



Leonardo Helicopters

# Safety Assurance (SA) Principles & Tools

(SRS-101&102 supporting documentation)

Cascina Costa

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Electronics



Helicopters



Aircraft



Cyber &  
Security



Space



Unmanned  
Systems



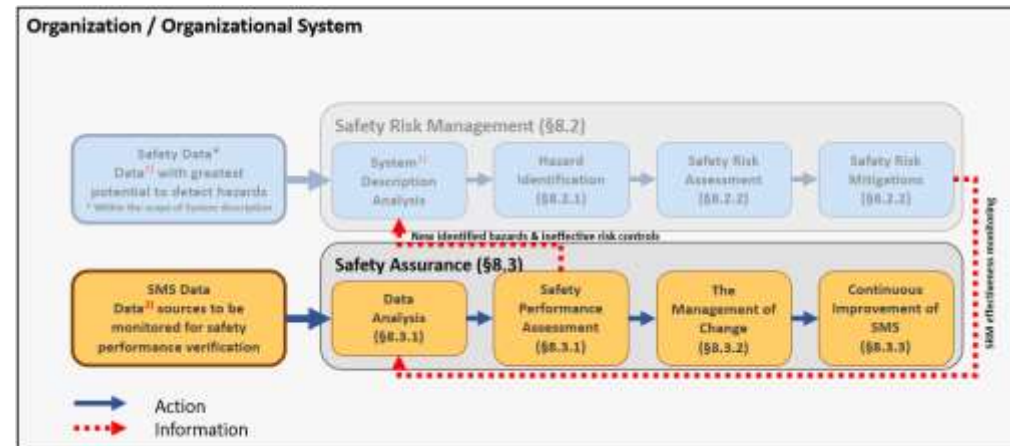
Aerostructures

# The Company Safety Assurance



## Safety Assurance (SA)

- Safety Assurance (SA) relies on the following activities:
  - **Safety performance monitoring and measurement.**
  - **Process for the management of change.**
  - **Continuous improvement of the SMS.**



- SA consists of processes and activities undertaken by the Organization to determine **whether the SMS is operating according to expectations and requirements.**
- The Company and the relevant Organizations shall **continually monitor** their internal processes as well as their operating environment to detect changes or deviations that may introduce emerging safety risks or the degradation of existing risk controls. Such **changes or deviations may then be addressed with the SRM process.**

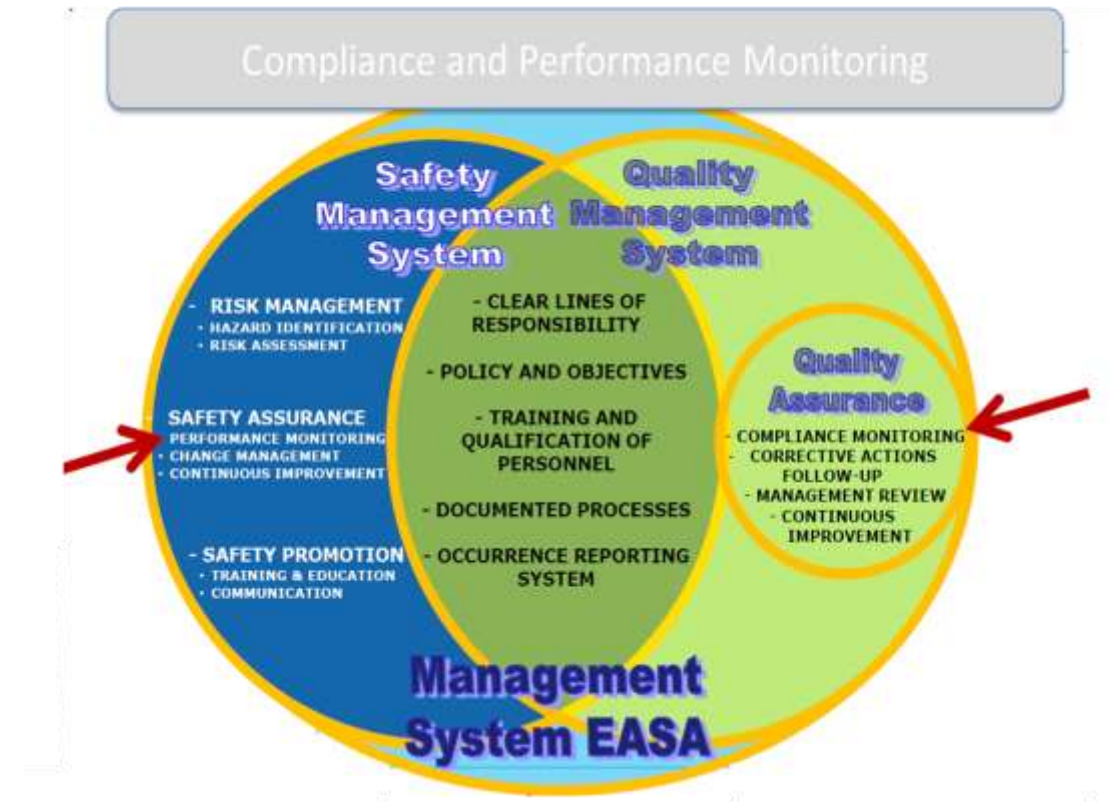


# The Company Safety Assurance



## Safety Assurance (SA) vs Quality Assurance (QA)

- The Company Safety Assurance process is complemented by that of Quality Assurance.
- While **Quality Assurance** typically focuses on the **Organization's compliance with regulatory requirements** (including SMS ones), Safety Assurance specifically monitors the effectiveness of safety risk controls and the whole SMS in place.
- Only a **strict collaboration between SMS and QAS** can facilitate the creation of the Safety Management Environment forecasted by ICAO and EASA Rules.



