

CANSO Standard: Common Safety Method on Risk Evaluation and Assessment for ANSPs

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GENERAL PRINCIPLES APPLICABLE TO THE RISK MANAGEMENT PROCESS

1

Introduction

1.1 This guidance sets out the CANSO Standard for a common safety method on risk evaluation and assessment for ANSPs. It applies to all ATM/ANSP ground based functional changes¹, whether people, procedures or equipment and includes changes to the interactions between these elements. A block diagram of the overall process steps that comprise the approach is illustrated in Annex A.

1.2 Practitioners should note that once selected this process must be applied in its entirety. It is not possible to select and apply individual process elements.

2 Determining the safety significance of a change

2.1 In the first instance, the ANSP should consider the potential safety significance of the change on the safety of the functional system. The ANSP should conduct a preliminary functional system definition. This should include a clear statement of what is being changed, the scope of the change and provide sufficient detail to determine whether the proposed change has a significant impact on safety, see Figure 1 below.

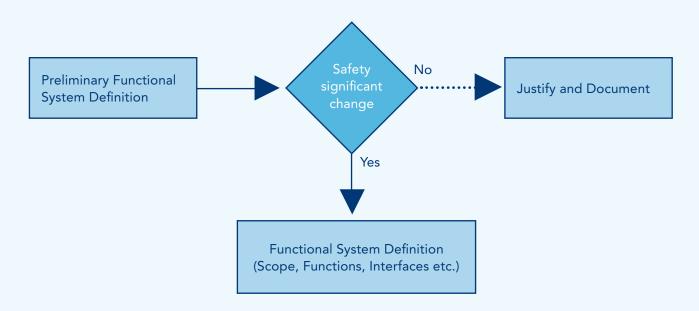


Figure 1: Safety significance of the change

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¹Examples of a ground based functional change include the obvious examples of opening a new control tower, fundamental change in training programme for ATCOs and replacement technical system, etc. Less obvious types of changes in scope include changes in building security, change in power supplier and changes in management structure etc., which can also have a significant impact on safety.

2.2 The ANSP should decide, by expert judgement, the safety significance of the change based on the following criteria:

- failure consequence: credible worst-case scenario in the event of failure of the functional system under assessment, taking into account the existence of safety barriers, such as safety nets, which may be outside the scope of the functional system;
- novelty used in implementing the change: this concerns both what is innovative in the aviation sector, and what is new just for the organisation implementing the change;
- complexity of the change: the number of multiple functional systems and interfaces impacted, the number of stakeholders that the change is dependent upon;
- d. ability to monitor the change and take appropriate interventions;
- e. reversibility: what is the opportunity to revert to the previous functional system, is transition proposed to be implemented as a single one off event;
- f. inter-relationship with recent changes: assessing the significance of the change taking into account all recent² safetyrelated modifications to the functional system under assessment and which were not judged as significant.

2.3 Experts involved in determining the significance of the change would typically include as a minimum; operational user(s), a technical expert familiar with the specific detail of the change, a safety specialist and relevant stakeholder(s).

2.4 Essentially, the majority of changes to functional systems are likely to impact one or more of these criteria and therefore will be deemed to be safety significant. This does not, however, preclude the possibility of a change to a functional system not impacting the Air Navigation Service provision.

2.5 If the change is determined to be safety significant then the steps described in the risk management process in Section 6 should be applied, first of which is developing a Functional System Definition. Otherwise, the ANSP should document the justification for the decision and then take no further action under this process other than to apply the organisation's existing change management processes.

3

Risk management process

3.1 The risk management process applies to all safety significant changes as determined by the criteria in paragraph 2.2.

3.2 The risk management process should start by describing in detail the change to the functional system under assessment and comprise the following activities:

- a. the risk assessment process, which should identify the hazards, the risks, the associated safety measures and the resulting safety requirements to be fulfilled by the functional system under assessment;
- b. demonstration of the compliance of the functional system with the identified safety requirements; and
- c. management of all identified hazards and the associated safety measures.

