Better legislative adaptability and flexibility.
- Improved focus on the individuals in the aviation system and their role in safety.
- Will lead to a more active involvement and interaction of all actors in managing the system.

To illustrate, Reg. (EU) No 1216/2011 lays down a performance scheme for Air Navigation Services (ANS) and network functions, which includes SPIs to address both the State and the ANS Provider. Work is underway to develop performance schemes for the total aviation system and this is a prerequisite for a performance based environment. The European Commission has consequently launched a study to gain more knowledge, the outcome of which is expected end of 2014 and will participate to a more ambitious project towards “better rules”.

A performance-based regulatory environment that is more focussed on the management of SPIs and risks will also nurture the design of rules by better identifying the failure conditions and enhancing the mitigation strategies. Regulatory standards that deal with high-consequence, low-probability events are likely to differ in significant ways from those dealing with low-consequence high-probability events.

Today, certain rules are based on this approach (e.g. CS 25.1309) and have already proven successful. PBR should not be mistaken for ‘deregulation’ or ‘absence’ of any binding or concrete rules. It is not a relaxation or substitute of the prescriptive system. Continued adherence to

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prescriptive rules remains a success factor in a PBE to meet the targets. However, introduction of PBR can facilitate the continuous improvement of aviation safety.

6. Risk- and Performance-Based Oversight

6.1 Basic principles

Compliance-based oversight (CBO) relies on the assumption that if an organisation is fully compliant with the applicable safety requirements, then an adequate level of safety is achieved. Therefore it verifies that the regulated entities meet all applicable regulatory requirements and requires such verifications to be repeated at regular intervals, regardless of the level of maturity achieved by the organisation under scrutiny. This approach has proved to work since the early years of aviation and has helped to achieve the current safety levels. However, the regulatory environment in several domains has reached a level of complexity where further safety improvements cannot be achieved by following a purely compliance-based approach.

Performance-Based Oversight (PBO) means a new approach for Aviation Authorities to discharge their responsibilities, as the stakeholders are required to measure the safety performance of their activities and find a way to better target the safety areas posing greater concern or need. Setting-up targets and monitoring them would help to achieve better safety performance.

In addition, Risk based oversight² (RBO) provides a mechanism for better identifying hazards, measuring associated risks as well as demonstrating effective mitigation of these risks. Ultimately it would allow the Competent Authority to focus its attention on organisations that require additional or higher attention. Accepting that the prerequisites and system requirements described in this paper must be in place before RBO can be implemented, the use of a risk based methodology, supported by data, is good safety practice. A robust and standardised approach to RBO benefits the Competent Authority because it provides a system wide risk picture. The continuous monitoring approach provides an additional layer of surveillance monitoring to: first of all address shifts in the risk profile of the organisation, but also to assure the regulator that the established surveillance intervals are appropriate.

In both cases, PBO and RBO rely on the same process: safety modelling, data collection and analysis of safety data allows to identify and measure SPIs and set-up associated targets. These are used to monitor, in the case of PBO, the level of safety performance, and, in the case of RBO, the effectiveness of the safety barriers (mitigation strategies for risks).

In the initial stage of a PBE, oversight will benefit from data already available to provide an indication of the areas of greater concern, which allows oversight to be risk-based (=RBO). In a more mature system, a broader set of indicators will become available, including those stemming from PBR. In this case, oversight will expand beyond RBO, focusing on the overall performance

² For more details see WP/365 “PRINCIPLES OF RISK BASED OVERSIGHT (RBO)” presented by Canada at the 38th ICAO General Assembly

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(=PBO) and consequently adapting its planning and contents. By doing so, the Competent Authority looks at how effectively the organisation complies with the aviation regulations and not just whether the organisation complies. Whereas in prescriptive regulatory schemes, compliance can be achieved without it being effective; the goal of performance based regulations is to encourage effective compliance. Consequently, the performance of the organisation may be used as an input into the level and planning of oversight.

The publication of ICAO Annex 19 recognizes safety management as the way forward in dealing with aviation safety risks. Any performance based approach to oversight must consider the safety performance of regulated entities both at an individual and aggregate level (state), in respect to:

- comply with the applicable requirements,
- implement and maintain effective safety management,
- identify and manage safety risks by setting and achieving adequate targets, and
- achieve and maintain safe operations.

6.2 Resources, competence and methodology

In a time of resource scarcity and continued growth in all sectors of the aviation industry, Competent Authorities are being called upon to respond to these competing challenges in an appropriate manner. Not all organisations are created equal and thus one Competent Authority needs to allocate resources more effectively using data-driven judgements. The application of these principles to oversight planning provides a mechanism for applying resources where they are most required. “Effective compliance” builds confidence and demonstrates to the Competent Authority that the systems in place effectively meet the safety objectives on an on-going basis.

