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Safety Risk Management (SRM) Principles & Tools

(SRS-101&102 supporting documentation)

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The Company Safety Risk Management

Safety Risk Management (SRM)

- SRM relies on the following activities (often named HIRM):
  - **Hazard Identification (HI)**
  - **Safety Risk Assessment and Mitigation (RM)**

- The **aim of SRM is to prevent the occurrence of serious incidents or accidents**.

- SRM is a core activity of the Company SMS because it incorporates **decision making tools and provide a formalized approach to safety.**

- The result of the SRM is **actionable safety intelligence consisting of safety recommendations;** this is where a risk-based decision-making process starts. In general, SRM is used to evaluate the need for, and to develop, safety risk controls for new and existing safety issues in the Design/Production/Services Systems.

- **The SRM final goal is to put in place tools for identifying hazards, analyzing them** (in terms of probability and severity of the consequences), **assessing them** (in terms of tolerability) **and controlling them through "safety barriers" able to prevent and/or mitigate them.**

The Company Safety Risk Management

Safety Risk Management (SRM)

The Company Safety Risk Management shall be performed in the following processes and components:

- **Hazard identification;**
- **Safety Risk Assessment and Mitigation process;**
- **Safety performance monitoring and measurement (within Safety Assurance);**
- **The management of change (within Safety Assurance);**
- **Safety investigation;**
- **Emergency Response Plan (ERP)**

The Company SRM main objective is to make sure that **all risks in the previous processes are identified and remain at an acceptable level**, through the application of a systematic, robust and intellectually cohesive **Risk Assessment and Risk Mitigation process**.

Risk Assessment has a central role and is the most challenging part of the risk management process for aviation operations. This is due to the subjectivity involved in determining the severity of the consequences when a hazard is released and the lack of quantitative information on the probability of this occurring.

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Hazard Identification (HI)

1) **A hazard is a condition or an object with the potential to cause or contribute to an aircraft incident or accident.**
   - Hazards can **originate from technical, environmental, human and organizational factors**.
   - With regard to design, certification, manufacturing, in-service and maintenance activities, hazards are the conditions that could lead to a noncompliant/nonconforming product that, if not addressed, could raise the risk to an unacceptable level.
   - The biggest source of hazard identifications are: **Staff reports, FDM Flight Data Monitoring, Safety Audits, etc**.
2) The Company HI process consists of:
   a) **analyzing high risk organization activities or organizational change**
      - by internal proactive assessments, learning from own people/expert sessions, brainstorming on new hazards (e.g. coming from new technologies with features not yet totally captured by rules/procedures) (see also Appendix 1);
      - by elaborating on known hazards.
   b) **analyzing data from both internal and external sources** (e.g. continued airworthiness data, operators' feedback, subcontractors' information, hazards identified by Authorities or data from voluntary reporting) (see also Appendix 2).
3) Hazards can be identified :
   - **based on data from events that have occurred (reactive methods)**; or
   - **in anticipation of potential events that could lead to an unacceptable risk (proactive methods) with a dedicated assessment.**

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Hazard Identification (HI) – Main source of data

Regarding the HI process of collecting and analyzing operational data, to identify Safety Issues or threats (hazards), these are the main sources of Safety Data:

- **Company Internal (for manufacturing PO or maintenance activities MO or both)**
  - Occurrence Reporting
  - Voluntary Occurrence Reporting
  - Safety and Compliance Monitoring and Audits
  - Questionnaires / personal Surveys
  - Safety Survey and inspection
  - any work performed not in accordance with approved data
  - any tool deviation detected during calibration;
  - FOD (Foreign Object Damage)
  - Internal Safety Reporting
- **Company Internal (for Continued Airworthiness activities DO)**
  - in service events (e.g., failures, malfunctions, or defects)
  - quality escapes
  - flight test events;
  - supplier notices of escapement;
  - non-compliance's related to product certificates or approvals.
- **External**
  - accident and incident reporting (both Company or customers)
  - supplier notices of escapement (…)
  - technical publications from manufacturers
  - Safety Information Bulletins, safety alerts and other safety publications from EASA, the European Commission, ENAC, the National Aviation Authorities, ICAO, Eurocontrol, the FAA and other authorities worldwide
  - websites such as http://www.ntsb.gov/, http://www.ansv.it/, SKYbrary
  - safety publications by national or international associations and safety initiatives
  - safety publications by industry and research Organizations by national or international associations and safety initiatives such as ESPN-R and IHSF https://www.easa.europa.eu/easa-and-you/safety-management/safetypromotion/european-safety-promotion-network-rotorcraft-espn-rhttp://ihsf.aero/;
  - professional journals, conference proceedings, safety campaigns, helicopter safety days
  - benchmarks between operators, data aggregated at sector level or by the manufacturers, etc.
  - Safety External stakeholder process

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Hazard Identification (HI) – Occurrence and Hazard Reporting

The Company reporting system is both **reactive (accident/incident reports etc.) and proactive/predictive (e.g., hazard reports, etc.).**

The aim is to capture internal occurrences including accidents, incidents, and other occurrences relevant the SMS, e.g.:

- **Events:** even if a distinction needs to be made between **mandatory reports (accidents, serious incidents, major defects,** etc.) which are required to be notified to the competent authority and other routine occurrence reports which remain within the Company.
- **Reporting system:** specifically a **voluntary hazard/occurrence reporting system**, incorporating appropriate identity/data protection as applicable. All employees are advised that the Company will not initiate disciplinary actions against an employee who discloses a safety related occurrence.
- **High consequence reports and associated recommendations:** addressed to and reviewed by appropriate level of Company Top Management.
- **Near errors or near misses reporting: this will be treated as "free lessons**." There could be a "learning opportunity" that occurs without the expense of an hazardous event. Reporting of these events is to be encouraged and is the duty of every employee. These "free lessons" will enable the Company to develop "safety nets" or corrective actions to help ensure that a "near miss" never becomes a hazardous event.

- **The Company has developed a Voluntary Reporting System for employees for reporting safety information.**
- **The system is designed to protect the identity of the employee who provides the information.**

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Hazard Identification (HI) – The Reporting System

The Company uses two types of reporting systems:

1) **Mandatory Reporting** System requires the reporting of certain types of events. This necessitates implementation of detailed regulations identifying the reporting criteria and scope of reportable occurrences.
   - **Mandatory reporting systems tend to collect more information related to high consequence technical failures than on other aspects of operational activities.**

2) **Voluntary Reporting** System allows for the submission of information related to **observed hazards or inadvertent errors without an associated legal or administrative requirement** to do so.
   - In these systems, regulatory agencies or Organizations may offer an incentive to report. For example, enforcement action may be waived for reports of inadvertent errors or unintentional violations. Under these circumstances, **reported information should be used solely to support the enhancement of safety**. Such systems are considered non-punitive as they afford protection to reporters thereby ensuring the continued availability of such information to support continuous improvements in safety performance.
   - Voluntary reporting systems, requiring that any identifying information about the reporter is known only to gatekeepers in order to allow for follow-up action. Voluntary events and incident reporting systems facilitate the disclosure of hazards leading to human error, without fear of retribution or embarrassment.

The Company tools for safety reporting are accessible to all personnel in paper or digitized forms (PC / App).

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Hazard Identification (HI) – The Voluntary Reporting System

The key objective of the Company Voluntary Reporting System is to **enhance the safety of the Company aviation activities** through the collection of Voluntary Occurrence Reports (VOR) on actual or potential safety deficiencies that would otherwise not be reported through other channels. The Voluntary Reporting System is managed by the **Safety Manager (SM) in each Local SMS**.

- **When to make such a report.** The report shall be done when:
  - the originator wishes for others to learn and benefit from the incident or hazard but are concerned;
    - about identity protection;
    - there is no other appropriate reporting procedure or channel;
    - the reporter has tried other reporting procedures or channels without the issue having been addressed.
- **How are reports processed:**
  - The system focuses on the **protection of the originator's identity when processing the data**. Every VOR will be assessed, analyzed and validated by the SM. When all information is complete and coherent, the SM will de-identify the report and enter the data into the database.
  - If additional information is not needed, the SM, having registered the date, **will eventually return the report to the originator within max 10 (ten) working days providing the relevant feedback.**

If the content of a report suggests a situation or condition that poses **an immediate or urgent threat to aviation safety, the report will be handled with priority** and referred, after de-identification, to the relevant Organizations or Authorities as soon as possible to enable the necessary safety actions.