3.3 This risk management process is iterative. The process ends when the compliance of the functional system with all safety requirements necessary to accept the risks linked to the identified hazards has been demonstrated and accepted.

3.4 Any risk assessment conducted using this process should always be proportionate to the extent of the risk assessed. A proportionate risk assessment is one where the effectiveness of the hazard control measures and the methodologies

being applied are balanced against the associated cost, time and effort.

<u>4</u>

General obligations

4.1 The risk management process described should be applied by the ANSP who initiates the change to the functional system and who acts as coordinator of the change where there are multiple stakeholders.

4.2 The ANSP is responsible for the change and the satisfactory completion of the associated risk management process. The ANSP should ensure that risks introduced by suppliers and service providers, including their subcontractors, are appropriately managed. To this end, the ANSP may request that suppliers and service providers, including their subcontractors, participate in the risk management process.

4.3 Without prejudice to civil liability in accordance with the legal requirements of the State, the risk assessment process should also fall within the responsibility of the ANSP. In particular the ANSP should decide, with agreement of the stakeholders concerned, which will be in charge of fulfilling the safety requirements resulting from the risk assessment. This decision should depend on the type of safety measures selected to control the risks to an acceptable level. The demonstration of compliance with the safety requirements should be conducted according to Section 7.

4.4 A fundamental part of the risk management process is for the ANSP to develop a Safety Plan, which is maintained during the life of the project. It should identify the different stakeholders' tasks, as well as their risk management activities. The ANSP should coordinate close collaboration between the different stakeholders involved, according to their respective tasks, in order to manage the hazards and their associated safety measures.

5 Interface management

5.1 For each interface relevant to the functional system under assessment the stakeholders concerned should cooperate in order to identify and manage jointly the hazards and related safety measures that need to be handled at these interfaces. The management of shared risks at the interfaces should be coordinated by the ANSP.

5.2 When, in order to fulfil a safety requirement, a stakeholder identifies the need for a safety measure that it cannot implement itself, it should, after agreement with another stakeholder, transfer the management of the related hazard to the latter using the process described in Section 8.

5.3 For the functional system under assessment, any stakeholder who discovers that a safety measure is non-compliant or inadequate is responsible for notifying it to the ANSP, who should in turn inform the stakeholder implementing the safety measure.

5.4 The stakeholder implementing the safety measure should then inform all the stakeholders affected by the problem either within the functional system under assessment or, as far as known by the stakeholder, within other existing functional systems using the same safety measure.

5.5 When agreement cannot be found between two or more stakeholders it is the responsibility of the ANSP³ to find an adequate solution.

<u>6</u> Description of the risk assessment process

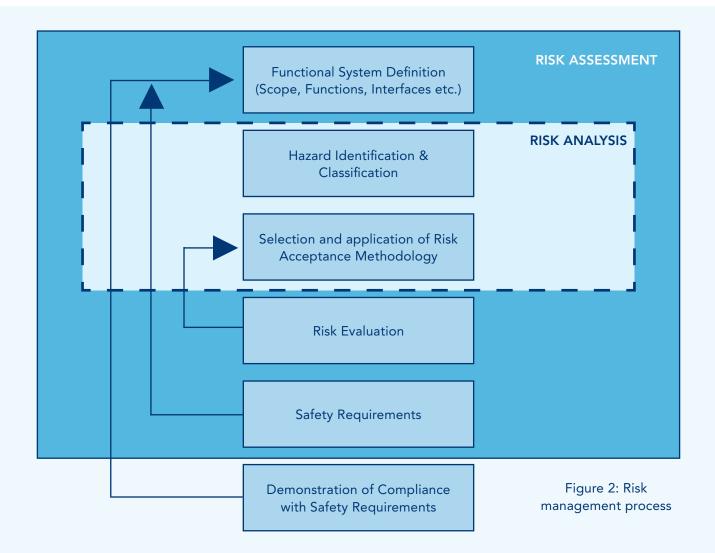
6.1 General description

6.1.1 The risk assessment process (see Figure 2 below) is an iterative process that comprises:

- a. the functional system definition;
- b. the risk analysis including the hazard identification;
- c. the risk evaluation; and
- d. the safety requirements.