In order to be effective, the PBO methodology must be able to assess whether the required performance or objectives established in the regulations have been met in a manner that is appropriate to the organisation. To that end, the Competent Authority must be able to distinguish different levels of achievement, recognising good and poor performance.

Competence of inspectors and oversight methods will consequently need to evolve to include more interaction, monitoring, negotiation of targets and objective judgment. This would apply equally to regulated entities and Authorities’ staff involved.

PBO and RBO will not remove States’ responsibilities in the supervision of aviation activities and does not necessarily mean “less oversight”. However it will help States to better share responsibilities and make a better use of their oversight resources (planning and targets). During the initial phase of its introduction, it can be easily predicted that PBO will require additional, though better targeted, efforts to be deployed.

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The role of Authority inspectors will need to change, working in closer collaboration with the organisation, engaging in a dialogue on safety assurance³ and safety objectives rather than just checking compliance with prescriptive regulatory requirements. The focus will be more on how risks are mitigated and on assessing the effectiveness of the mitigation process. Finally, as oversight will be mainly based on performance, the ability to measure safety performance should also become part of the inspectors' competence. This means a basic understanding of safety analysis techniques and an understanding on how to work with SPIs.

Transitioning from Compliance-Based Oversight (CBO) to PBO / RBO will depend on the human and technical capital of the NAA. However there is a risk that some NAAs may move too fast towards PBO/RBO when their environment is not prepared enough or when emphasis on CBO is still needed. Insufficient resources and competence would negatively impact the oversight activities and potentially the safety performance.

7. Additional challenges

In contrast with a purely prescriptive system, a PBE depends on the ability of competent authorities and organisations to specify, measure, and monitor performance. A key element to the success of PBE is the management of reliable and appropriate data that can provide decision makers with the detail they need to make the right choices. It is vital that an intelligence picture is provided with the appropriate level of detail, to make the right decisions. Furthermore, while it seems easy to specify the desired performance of a basic system or process, there may be areas of the system where, for the sake of clarity, harmonisation or a level-playing field, prescriptive rules will remain the only option. For instance there may be a case where authorities or organisations are not willing or not able to use a PBE. The balance between performance-based and prescriptive rules will need to be determined.

The further introduction of PBR requires a fundamental change in the safety regulatory mind-set and the concepts enabling a PBE will need to be considered in the on-going review of the Basic Regulation⁴. Furthermore, a shift of responsibilities will take place as the regulated entity will be able to choose the means that will fulfil the performance goals. Yet, performance needs to be measured through SPIs in order to ensure that the performance goal is fulfilled. As already mentioned in previous section, this will obviously have a significant impact on the way oversight will be performed: oversight of performance based rules will require a different and a more advanced approach as it will trigger discussions on the basis of SPIs and targets whether the applied method is suited to meet the performance goal. An exchange of views, rather than one-way communication from the competent authority to the regulated entity, will most likely take place.

³ Identification, measurement and achievement of safety objectives

⁴ Ref. European Commission Roadmap "Policy initiative on aviation safety and a possible revision of Regulation (EC) No 216/2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency"

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Hence, as the overseeing authority will have the last say, this different kind of oversight becomes a challenge in terms of appropriately measuring performance. The same type of dialogue will be necessary during the design and maintenance of PBR.

8. Next Steps

This document is made available via the EASA website . In parallel EASA is working on two extensive documents that will further substantiate and elaborate the practicalities of 'Performance Based Regulation (PBR)' and ' Performance Based Oversight (PBO)'. Both documents should be ready by spring 2015 and will provide, after consultations with the Member States and the key stakeholders via divers consultative mechanisms/activities, the way and manner in which more PBR can be introduced into the system and how adequate PBO could be performed.

9. Conclusion

The ever growing complexity in the aviation system demands an evolution in the management of safety towards a PBE that focusses in particular on the management of risks. PBE will help to develop PBR as well as PBO that will be needed to maintain the high safety levels of recent years in light of the expected expansion of air traffic and aviation activity over the next 15 years. A PBE does not fully replace the traditional forms of a prescriptive regulatory system but is rather a complement to it. Compliance remains a necessary foundation and this equally applies to the certification of products and organisations as well as the oversight activities. However, the greatest challenge is in the collection and effective analysis of the necessary performance information to help identify risks, develop the correct mitigations, drive the performance – and risk-based oversight and foster PBE.

The move to a more PBE should thus appropriately and gradually complement the existing prescriptive regulatory system. Oversight will need to be adapted as well, with an increased focus on the achievement on safety objectives rather than on the method followed to achieve them. Several enablers for a PBE are already in motion in the EU/EASA system, in coherence with the EASP. However, a PBE requires additional efforts, resources and profound changes to reshape the functioning of the regulating bodies, regulated entities and their interactions as well as a new cultural and managerial approach to safety.

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