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Hazard Identification (HI) – External accident / incident reporting

All the Company and Local SMS will also take in consideration the **accidents, reports, incidents investigation and follow-up, involving the Company aircrafts and to customers**, to assure prevention of further occurrences in case training is required as a preventative action.

Each Local SMS receives the relevant information on accident/incidents involving the Company aircrafts from the Accidents/Incidents Investigations department.

All the external accident/incident reports/information received by each Local SMS are analyzed (initial analysis) by the Safety Manager in order to identify the accident/incident triggering events.

The initial analysis assesses if the Local SMS's activities had a role (directly or indirectly) in the accident/incident outcome. If so, the **Safety Manager will put together an Safety Action Group (SAG) (or specific SWG) to perform a detailed Safety data analysis** in order to identify potential Safety Issue / hazards which need to be formally risk assessed to determine the level of risk and to design appropriate risk reduction measures.

If there is no impact on training the main information on the event is posted by the SM on the Company Intranet Safety page to promote awareness.

The Company Safety Risk Management

Safety Risk Assessment and Mitigation (RM)

The Company SRM process requires the analysis of safety risks, originated by identified hazards, to determine their severity and probability of happening.

Safety risks shall also be assessed to **determine their acceptability**; the aspects to consider in the assessment include: **technical matters, processes, human behaviors and organizational aspects (including interface management).**

A large part of the Company SRM process may already be monitored in the frame of **compliance with other regulations,** such as the following:

- **during design and certification**: compliance with existing **certification procedural and airworthiness regulations**, defines an acceptable safety risk;
- **during manufacturing**: a product's conformity to its approved design and conditions for safe operation are already defined **by Part 21 requirements**. The associated manufacturing and conformity attestation processes are an suitable way to achieve an acceptable level of safety risk;
- **during the Continued Airworthiness (CA) phase (including in-service and maintenance):** safety risk acceptability is defined by the continued airworthiness for in service products. Safety risk acceptability during the continued airworthiness phase should be based on consideration of the applicable airworthiness standards and the assurance that no unsafe condition exists. A product in an unsafe condition implies unacceptable safety risk and requires appropriate safety risk management through proper mitigating and corrective actions.

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Safety Risk Assessment and Mitigation (RM) (cont.)

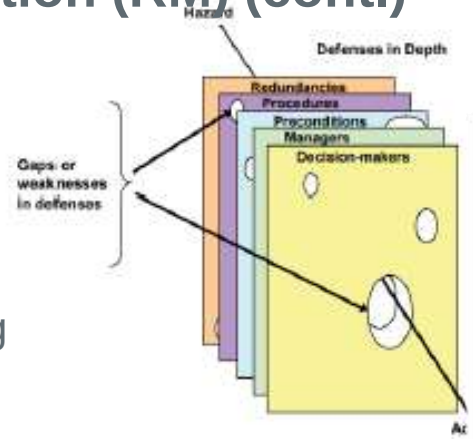

Figure 5: Defenses in Depth Philosophy

The Company SRM that combines the following processes and components:

- **system description**;
- **hazard identification**;
- **estimate of the severity and likelihood** of the consequences of the occurring hazard;
- **evaluation of the risk**;
- **risk mitigation**;
- **claims, arguments and evidence** that the safety action(s) have been met and documented in a safety case;
- **monitoring of the results**;
- **safety investigation**.
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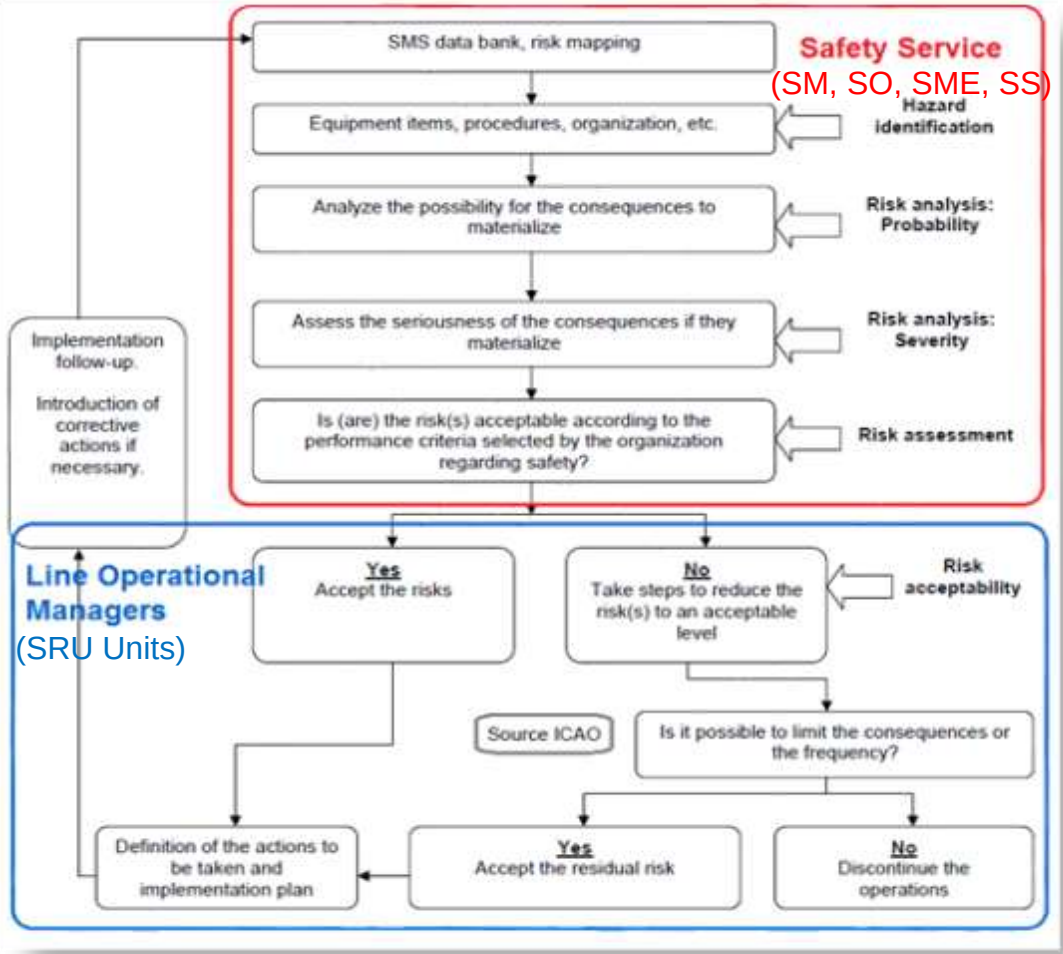

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Safety Risk Assessment and Mitigation (RM) (cont.)

- **Engineering judgement/qualitative assessment shall be considered as minimum acceptable means** to identify and assess safety risks.
- Organizations that have implemented a process for **Continued Airworthiness (CA), have already the main foundations for collecting, analyzing and mitigating risks related to the product and its utilization**. The CA process:
  - includes **failure, malfunction and defects collection, risk analysis and actions to maintain product airworthiness**, and is a major contributor to the Company SRM process and an input to the Safety Assurance (SA).
  - includes contributions from all stakeholders, such as Design, Manufacturing, Training and Maintenance Organizations.
- **CA activities shall be complemented with proactive Safety Risk Management** to enhance the product safety beyond continued airworthiness duties.
- **Once the safety risk controls have been implemented, the safety performance shall be monitored through SA.**
- **The Company SRM outputs shall be documented.** This should include the hazard and any consequences, the safety risk assessment and any safety risk control actions.
  - These are captured in a **register so they can be tracked and monitored (Company/SMS HIRM Libraries).**
  - The SRM documentation becomes a **historical source of the Company safety knowledge** which can be used as reference when making safety decisions and for safety information exchange.
  - This safety knowledge provides material for **safety trend analyses and safety training and communication**. It is also useful for internal audits to assess whether safety risk controls and actions have been implemented and are effective