The risk assessment process should comply with the processes of hazard management as described in paragraph 8.1. 6.1.2 The functional system definition should address, as a minimum the:

- a. objective, e.g. intended purpose;
- sub-functions and elements, where relevant (including e.g. human, technical and operational elements);
- c. boundary including other interacting functional systems;
- d. physical (i.e. interacting sub-systems), input and output interfaces;
- e. environment (e.g. traffic loading, complexity, class of airspace etc);
- f. existing safety measures and, after



iterations, definition of the safety requirements identified by the risk assessment process; and

g. assumptions which should determine the limits for the risk assessment.

6.1.3 A hazard identification should be carried out on the functional system definition, in accordance with paragraph 6.2. It should include both normal and abnormal conditions; where abnormal conditions are considered to be changes in the operational environment that the functional system may exceptionally encounter (e.g. change of runway etc.).

6.1.4 For the hazards that are not considered to be broadly acceptable, the risk acceptability of the functional system of each hazard should be evaluated using one of the following risk acceptance methodologies:

- a. the application of codes of practice (paragraph 6.3);
- b. a comparison with similar reference functional system (paragraph 6.4); and/or
- c. an explicit risk estimation (paragraph 6.5).

6.1.5 As depicted in Figure 7 (Annex I), the ANSP should apply the codes of practice in preference to the similar reference function system and the similar reference functional system in preference to explicit

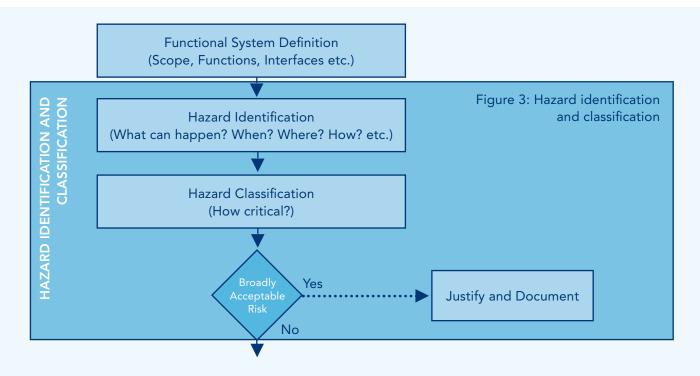
risk estimation. The ANSP should also demonstrate during the risk evaluation that the selected risk acceptance methodology is adequately applied and used consistently.

6.1.6 The application of these risk acceptance methodologies should identify possible safety measures which make the risk(s) of the functional system under assessment acceptable. Among these safety measures, the ones selected to control the risk(s) should become the safety requirements to be fulfilled by the functional system. Compliance with these safety requirements should be demonstrated in accordance with Section 7.

6.1.7 The iterative risk assessment process can be considered as completed when it is demonstrated that all safety requirements are fulfilled and no additional reasonably foreseeable hazards have to be considered.

6.2 Hazard identification and Classification

6.2.1 The ANSP should systematically identify all reasonably foreseeable hazards for the functional system and its interfaces under assessment (see Figure 3 below). The ANSP is responsible for ensuring the assessment team is sufficiently competent and comprises a wide



range of technical expertise. All identified hazards should be registered in the hazard record in accordance with Section 7.

6.2.2 To focus the risk assessment efforts upon the most important risks, the hazards should be classified as to whether they are broadly acceptable or not. This will be undertaken through expert judgement. Hazards associated with broadly acceptable risk need not be analysed further but should be registered in the hazard record. Their classification should be justified.

6.2.3 As a criterion, risks resulting from hazards may be classified as broadly acceptable when the risk is to all intents and purposes insignificant, negligible, or so small that it is not reasonable to implement any additional safety measures. The expert judgement should take into account that the contribution of all the broadly acceptable risks does not exceed a defined proportion of the overall risk.

6.2.4 It is expected that the type of hazards classified as broadly acceptable are those that could be considered as catastrophic hazards such as a meteor strike, tsunami etc. but that are sufficiently unlikely to occur such that they constitute a broadly acceptable risk.

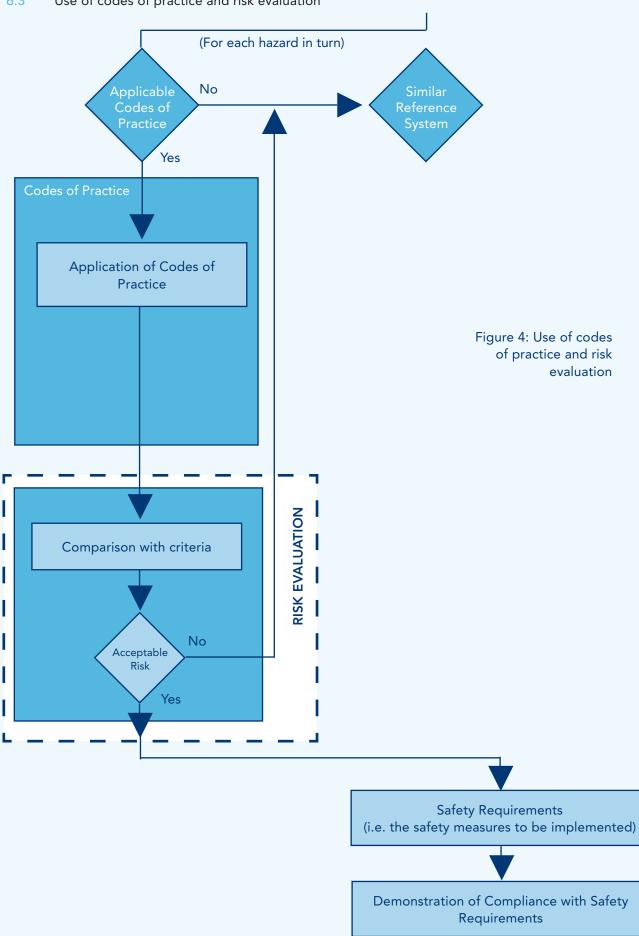
6.2.5 During the hazard identification, safety measures may be identified. They should be registered in the hazard record according to Section 7.

6.2.6 The hazard identification only needs to be carried out at a level of detail necessary to identify where safety measures are expected to control the risks in accordance with one of the risk acceptance methodologies mentioned in paragraph 6.1.4. Iteration may thus be necessary between the risk analysis and the risk evaluation phases until a sufficient level of detail is reached for the identification of hazards.

6.2.7 Whenever a code of practice or a reference functional system is used to control the risk, the hazard identification can be limited to:

- the verification of the relevance of the code of practices and/or of the reference functional system;
- b. the identification of the deviations from the code of practices or from the reference functional system.

6.2.8 Individual hazards may be closed through the application of one of the risk assessment methodologies described in paragraph 6.1.4. It is likely that for most major changes a combination of the three methodologies will be used. However, given the possibility of a range of hazards it may be more efficient and practical to apply one methodology to all the hazards.



6.3 Use of codes of practice and risk evaluation

6.3.1 The ANSP, with the support of other involved stakeholders and based on the requirements listed in paragraph 6.3.2 should analyse all identified hazards to establish whether they can be appropriately covered by the application of relevant codes of practice (see Figure 4 on the previous page).

6.3.2 The codes of practice should satisfy at least the following requirements:

- a. be widely acknowledged in the aviation domain. If this is not the case, the use of the codes of practice will have to be justified;
- b. be relevant for the control of the considered hazards in the functional system under assessment; and
- c. be publicly available for all stakeholders who want to use them.

6.3.3 To be satisfied that the code of practice is relevant for the control of the specific hazard, the ANSP must demonstrate that

- a. the hazards have been correctly identified;
- b. the code(s) of practice are relevant to the hazards; and
- c. the application of the code of practice controls the hazards.