The Company Safety Risk Management

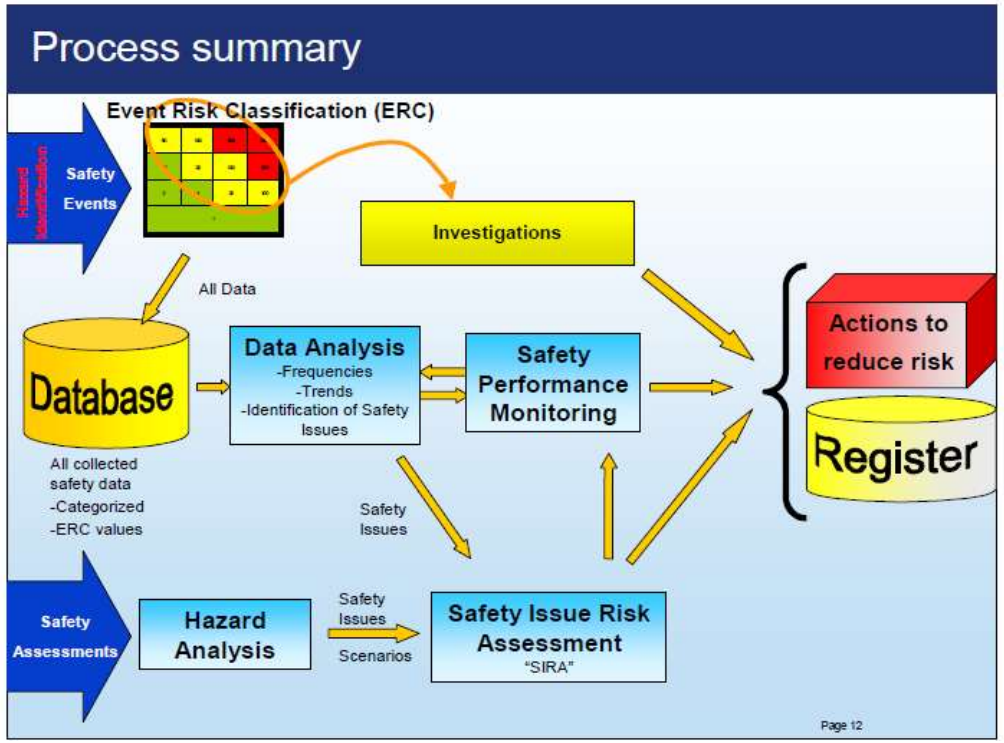
Scope of Safety Risk Assessment

The Company Risk Assessment primary focus is on **operational Flight Safety risks**, i.e. any risks that could harm the occupants of an aircraft (passengers and crew) as for FALs, ATO and Experimental Flights, though the risk assessment may be extended to all aviation operational risks (PO, DO, MO, etc.).

Operational Risk Assessment is needed in three different contexts:

1) **Individual Safety Events** may reflect a high level of risk and consequently require urgent action. Therefore all incoming events need to be risk assessed. This step is called **Event Risk Classification (ERC).**

2) **Data Analysis and Hazard Identification/Analysis process**: these may lead to the identification of **Safety Issues**, which need to be risk assessed to determine what actions, if any, are needed. This step is called **Safety Issue Risk Assessment (SIRA)**. The whole process ensures that any necessary safety actions are identified, meanwhile creating a Register for following up risks and actions and providing a Safety Performance Monitoring function.



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Scope of Safety Risk Assessment (cont.)

3) from time to time there is a need to carry out **Safety Assessments**, typically related to a **new or revised activity**. The activity needs to be risk assessed at the planning stage, according to the "**Management of Change**" process. This consists of prospective analysis: **an assessment capable of predicting and anticipating in advance the consequences of systemic interactions**, given certain initiating events and boundary conditions.

- **In the first two cases, the assessment is based on Hazard Identification data**. The result is an operational risk profile, i.e. an overview of all operational risks.
- In the third case, **there may be no data available** if the planned activity is new or a change of the Organization.

In all three cases, the risk assessment shall consider the potential consequences in addition to the observed actual consequences of events.

Both ERC and SIRA are based on new concepts that make the assessments conceptually more robust whilst keeping them pragmatic and simple.

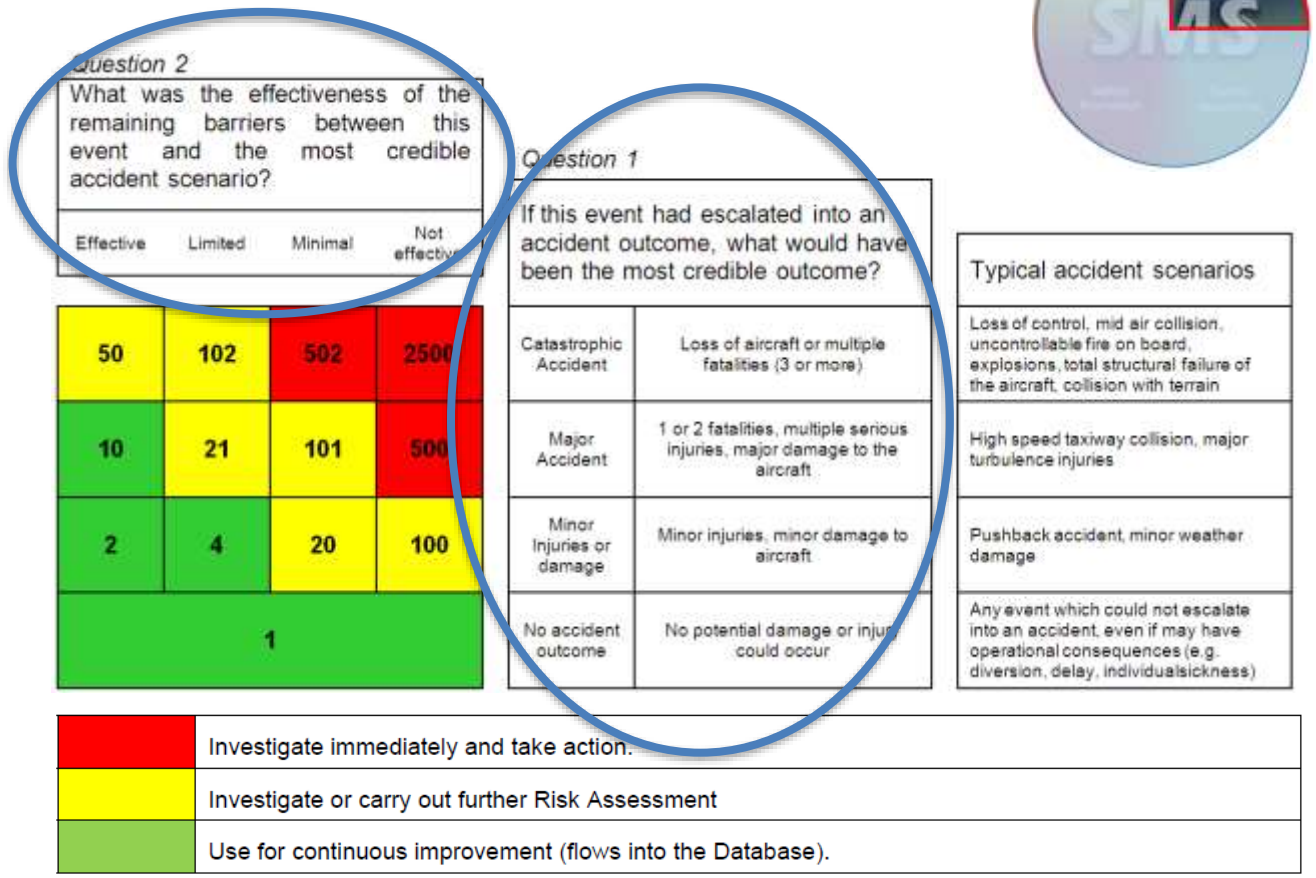
The Company Safety Risk Management

Event Risk Classification (ERC)

The main objective of ERC is to act as the **first screening of all incoming safety data and to identify when urgent action is necessary**. The ERC should take place preferably within one or two days of the event and be carried out by a person with operational experience who has been trained in risk assessment, a Safety Specialist.

The ERC may typically apply to safety events detected during Flight Simulation training, Flight Operations.

The ERC is based on the concept of **"event-based risk" (EBR), which is an assessment of the risk associated with that one event** (and not the risk associated with all similar events).



The ERC value is based on **two questions (see ovals) and has two outputs**.

1) first output is **a recommendation on what should be done** about the event.
2) second output is a **number, called the ERC risk index,** a quantitative relative risk value useful in statistics.

In case of several possible accident outcomes, ERC should be run on each. The priority would be **on those with highest scores**.