6.3.4 If one or more hazards are controlled by codes of practice fulfilling the requirements of paragraph 6.3.2 then the risks associated with these hazards should be considered as acceptable. This means that:

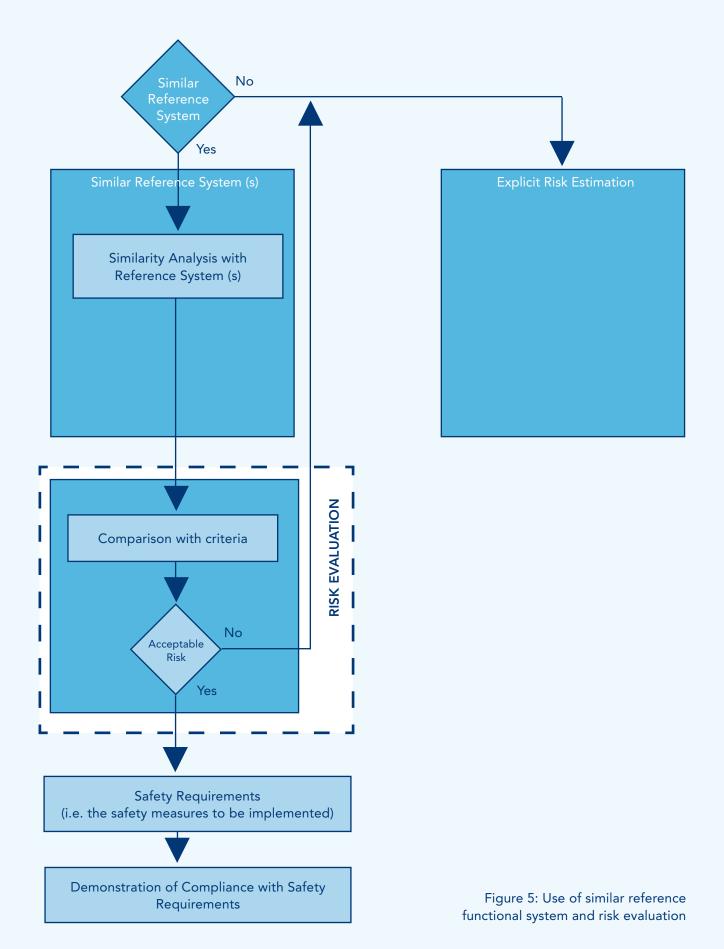
- a. these risks need not be analysed further; and
- the use of the codes of practice should be registered in the hazard record as safety requirements for the relevant hazards.

6.3.5 If the risk for a particular hazard cannot be made acceptable by the application of codes of practice, additional safety measures should be identified applying the similar reference functional system methodology.

6.3.6 For hazards that are controlled by codes of practice the risk management process may be limited to:

- a. the hazard identification in accordance with paragraph 6.2.6;
- b. the registration of the use of the codes of practice in the hazard record in accordance with paragraph 6.3.4; and
- c. the documentation of the application of the risk management process in accordance with Section 9.

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6.4 Use of similar reference functional system and risk evaluation

6.4.1 For those hazards that cannot be covered by an applicable code of practice, the ANSP with the support of other involved stakeholders, should determine whether the remaining hazards can be covered by a similar reference functional system (see Figure 5 on the previous page).

6.4.2 A similar reference functional system should satisfy at least the following requirements:

- a. it has already been proven in-use to have an acceptable safety level;
- b. it has comparable functions and interfaces as the functional system under assessment;
- c. the functional dependencies are no more onerous than the functional system under assessment;
- d. it is used under similar operational conditions (separation standard etc.) as the functional system under assessment; and
- e. it is used under similar environmental conditions as the functional system under assessment.

6.4.3 If a similar reference functional system fulfils the requirements listed in paragraph 6.4.2 then for the functional system under assessment:

- a. the risks associated with the hazards covered by the reference functional system should be considered as acceptable;
- b. the safety requirements for the hazards, which are covered by the reference functional system, may be derived from the safety analyses or from an evaluation of safety records of the reference functional system; and
- c. these safety requirements should be registered in the hazard record as safety requirements for the relevant hazards.

6.4.4 In the case of paragraph 6.4.3 (a), it is unlikely that in-service history alone will prove that a high integrity system has an acceptable safety level. Evidence that sufficient safety engineering principles were used in the development of the similar reference functional system will need to be confirmed.

6.4.5 There may be circumstances where some functions within a reference functional system do not fulfil all the requirements listed in paragraph 6.4.2, additional safety measures should be identified for these deviating functions, applying the explicit risk estimation methodology.

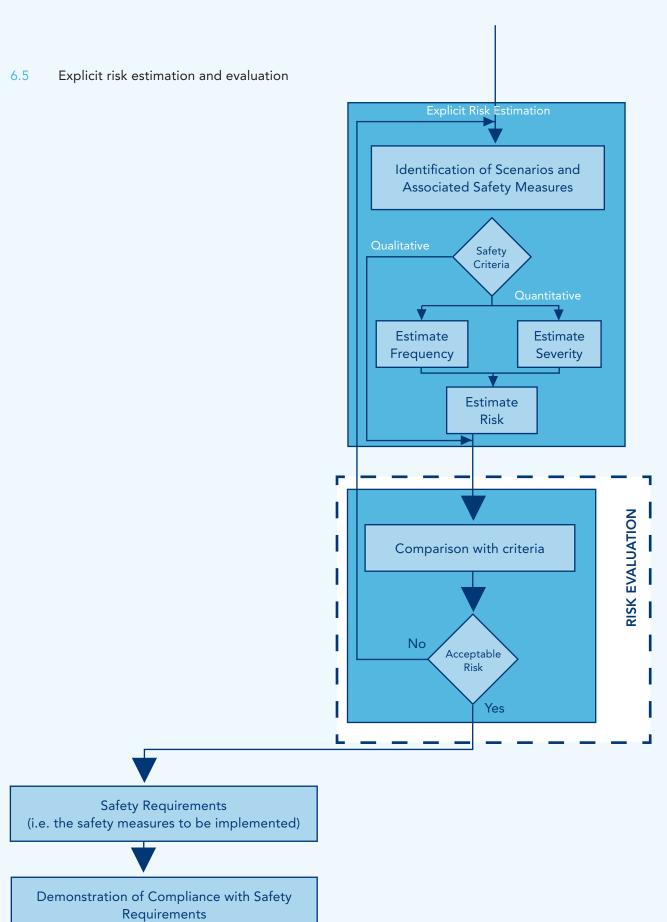


Figure 6: Explicit risk estimation and evaluation

6.5.1 When the hazards are not covered by either applicable codes of practice or a similar functional reference system as described in section 6.3 and 6.4 respectively, the demonstration of the risk acceptability should be performed by explicit risk estimation methodology. Risks resulting from these hazards should be estimated either quantitatively or qualitatively, taking existing safety measures into account.

6.5.2 The acceptability of the estimated risks should be evaluated using risk acceptance criteria (see Figure 6 on the previous page) using estimates of severity and frequency of the risk. The risk acceptance criteria are used to judge whether the risk has been sufficiently reduced, and to an acceptable level, to permit the implementation of the change. This process does not impose any specific tools or techniques which should be used for explicit risk estimation but this may include the application of an approved risk classification scheme or the demonstration that the change achieves a target level of safety, which should be in accordance the ANSP's SMS.

6.5.3 Depending on the risk acceptance criteria, the acceptability of the risk may be evaluated either individually for each associated hazard or globally for the combination of all hazards considered in the explicit risk estimation. If the estimated risk is not acceptable, additional safety measures should be identified and implemented in order to reduce the risk to an acceptable level.

6.5.4 When the risk associated with one or a combination of several hazards is considered as acceptable, the identified safety measures should be registered in the hazard record.