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Risk Assessment: Description and Evaluation

Risk combines two dimensions, both to be assessed: **likelihood of hazard consequences and their severity.**

1) Analysis of likelihood / probability

- Assessment of likelihood / probability is based on the following two way process:
  - **hazard consequences are analyzed to establish possible causes or contributing factors,**
  - **causes and contributing factors are then further analyzed to determine likelihood of an occurrence.**
- In the causal analysis of consequence, **human and organizational factors will be considered** for their possible contributing effects. Accordingly, direct causes (‘unsafe acts’), workplace factors and Organizational factors (‘error provoking or latent conditions’) will be considered as well.
- The effects of existing likelihood-reducing factors and barriers that influence the chain of events need to be also considered and documented, taking into account the following:
  - **certification requirements;**
  - **maintenance procedures;**
  - **existing normal and abnormal procedures;**
  - **technical measures/equipment;**
  - **training;**
  - **other human and Organizational factors.**

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Risk Assessment: Description and Evaluation (cont.)

1) **Analysis of likelihood / probability (cont.)**

Likelihood may be expressed using terminology such as:

- **very low;**
- **low;**
- **medium;**
- **high; and**
- **very high.**

The following table is an example of what the Company may use for determining likelihood

RISK LIKELIHOOD	MEANING	VALUE
FREQUENT	**Likely to occur many times.** Has already occurred in the Company (Freq. > 3 times per year – indicative*). Has occurred frequently in the history of the aviation industry.	5
OCCASIONAL	**Likely to occur sometimes.** Has already occurred in the Company (Freq. < 3 times per year – indicative*). Has occurred infrequently in the history of the aviation industry.	4
REMOTE	**Unlikely to occur, but possible.** Has already occurred in the Company at least once or. Has seldom occurred in the history of the aviation industry.	3
IMPROBABLE	**Very unlikely to occur.** Not known to have occurred in the Company but has already occurred at least once in the history of the aviation industry.	2
EXTREMELY IMPROBABLE	**Almost inconceivable that the event will occur.** It has never occurred in the history of the aviation industry.	1

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Risk Assessment: Description and Evaluation (cont.)

2) Analysis of severity

- The severity of all hazard consequences is then analyzed. The analysis will consider **immediate consequences and consequences that only become apparent afterwards**, such as effects on the natural and work environment.
- Consequences are grouped such as loss or damage of **life/health, environment, material values/assets, functions and reputation**.

SEVERITY OF OCCURRENCE	MEANING				VALUE
	PERSONNEL	ENVIRONMENT	MATERIAL VALUES & ASSETS	REPUTATION	
CATASTROPHIC	Multiple fatalities	Massive effects (pollution, destruction, etc.)	Catastrophic financial loss Damage > 1 M€	International impact	E
HAZARDOUS	Fatality	Effects difficult to repair	Severe financial loss with long term effects Damage < 1 M€	National impact	D
MAJOR	Serious injuries	Noteworthy local effects	Substantial financial loss Damage < 250K€	Considerable impact	C
MINOR	Light injuries	Little impact	Financial loss with little impact Damage < 50K€	Limited impact	B
NEGLIGIBLE	Superficial or no injuries	Negligible or no effects	Financial loss with negligible impact Damage < 10K€	Light or no impact	A

- The determination of severity is normally of a **descriptive (qualitative/ordinal terms) nature except when relevant calculations (quantitative) can or should be applied**. A qualitative analysis describes the chains of events that could follow from the hazard and its possible consequences. Quantitative analysis is used to calculate

- **Severity can be expressed using terminology like ‘very small, small, medium, large and very large’. The meaning of each term is then expressed in words and/or numbers / ranges.**
- Beside is an example that the Company and Local SMS may use for determining severity.

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Risk Assessment: Description and Evaluation (cont.)

2) Analysis of severity (cont.)

- In the analysis of severity of each consequence, **human and organizational factors are primarily considered** for their possible contributing effects.
- The **effects of existing recovery controls and barriers** that influence the consequence itself or the consequence chain **should be considered**, as applicable:
  - certification requirements (e.g. fire protection);
  - existing abnormal and emergency procedures;
  - secondary safety measures (e.g. crashworthiness, personal protective equipment);
  - technical measures/equipment;
  - training;
  - human and organizational factors;
  - emergency preparedness.
- **Risk levels may vary over time** depending on the nature of the operation(s) (machines and equipment, procedures and documentation, flight environment, personnel qualification, duration of the tasks, etc.).

Or, alternative example

Severity of Occurrence	Meaning	Value
Catastrophic	Equipment destroyed Multiple deaths	A
Hazardous	A large reduction in safety margins, physical distress or a workload such that the operators cannot be relied upon to perform their tasks accurately or completely Serious injury Major equipment damage	B
Major	A significant reduction in safety margins, a reduction in the ability of the operators to cope with adverse operating conditions as a result of an increase in workload or as a result of conditions impairing their efficiency Serious incident Injury to persons	C
Minor	Nuisance Operating limitations Use of emergency procedures Minor incident	D
Negligible	Few consequences	E

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Risk Assessment: Description and Evaluation (cont.)

3) Risk description

- The risk description forms the basis for risk evaluation and mitigation. Based on the results of the likelihood and severity analysis, the risk is described as a **combination of the likelihood of occurrence and the associated severity**.
- Depending on the analysis method and the risk acceptance criteria, the description is either qualitative and/or quantitative. The level of detail depends on the level of detail in the likelihood and severity analysis.
- One method that can be used for risk description is a **risk matrix combining risk likelihood and risk severity**.
- If a hazard has more than one consequence, the risk may be expressed as a combination of **the likelihood and severity for each of the consequences.**
- Uncertainties in the risk description are to be identified and documented. If the analysis is based on critical assumptions or other conditions that could affect the assessment, these are to be identified and documented.

4) Risk evaluation

- The results of the risk analysis is compared to the criteria for acceptable risk.
- This comparison is documented using a format that can be used by decision makers.
- One method that can be used is a **Risk Tolerability Matrix combining the analysis results and the risk acceptance criteria.**

SAFETY RISK ASSESSMENT Risk Severity					
Risk Probability	*Neglig* (E)	*Minor* (D)	*Major* (C)	*Hazardous* (B)	*Catastrofic* (A)
Frequent (5)					
Occasional (4)					
Remote (3)					
Improbable (2)					
Extremely Improbable (1)					

Example of Risk Tolerability Matrix

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Risk Assessment: Description and Evaluation (cont.)

4) Risk evaluation (cont.)

a) **Unacceptable Risk Level**: the red zone in the matrix: risk is too high to continue operating.

Action required: Prohibit/suspend the operation. Operation may be resumed only when risk level is returned to tolerable or acceptable.

Management levels who have the authority to make decisions regarding risk tolerability:

- For the risk evaluation validation: The assumptions made for the determination of the risk level and its tolerability are to be validated by the Safety Manager.
- For the authorization of operations: Management level which has the authority to authorize operations at this level of risk: not applicable: operations cannot be authorized at this risk level.

b) **Tolerable Risk Level**: the yellow zone in the matrix: the risk level can be tolerated for the operation, providing that appropriate mitigation measures are in place.

Action required: Introduce appropriate mitigation measures.

Management levels who have the authority to make decisions regarding risk tolerability:

- For the risk evaluation validation: The assumptions made for the determination of the risk level and its tolerability are to be validated by the Safety Manager.
- For the authorization of operations: Management who have the authority to authorize operations at this level of risk: the Accountable Manager.

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Risk Assessment: Description and Evaluation (cont.)

4) Risk evaluation (cont.)

c) **Acceptable Risk Level**: the green zone in the matrix below: risk is tolerable and can be accepted for the operation.

Action required: Monitor.

Risk is considered sufficiently controlled and no additional risk mitigation measures are required.

However, in line with the ALARP concept, actions may still be taken to further reduce the risk level if feasible and reasonable. Additionally, any assumptions used to make an assessment shall be monitored to ensure they remain valid.

Management levels who have the authority to make decisions regarding risk tolerability:

- For the risk evaluation validation: The assumptions made for the determination of the risk level and its tolerability are to be validated by the Safety Manager.
- For the authorization of operations: Levels of management who have the authority to authorize operations at this level of risk: not applicable: no special authorization is required.

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Investigations

The purpose of the Company safety investigation is to **find out more about the event and its causes**. Its scope extends beyond the scope of occurrences required to be reported to the competent Authority.

Less serious events or occurrences are indications that there may have been a failure in the defenses provided by the SMS or that a defense many not have been appropriate or effective.

Investigations consist of collecting and analyzing events, determining causal and contributing factors, drawing up conclusions and making safety recommendations as applicable.

Investigations could be performed also by external organizations, like suppliers.

Investigations are carried out in particular in the case of:

- **accidents, incidents and occurrences;**
- **discovery of new hazards and risks;**
- **recurrent safety risks.**

The SM may, at any time, decide to launch an investigation procedure on an opportune basis. Beside the Company investigation procedure.