6.5.5 The explicit risk estimation and evaluation should satisfy at least the following requirements:

- a. the methods used should reflect correctly the functional system under assessment and its parameters (including all operational modes); and
- b. the results should be sufficiently

accurate to serve as robust decision support, i.e. minor changes in input assumptions or prerequisites should not result in significantly different requirements.

2

Demonstrations of the compliance with safety requirements

7.1 Prior to the safety acceptance of the change, fulfilment of the safety requirements resulting from the risk assessment phase should be demonstrated under the supervision of the ANSP.

7.2 This demonstration should be carried out by each of the stakeholders responsible for fulfilling the safety requirements, as decided in accordance with paragraph 4.2.

7.3 Any inadequacy of safety measures expected to fulfil the safety requirements or any hazards discovered during the demonstration of compliance with the safety requirements should lead to reassessment and evaluation of the associated risks by the ANSP according to Section 3. The new hazards should be registered in the hazard record according to Section 8.

7.4 Additionally, it is recommended that an independent assessment of the risk management process is performed which should form part of the safety acceptance of the change. This should be undertaken by either an external body or independent in-house representative.

8

Hazard management

8.1 Hazard management process

8.1.1 Hazard record(s) should be created or updated (where they already exist) by the ANSP during the design, implementation and acceptance of the change or the delivery of the safety assessment report. The hazard record should also track the progress in monitoring risks associated with the identified hazards. The hazard record should include all hazards, together with all related safety measures and functional system assumptions identified during the risk assessment process. In particular, it should contain a clear reference to the origin and to the selected risk acceptance methodologies and should clearly identify the stakeholder(s) in charge of controlling each hazard. Where multiple stakeholders maintain separate hazard record the ANSP should be responsible for coordinating the management of the overall record.

8.2 The hazard record should be updated if:

- other significant changes occur to the system;
- b. a new hazard is discovered;
- c. there are new accident of incident data; or
- d. assumptions about the system have changed.

8.3 Stakeholder Management

All hazards and related safety requirements which cannot be controlled by one stakeholder alone should be communicated to another relevant stakeholder in order to find jointly an adequate solution. The hazards registered in the hazard record of the stakeholder who transfers them should only be recorded as 'controlled' when the evaluation of the risks associated with these hazards is made by the other stakeholder and the solution is accepted by all concerned.

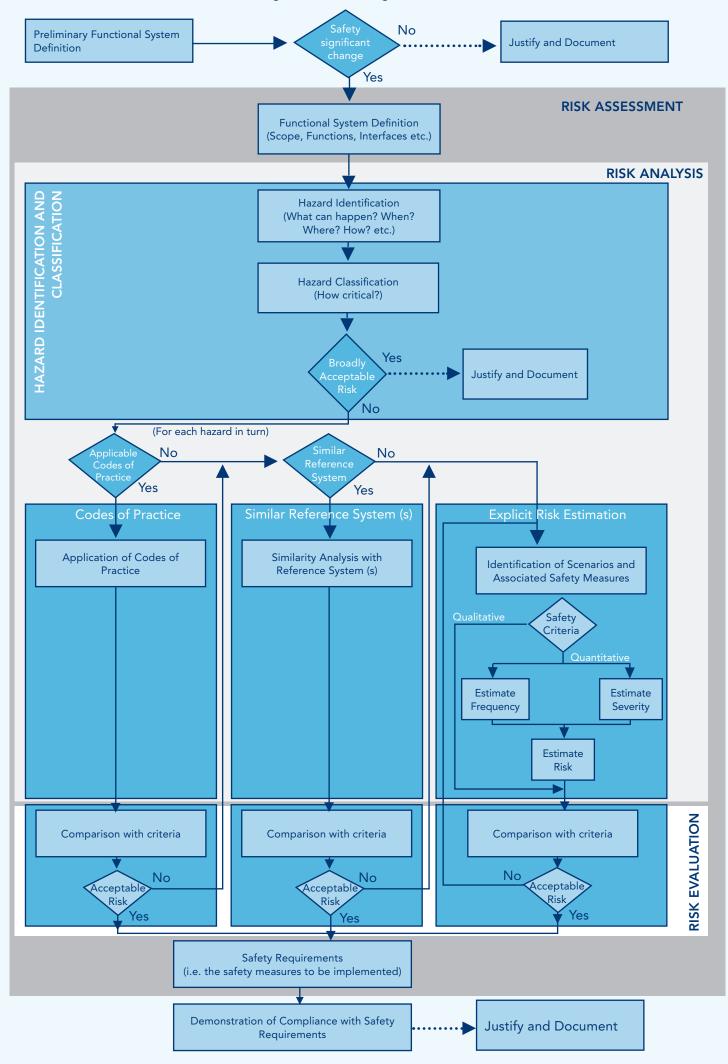
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Evidence from the application of the risk management process

9.1 The risk management process used to assess the safety levels and compliance with safety requirements should be documented by the ANSP in such a way that all the necessary evidence showing the correct application of the risk management process is available. 9.2 The document produced by the ANSP under paragraph 9.1 should at least include:

- a. description of the organisation and the experts appointed to carry out the risk assessment process; and
- b. results of the different phases of the risk assessment and a list of all the necessary safety requirements to be fulfilled in order to control the risk to an acceptable level.

Figure 7: Risk Management Framework



Definitions

'ANSP' means the Air Navigation Service Provider proposing the change that may be subject to risk assessment;

'catastrophic consequence' means fatalities and/or multiple severe injuries and/or major damages to the environment resulting from an accident;

'code of practice' means a written set of rules or standards that are widely accepted that, when correctly applied, can be used to control one or more specific hazards and are publicly available;

'function' means a task or activity that a human has been trained or systems equipment has been designed to perform;

'functional system' means a combination of systems (equipment, procedures and human resources) organised to perform a function within the context of air navigation service provision;

'hazard' means a condition that could lead to an incident;

'hazard identification' means the process of finding, listing and characterising hazards;

'hazard record' means the document in which identified hazards, their related measures, their origin and the reference to the organisation which has to manage them are recorded and referenced;

'interfaces' means all points of interaction during a functional system or subsystem life-cycle, including operation and maintenance where different stakeholders will work together in order to manage the risks;

'reference functional system' means a functional system proven in use to have an acceptable safety level and against which the acceptability of the risks from a functional system under assessment can be evaluated by comparison;

'risk^{4'} two definitions are proposed; 1- the predicted likelihood and severity of the consequences or outcomes of a hazard [ICAO Annex 19] and 2- the effect of uncertainty on objectives ISO [31000:2009]. The reader should select whichever definition best aligns with their required purpose; 'risk analysis' means systematic use of all available information to identify hazards and to estimate the risk;

'risk assessment' means the overall process comprising a risk analysis and a risk evaluation;

'risk acceptance criteria' means the terms of reference by which the acceptability of a specific risk is assessed; these criteria are used to determine that the level of a risk is sufficiently low that it is not necessary to take any immediate action to reduce it further;

'risk acceptance methodology' means the rules used in order to arrive at the conclusion whether or not the risk related to one or more specific hazards is acceptable;

'risk estimation' means the process used to produce a measure of the level of risks being analysed, consisting of the following steps: estimation of frequency, consequence analysis and their integration;

'risk evaluation' means a procedure based on the risk analysis to determine whether the acceptable risk has been achieved;

'risk management' means the systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risks;

'safety' means freedom from unacceptable risk of harm;

'safety measures' means a set of actions either reducing the rate of occurrence of a hazard or mitigating its consequences in order to achieve and/or maintain an acceptable level of risk (likely to result in the derivation of safety requirements);

'safety requirements' means the safety characteristics (qualitative or quantitative) of a functional system and its operation (including operational rules) necessary in order to control risk.;

'stakeholders' means all parties which are, directly or through contractual arrangements, affected by the change.

⁴ The definition of risk does not refer to the severity of the 'harm' caused, this is because in ATM there are typically two outcomes; 'no effect' or a catastrophic accident and there is insufficient granularity in the degree of severity of the harm.

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