STAGE	REMARKS
Decision to launch an investigation	• Put together an investigating team. • The person(s) conducting the investigation shall be technically qualified and has access to other personnel with expertise that may assist with the investigation
Activity planning	• Define and breakdown the activities. • Define the investigation needs.
Data collection	• Collect evidence about the event. The following relevant sources can be used: - Physical examination; - Documentation and files; - Interviews with the persons involved; - Observation of actions; - Simulations; - Expert consultancy; - Safety database.
Scenario identification	• Identify/reconstruct the scenario.
Scenario analysis	• Analyse the facts, determine the causes and identify the associated hazards. • Integrate all investigation elements. • Determine "what" and "why" the event happened, rather than, "who's" to blame, • Look at organizational factors that may have exacerbate the situation.
Risk assessment	• Determine risk level and assess risk acceptability.
Risk control / Mitigation analysis	• Identify and assess risk controls/mitigations.
Correction/Prevention	• Determine corrective/preventive action.
Safety communication	• Communicate the investigation results to all those concerned.
Completion of the investigation	• Close and archive the file.

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Management of Risk Assessment

The meetings of the Safety Action Group (SAG) for risk assessment resulting from the hazards represents **an official, documented and recorded process, performed to determine the magnitude of the risks identified in the Company**, and to establish whether measures are needed to contain it within defined limits and to contribute to control these risks to an acceptable or tolerable level.

The SAG may propose to release comprehensive written documentation (e.g. **like Safety Operation Procedures (SOP) or other output like Safety Briefing**) relevant to the event and as risk control measure:

- if indicated from the outcomes of risk assessments carried out in accordance with the procedure
- for managing safety risks;
- following incident investigation which recommends a need for documentation development;
- as a result of non-conformities raised from safety audit reports and/or inspections.

- In such a case the documentation should be written to successfully carry out the procedure in a safe manner, in a concise, logical, step-by-step, easy-to-read format;
- The documentation shall be archived in proper manner;
- The documentation should clearly lay down instructions for operation, including the purpose of the work or process, any rules information and standard considered, definitions, establish and record for distribution responsibility.

The Company Safety Risk Management

Risk Controls

Identification of Risk Control (Mitigation) measures

- The risk evaluation forms the basis for deciding on risk control (mitigating) measures and in assessing the effectiveness of these measures.

- **Risk control measures identify the consequences associated** with both an **unacceptable risk and tolerable risk** and where further risk reduction measures are feasible and reasonable.

- **Identification of possible mitigation is based on the risk description and evaluation**, considering in particular any uncertainties identified and critical assumptions made.
- Controls that may eliminate the consequence of a hazard, likelihood-reducing measures and severity reducing measures are identified. The measures should address the **human factors (e.g. training and competence), equipment or organizational factors (e.g. procedures).**

- In the Company, the personnel contribute to the definition of risk control measures in particular where they concern personal equipment (i.e. flight equipment), by their acceptance and use.

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Risk Controls

Risk control priorities

Risk control measures are implemented based on the following priorities:

1) **eliminate the consequences of the hazard**;
2) **reduce the likelihood of occurrence** (improve the effectiveness of Avoidance & Recovery barriers);
3) **reduce the severity** (improve the effectiveness of mitigation barriers).

Risk Control types

Generally two different types of risk controls:

- **passive technical controls** (e.g. systems redundancy, double controls, check lists);
- **active technical controls** (e.g. automatic systems);

Risk Control effect assessment

The risk mitigating effect of the controls are assessed with respect to:

- **functionality:** Does the measure influence the ability to perform the activity?
- **robustness:** Will the measure be effective under varying conditions and over time?
- possible other effects such as **introduction of new risks**.

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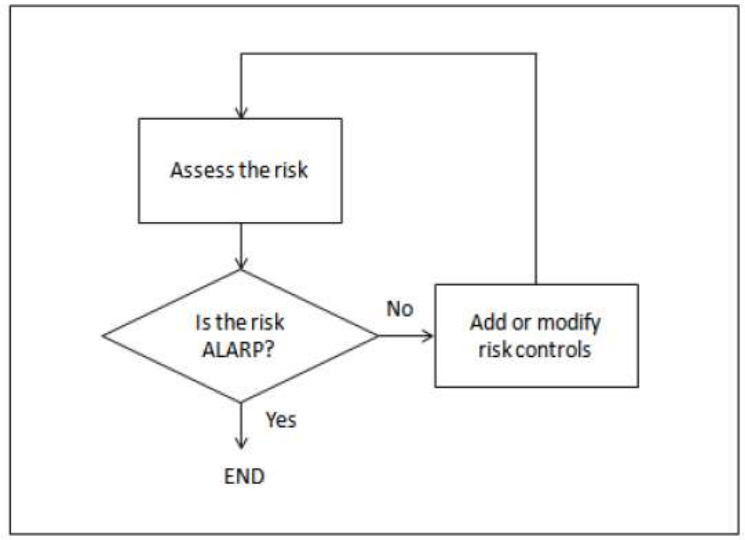
Risk Controls

Risk Control effect assessment

- When identifying risk control measures, **any new risks** that may arise from the implementation of such measures (‘substitution risks’) **should be identified**.
- **Risk is re-assessed** considering the effects of the proposed risk control effects, as illustrated in the beside table.
- The measures are not necessarily sufficient to bring the risk level back to an acceptable or tolerable level in a first round: if the risk acceptance criteria require further risk reduction, the comparison **(Iterative Risk Reduction Process)** describes the optimization process.
- **So new risk controls are added, or existing risk controls are modified, until the risk is As Low As Reasonably Practicable (ALARP).**
- The ALARP concept combines the **technical feasibility of further reducing the safety risk and the cost**; demonstrating that the safety risk is ALARP means that any further risk reduction is either impracticable or grossly outweighed by the cost.

Risks Assessed	Initial Risk Level	Risk Control	Resulting Risk Level
Risk 1			
Risk 2			
Risk 3			



Iterative Risk Reduction Process

The Company Safety Risk Management

Cost Benefit Analysis

The proposed mitigation measures are subjected to a Cost Benefit Analysis, which helps to determine the most appropriate measures. **The considered appropriate mitigation should achieve the desired safety benefits and should be economically acceptable**.

The Company manages the Cost Benefit Analysis through the Matrix provided below as a decision-making aid:

- **Unacceptable Cost-Benefit Level (score higher than 3)**: the red zone in the matrix above: Cost-Benefit Level is too high to implementing the mitigation measures. Review the risk analysis to find new solutions.
- **Tolerable Cost-Benefit level (score equal to 3):** the yellow zone in the matrix above: Cost-Benefit level can be tolerated for the implementation of mitigation measures. If possible, reduce the cost of the implementation of the mitigation measures.
- **Acceptable Cost-Benefit Level (score from 1 to 2):** the green zone in the matrix above: Cost-Benefit Level is accepted for the implementation of mitigation measures. The mitigation measures can be adopted as are.

The final scope is to confine the operation within the "**Safety Space" with a careful balancing between financial and safety management.**

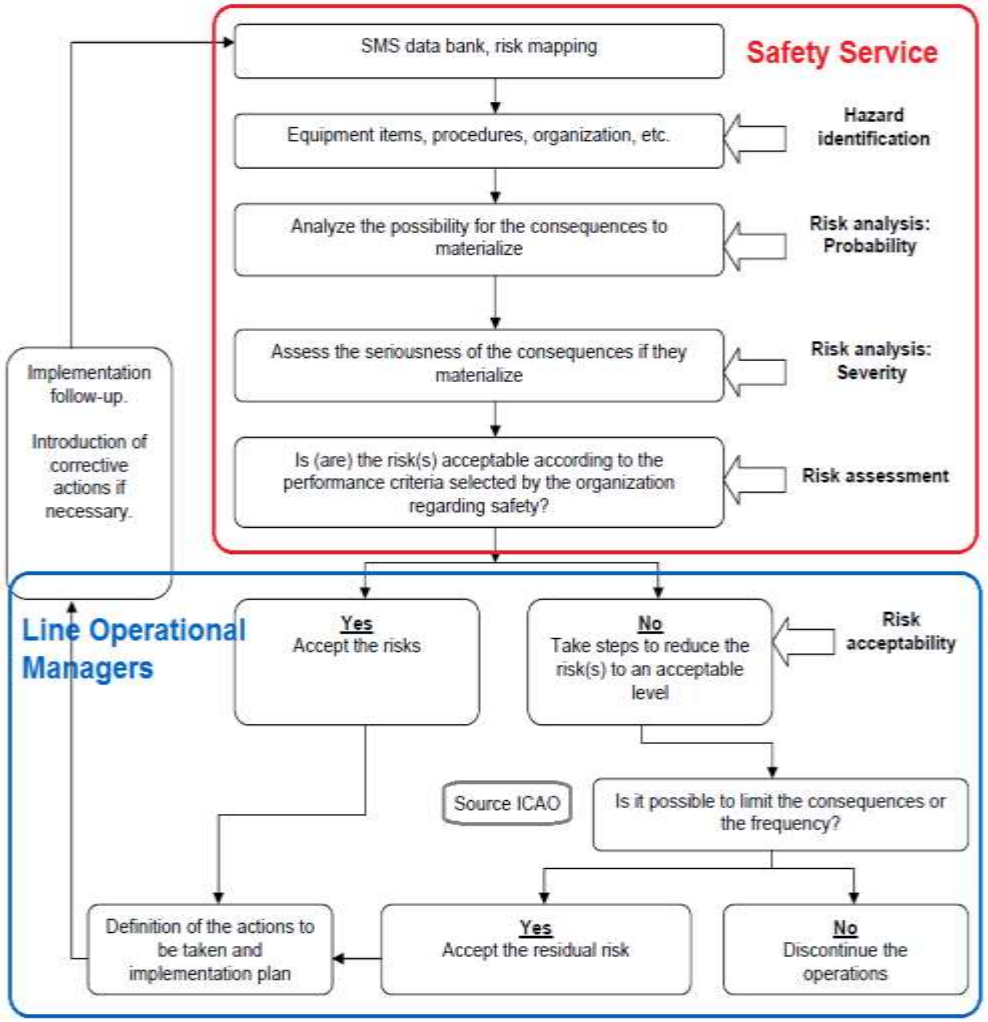
		BENEFITS		
COSTS		High	Average	Low
	Low	1	2	3
	Average	2	3	4
	High	3	4	5

The Company Safety Risk Management

Implementation of Risk Control Measures

Implementation of the Risk Control (mitigation) Measures may, depending on the nature of these measures, give rise to an **implementation plan identifying who is in charge, the resources needed, the deadline, and the stages of implementation**. The implementation plan is periodically reviewed until completion or revision.

- **Accepting the risk**, the line manager acknowledges that the risk event or condition may be realized and willingly accepts the risk with the consequences. Accepting a risk does not mean that it is being ignored.
  - **Before accepting the risk, the line manager should identify the resources, schedule, and cost needed to overcome the risk**.
- **Not accepting the risk,** different path can be used:
  - **Risk avoidance**, the line manager eliminates the risk event or condition by taking an alternate path;
  - **Risk transfer** includes reassigning the risk responsibility to another entity;
  - Risk control entails controlling the risk by **taking action to reduce the likelihood of a risk event or condition**



The Company Safety Risk Management

Risk Register

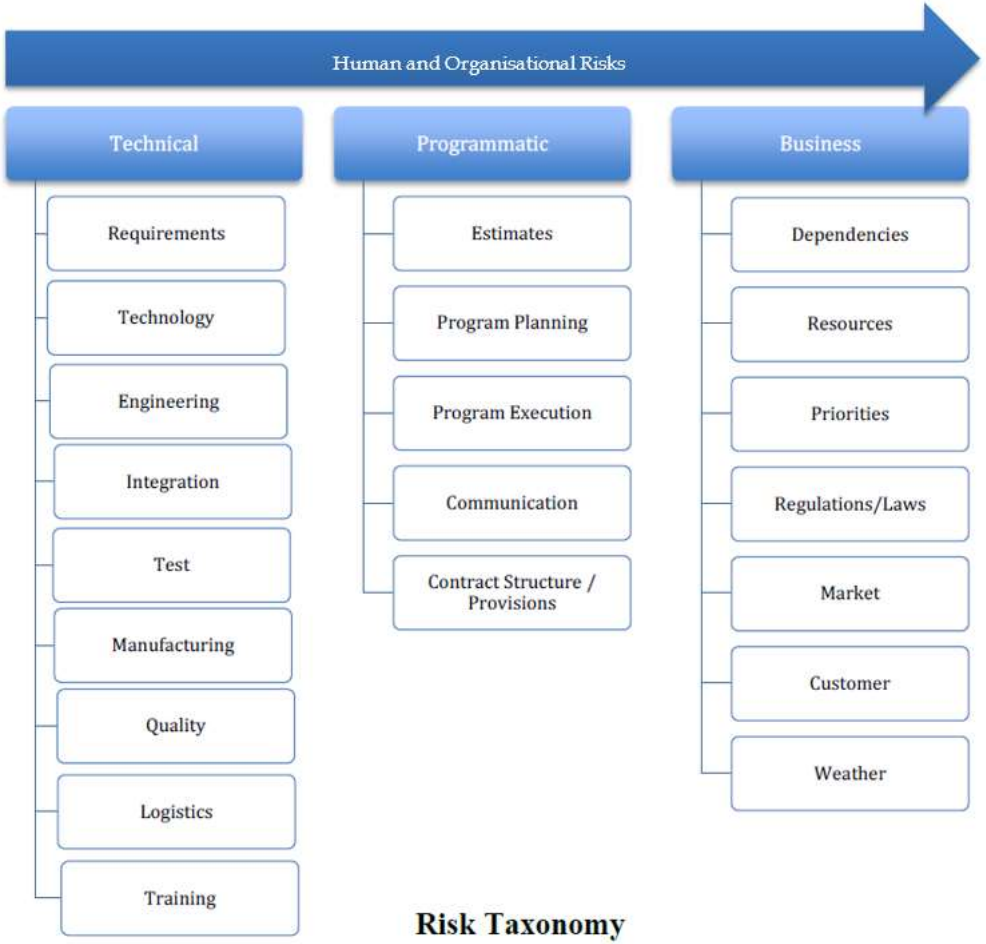
All implementation plans are managed through the Company Risk Register, which contains:

- **safety issues;**
- **their risk values;**
- **agreed actions;**
- **responsible people and target dates for actions;**
- **progress with actions and impact on risk levels.**

The course of actions described in this guide can be summarized according to the following block diagram.

Risk Taxonomy

Generally speaking risks can be broadly grouped into three categories: technical, programmatic, and business as per the following figure.



Risk Taxonomy

The Company Safety Risk Management

Safety Risk Assessment and Safety Register Forms

	Safety Risk Assessment	Nr..... Date.....
Function/Department	**Process**	**Originator** .....

Hazard ID/Code	
Hazard Specific Description OR/BT	
Cause	
Effect	
Corrective Action Taken	
Mitigation Action	
Attached Docs	

PROBABILITY		B	M
5 Frequent	Likely to occur often		
4Occasional	likely to occur sometime		
3 Remote	Possible but unlikely to occur		
2Improbable	Possible but extremely unlikely to occur		
1 Extremely Improbable	Never occurred in the history		

SEVERITY SPECIFIC FOR EACH AREA		B	M
ACatastrofic	Fatality or destroy H/C		
B Hazardous	Serious injury or substantial H/C damage		
C Major	Major injury or minor critical damage		
D Minor	Emergency situation or reduce capability with no injury		
E Negligible	No safety effect		

B: Basic Analysis
M: After Mitigation Action Implementation

SAFETY RISK ASSESSMENT

	Neglig	Minor	Major	Hazardous	Catastrofic
Frequent					
Occasional					
Remote			B		
Improbable		M			
Extremely Improbable					

NOTE: Indicate Basic (B) and after mitigation(M) results analysis

- Risk Level Unacceptable Prohibit/(Suspend Operation)
- Risk Level Tolerable via implementing mitigation measures
- Risk Level Acceptable

Approved by	Organization Safety Manager	Date.....
Authorized by	Organization Accountable Manager	Date.....

SAFETY HAZARD & RISK MANAGEMENT DATABASE

REFERENCE	Hazard-TA.OHR/ Safety Communication-TA. Safety Case AWTA.	DATE ISSUE BY	1/27/2020 Flight Safety Office						
SPACE RESERVED TO FLIGHT SAFETY OFFICE							SPACE RESERVED TO PRODUCTION OWNER'S		
ID	HAZARD (H) THREAT (T)	SOURCE	RISK LEVEL	DEPARTMENT / LOCATION	RECOMMENDED ACTION	RISK LEVEL	AGREED?	LINE MANAGER (REASON)	OWNER
1			MEDIUM			MEDIUM			
2			MEDIUM			LOW			
3			HIGH			LOW			

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Electronics

Helicopters

Aircraft

Cyber & Security

Space

Unmanned Systems

Aerostructures

Leonardo Helicopters

Appendix 1 to SRM Principles & Tools Best Practices for Hazard Identification

(SRS-101&102 supporting documentation)

Cascina Costa

November 2022, Issue 0

Appendix 1 to Safety Risk Management

Best practices for hazard identification

1) **Avoid trying to identify every conceivable or theoretically possible hazard**. This is neither possible nor desirable. Judgment is required to determine the adequate level of detail in hazard identification. Due diligence shall be exercised in identifying significant and reasonably foreseeable hazards related to the organization operations.
2) **Focus on the areas having the greater potential to introduce hazards that may lead to unacceptable safety risk**, e.g.,:
   - Accident scenarios (e.g., from investigations) if not yet covered by existing Continued Airworthiness process.
   - Human and organizational factors (e.g., activity which may lead to unacceptable risks and affect the safety of products or services, Special Processes assessment can be included in this frame).
   - Business decisions and processes changes (e.g., significant change in the principles of a processor in the organization structure or both).
   - Interface with other Organizations internal or external (e.g., manufacturing subcontractor of critical parts).
   - Novelty, criticality or complexity or both in product design, manufacturing or maintenance (e.g., introduction of additive manufacturing, inspection of composite structure).
3) **Identify hazard from review/analysis of available safety data, e.g.,:**
   - Safety reports/publications (e.g., reports from ICAO, Authorities, operators, associations).
   - Audit reports.
   - Safety surveys.

Appendix 1 to Safety Risk Management

Best practices for hazard identification (cont.)

- Investigations (e.g.in the frame of Continued Airworthiness).
- Safety analysis in the frame of safety enhancement initiatives.
- Data from Voluntary Reporting
- Subcontractors information

Following the above, it can be noted that Hazards can be identified:

- ➢ based on data from events that have occurred (reactive methods)
- ➢ or in anticipation of potential events that could lead to an unacceptable risk (proactive methods).

4) **Do not mix hazards with triggering / contributing factors** to keep a reasonable number of confirmed hazards necessary to be considered for risk assessment based on the complexity of the organization and/or product.

5) **Group hazards in categories, e.g.,:**

- Systemic hazards:
  - ➢ Organizational: management, resources, documentation, procedures.
  - ➢ Human: limitations of the person which in the system has the potential for causing harm, fatigue, stress.
- Operational hazards:
  - ➢ Technical: design.
  - ➢ Product operation.
- Environmental hazards:
  - ➢ Regulation, finance & budget, facilities, climate change.

Appendix 1 to Safety Risk Management

Best practices for hazard identification (cont.)

6) **Do not mix hazard with its foreseeable consequences.** A hazard is not subject to severity or likelihood classification, but its associated safety risk is.
7) **Consider that, depending on their nature, categorization and identification scenario:**
   - Not all identified hazards shall result in SMS action (i.e. safety risk analysis and risk control actions).
   - Several hazards can result in combined SMS actions
8) **Consider that several hazards are already subject to systematic risk assessment and risk mitigation** in the frame of product certification or continued airworthiness or both and may not need further SMS activities at product level, e.g.,:
   - “Hazard” taken into account in product design assessment through failure conditions for compliance demonstration with the type-certification basis.
   - “Hazard” identified in existing CA process with risk assessment/corrective actions (e.g. AD) at product level.

   Nevertheless, systemic risk assessments can be relevant (e.g., about organization, design, manufacturing or maintenance processes, tools, competencies).

   If other risk assessments are used, check (where applicable) that the resulting hazards, risks and severities identified by these methods are consistent with the existing levels retained during certification, and resolve discrepancies.
9) **Consider identifying hazards in an incremental manner** from initial SMS implementation up to SMS fully operative.
10) **Consider reviewing hazards in a continuous improvement loop.**

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Appendix 2 to SRM Principles & Tools
Hazard List - Generic and Function Specific

(SRS-101&102 supporting documentation)

Cascina Costa

November 2022, Issue 0

Appendix 2 to Safety Risk Management

Hazard List - Generic and Function Specific

- The following lists are intended to provide guidance. They should not be treated as complete, but rather to prompt a broader assessment of hazards.
- It is important to recognize that a general long-term slow decline in capability or facility performance may easily be missed, but needs to be addressed.

- **Generic Hazards**
  - Insufficient resource / priority given to management of risks once containment completed. In this context, this would be where this fundamental issue was affecting the management of a number of safety issues.
  - Excessively complicated process documentation that does not align with activities being undertaken.
  - Changes to statute or regulations.
  - Lack of communication within and between disciplines within the Company and with appropriate external organizations.
  - Ambiguities in responsibilities and accountabilities in joint programs.
  - Urgent off-site working, where necessary safety preparations have not been fully addressed.
  - Management of ageing aircraft, particularly where there are several different customers each with small numbers of aircraft.
  - Implications of customer changes to aircraft build standards or operating envelopes, particularly relating to safety modifications.
  - Decline in availability of competent staff in all areas necessary to manage safety.
  - Delays in authorizations to facilitate necessary safety mitigations.
  - Impact of organization or process change
  - Decline in competency at vendor organizations as products approach obsolescence.
  - Delays from vendor organizations in responding to safety concerns.
  - Implications of flight operations in locations with immature airworthiness management processes.
  - Operation of products by customers without an appropriate level of infrastructure, facility and competence.
  - Deliberately incurred or deliberately unreported damage to aircraft or aircraft parts.
  - Long-term deterioration of infrastructure.
  - Hazards leading to long-term chronic health problems.

Appendix 2 to Safety Risk Management

Hazard List - Generic and Function Specific (cont.)

- **Specific Hazards - Design**
  - Inadequate design methods or tools,
  - Requirement/Procurement Specification inadequate
  - Inappropriate DTA Issue or Release
  - Preliminary configuration Traceability (DMFG)
  - Incorrect design changes classification
  - Design Review Not Performed / Ineffective
  - Inadequate Test Requirements
  - Inadequate qualification process
  - Flight Manual/ Form 59 inadequate
  - Maintenance Manual / Maintenance Instructions insufficient
  - Maintenance Manuals not updated on time
  - VIL / Production Configuration not updated
  - System/Subsystem/Component Qualification documents insufficient
  - Incorrect Supplier technical capacity evaluation
  - Surveillance of Supplier Design process insufficient
  - Supplier DTA/QTR not analyzed and validated
  - System integration, between subsystems, inadequate
  - Inadequate Clearance / Chaffing
  - Insufficient Communication between Technical Departments
  - DTA Transfer from DO, not in line with the urgency
  - DTA transfer not to all Company MEs
  - Special Process Specifications Requirements in contradiction to each other
  - Incorrect Classification of SI / BT
  - Flight critical software not identified and managed correctly
  - Incorrect classification of Critical Parts
  - Not identifies Vital Points
  - Process Stability

- **Specific Hazards – Manufacturing Engineering**
  - Technical documentation not properly processed
  - Product Configuration not in line with the Technical Configuration
  - Design Change not considered
  - Traceability of AMD/ECR non assured
  - Traceability of Production Permits not assured.
  - STF incomplete, not updated and with some COMOs, NI, BT recalled inside
  - Production Configuration inside MIR not in accordance with “as Built” Configuration
  - Work order/Method/SMC do not recall changes or requests for changes to DTAs
  - Work order / Method / SMC do not recall the required inspection/control phase
  - Work order / Method / SMC do not have the required record phase
  - Work order / Method / SMC do not highlight that technical data are applicable or preliminary
  - Required material not in accordance with the DTA
  - Work order / Method / SMC recall Unqualified jigs tools, equipment
  - Work order / Method / SMC doesn’t require to record the S/N of the instruments utilized
  - Work order / Method / SMC doesn’t identified the valued required and doesn’t require to record the value of the measure obtained
  - Work order / Method / SMC doesn’t require to record the S/N of the components/parts installed
  - FAI requirement not implemented
  - FAI incorrect evaluation
  - Process/CND cards not updated with DTAs
  - Using Unapproved Suppliers
  - Issue of Purchase Requisition without Quality Codes
  - Production Configuration Management not i.a.w. requirements
  - Process Stability

Appendix 2 to Safety Risk Management

Hazard List - Generic and Function Specific (cont.)

- **Specific Hazards – Reception / Shipment**
  - Inadequate warehouse lay-out
  - Incorrect material acceptance
  - Failure to perform acceptance tests
  - Non conform materials stored in the wrong position
  - Materials in an environment not suitable for storage
  - Non-quarantined materials
  - Missing tagging of materials
  - Preservation requirement not executed,
  - Expired materials not quarantined / discarded
  - Materials accepted with missing documentation
  - Inadequate or incorrect material taking.
  - Conformity document Lost in Warehouse
  - Material distributed without acceptance
  - Damaged materials during handling
  - Packaging Identification of inadequate materials
  - Non-conforming Materials Issued to Production,
  - Items, non-conforming to the requirements, shipped outside
  - Lack of control / acceptance / qualification and requalification requirements
  - Insufficient ATP compliance documentation

- **Specific Hazards – Production**
  - Inadequate Production Document Management / superseded Documents
  - Unqualified production documentation changes
  - Inadequate machine installation or location.
  - Setting incorrect job parameters
  - Improper use of production documentation
  - Using wrong or obsoleted documents
  - Sequences of work phases not correct
  - Incorrect Parts handling and or preservation in the production area
  - Usage of tools or Instruments not suitable
  - Instrument out of calibration
  - Measurements not correctly performed
  - Inadequate installation control
  - Changes to the production documents not correctly managed
  - Wrong Installation
  - Missing QC / PP marking
  - Unsuitable personal qualification
  - Material "Life" expired during assembly
  - Contamination of material and / or product
  - FOD
  - Damages during transportation
  - installation of Critical SW not correct
  - Process Stability

Appendix 2 to Safety Risk Management

Hazard List - Generic and Function Specific (cont.)

- **Specific Hazards – Flight Line**
  - Unjustified flight authorization
  - Inadequate flight plan
  - Functional tests not performed or incorrectly performed
  - Workmanship inadequate
  - Poor Helicopter Inspections
  - Usage of wrong or outdated documents
  - Unsuitable aircraft placement
  - Maintenance inadequate
  - Maintenance activity without traceability
  - Maintenance activity performed without or superseded maintenance documentation
  - Non conformities incorrectly managed
  - Incorrectly used production documentation
  - Poor material Handling / Preservation
  - Ground Operations not performed in accordance with requirements
  - Ground/Flight operations not properly documented
  - Inadequate inspection
  - Incomplete defect list.
  - Airworthiness Certification not completed.
  - Service Bulletins List not complete.
  - Inadequate / Unclear Inspection Criteria
  - Helicopter delivery not in accordance to DTA and BT / ETI
  - Delivered non-upgraded helicopter documents
  - Installation of parts with red or green tag.
  - Unclear Deferred Defects List
  - Flight non conformities not reported on the Flight Log Book
  - Flight Operations performed without inspector signature on the Flight Log Book
  - Incorrect fuel supply, contaminated

- **Specific Hazards – Quality Control**
  - Inadequate Reception Check activity.
  - Usage of wrong or superseded inspection documents
  - Control test, in SAP, inadequate / missing/ superseded
  - Management of NC Parts not in accordance with the requirements
  - Inadequate Inspector Competence
  - Known defect, not properly reported
  - Stamped but not executed check phase
  - Insufficient test / ATP testing
  - Issuing N.C. Documents not coherent
  - Failure to mark the NC
  - Failure to issue non-conformance documents
  - Wrong / Inadequate issue of Conformity Documentation
  - Wrong or inadequate Log Card
  - Control Test Missing / Overrun / Inappropriate Tests.
  - Inadequate Product Management NC
  - Process Stability

Appendix 2 to Safety Risk Management

Hazard List - Generic and Function Specific (cont.)

- **Specific Hazards – Flight Operations**
  - Introduction of new aircraft types/technologies with unforeseen human factors aspects
  - Gap between skills, abilities, and attitude toward technology and automation of future crew members and the past design philosophies used in development of present aircraft
  - Obsolescence of current training methodologies for operation of advanced aircraft
  - Decreasing level of average pilot airmanship
  - Use of out-of-date manuals / supporting documents, including incorrect referenced material / manuals
  - Lack of or poor verification of equipment and instruments necessary to a particular flight or operation
  - Use of obsolete documents (flight crew manuals or charts on board)
  - Lack of, or poor crew resource management
  - Improper execution of procedures in all flight phases (including taxiing and parking)
  - Inadequate or complicated procedures
  - Equipment and instruments necessary for a particular flight or operation not available or malfunctioning
  - Lack of or poor communication (ATC, ramp, maintenance, flight Ops, cabin, dispatch, etc.)
  - Language barriers (Multiple languages)
  - Incorrect cargo loading and distribution
  - Improper or unauthorized hazardous materials carriage
  - Improper, inadequate, or lack of Notices to Airmen (NOTAMs) issuance
  - Improper weight and balance calculations
  - Lack of, incorrect or incomplete aircraft performance limitations verification
  - Lack of, incorrect or incomplete flight planning

- **Specific Hazards – Flight Operations (cont.)**
  - Loaded fuel quantity insufficient for the flight (Flight planning error, error during re-fuelling operation)
  - Wildlife hazard
  - Disturbance awareness, loss of awareness of the situation
  - Flight crew Psycho-Social Stresses (Challenging, timelines, inadequate resources, etc.)
  - Flight crew Self-Imposed Stresses (Fatigue (lack of sleep), Alcohol and substance abuse, Medications, Complacency)
  - Sudden Incapacitation (Heart attack, Stroke, Kidney stone, Seizure)
  - Subtle Incapacitation/Impairment (Nausea, Diarrhea, Carbon monoxide, Medication, Fatigue)
  - Loss of engine power (taking into account the type of operation and flight phase)
  - Lack of or poor aircraft dispatch or release
  - Lack of or poor maintenance release
  - Anomaly on flying controls, airframe, loss of components in flight, alteration of flight crew's, field of vision
  - Improper response to flight route changes
  - Navigational aid (radars, satellites, VOR, ADS-B, etc.) failures or anomalies
  - Error when entering data into the FMS
  - Meteorological phenomena (icing, heavy rain, fog, etc.)
  - Unsuitable fuel management
  - Incorrect, confusing, or incomplete communications between ATC and aircraft
  - Poor condition or inappropriate runway surface
  - Faulty, incorrect or incomplete airfield markings (especially in movement areas)
  - Misinterpreting apron markings
  - Ingestion of foreign object debris (FOD) control
  - Improper parking
  - Passenger failure to follow guidance

Appendix 2 to Safety Risk Management

Hazard List - Generic and Function Specific (cont.)

- **Specific Hazards – Suppliers**
  - Insufficient supplier design
  - Supplier Production / Testing Inadequate
  - Insufficient documentation supplied by the Supplier
  - Supplier Quality System Supplier decayed / degraded
  - Insufficient Supplier Material Management.
  - Inadequate non-compliance Classification
  - FAI performed not i.a.w. the requirements
  - Poor Technical Specification Management
  - Qualification of Special Processes not performed
  - Implementation of technical and production changes without Company approval.
  - Inappropriate Purchasing / Subcontracting Management
  - Inadequate shipping management.

- **Specific Hazards – Training**
  - Essential training items not taught
  - Transfer of knowledge not taking place or might be in jeopardy
  - The practice of skill omitted or not leading to proficiency
  - Incorrect use of documentation or essential information missing
  - Previous known errors / lessons learned not considered nor incorporated into the training
  - Insufficient information / guidelines for the delivery of training
  - Training not under direct control of the organization
  - Primary assessment of training delivery not conducted within organization

- **Specific Hazards – Purchasing**
  - Inadequate Purchase Order
  - Purchase Order placed to supplier not qualified
  - Purchase Order placed to supplier qualified for different class
  - Purchase Order placed to supplier having the special processes qualification expired
  - Purchase Order without quality codes
  - Insufficient Surveillance of Supplier quality system
  - Supplier Quality Plans not required or no evaluated

- **Specific Hazards – Maintenance**
  - Unauthorized repairs
  - Repairs carried out without Work order
  - Repairs carried out by not qualified personnel
  - Repairs / maintenance done not in accordance with the manuals / technical provisions
  - Release to Service inadequately issued
  - Removing the parts without tagging them
  - Failure to control the list of Service bulletins and ADs

- **Specific Hazards – Personnel**
  - Inadequate training
  - Inadequate training specifications.
  - Wrong skill assessment
  - Responsibility. not defined / unknown
  - Inadequate resource skills
  - Communication problems between area/people.

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THANK **YOU**
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