# The Company Safety Assurance



## Safety Assurance (SA) vs Quality Assurance (QA) (cont.)

**Compliance Monitoring (CM)** is an essential process of the Company SMS and it applies to all the Safety Management requirements.

This means that **each single task within the Company SMS has to be subjected to a rigorous Compliance Monitoring check (audit)** to evaluate the adherence to the Rules of all the stakeholders of the System: hazard identification, risk assessment and management, performance, monitoring etc.

The typical questions at which a compliance monitoring process shall give an answer are, for example:

- Have policies and procedures been defined?
- Are they implemented?
- Are the dangers identified?
- Are the risks assessed and managed?
- Is performance monitoring carried out as planned?
- Is information managed in the correct way?
- Are the requirements of the SMS well understood by all the actors?



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## Safety Assurance (SA) vs Quality Assurance (QA) (cont.)

On the contrary, and complementing the Company CM toward the full and effective implementation of a **robust SMS**, **Performance Monitoring (PM) consists of continuous verification of the effectiveness of the entire process** or part of it, for example, Risk Controls or, better, the means adopted to mitigate and manage risks.

The questions at which this part of the process shall answer are different, due to the different scope:

- How effectively have the risks been mitigated?
- Has overall safety performance improved over time?
- Are there Safety Performance Indicators (SPI) that show negative trends?
- Are the improvement identified actions defined and pursued?
- Are responsibilities clearly defined and distributed?
- etc.

In other words **CM relates to the verification that the Processes, whatever they are, are followed by an Organization while PM is relevant to the effectiveness and efficacy of those processes and their continuous improvement.**



# The Company Safety Assurance



## Safety Assurance (SA)

The Company Safety Assurance shall be achieved by monitoring the activities of the SMS with reference to 3 main tasks:

- 1) **Monitoring, gathering and analyzing data (data acquisition)**, which are fed into the SRM process.
- 2) **Safety performance measurement**: best understood as an assessment of the capability of managing risks. A determination of the **success in managing risks and effectiveness of implemented risk controls**, from both a Product and Organizational perspective.

When we refer to “Safety Performance” we should put in place a system be able to answer the following questions:

- a) Do we know what the most important risks in our operations are?
- b) How do we know about our risks?
- c) What are we doing about these risks?
- d) Are our risk controls still working?

- 3) **Management of change and SMS Continuous Improvement**: driving an iterative process where performance requirements evolve with the complete Organization maturity.

Because SMS has been designed such that **ineffective controls, new hazards, or potential hazards identified by the safety performance assessment are fed back into the SRM process** for hazard identification, risk analysis, risk assessment, and risk control:

➤ **the SA assures that the SRM is not an open loop exercise**



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## Data Acquisition



- **Data acquisition process is a pre-requirement** for the monitoring and part of the Company SA activity.
- Acquiring data and safety related data in the context of safety performance monitoring and measurement is a key input to check the level of achievement of the Company SMS versus safety objectives and to continuously improve the Company SMS.
- The means for data acquisition used by Safety Assurance are:
  - **the Hazard Identification (HI) process;**
  - **the internal / external source of data; and**
  - **the major Company processes/procedures (see figure)**



# The Company Safety Assurance



## Data Acquisition (cont.)

- **Internal:** This can rely on already implemented means, such as the **data gathering system used for Continued Airworthiness** when mandated by the applicable regulations, or the **monitoring of the Organization operations for malfunctions, defects, and quality escapes** that could result in unacceptable aviation safety risk.
- **External:** The data acquisition process shall include data collected in the monitoring of external stakeholders:
  - interfaces with **operators/Customers** of Company products and services;
  - interfaces with **suppliers**, in particular to encourage the exchange of safety data;
  - interfaces with **Authorities**;
- Data can be:
  - **quantitative:** used to identify and provide a clearer picture of the 'area' being measured. Statistical measures are generally used for this effort.
  - **qualitative:** data sources such as employee safety reports and in-depth causal analyses in accident reports are generally qualitative. This approach is valuable for hazard identification.
- Data is related to:
  - Products: oriented to Safety (**Lagging Indicators**)
  - Process: oriented to the SMS operation/implementation (**Leading Indicators**)
- Regardless of which part of the Company is in charge of processing the collected data and implementing corrective actions, the data should be reported to the SA function for the purpose of assessing the safety performance.





# The Company Safety Assurance



## Safety Performance Monitoring and Measurement

Safety performance monitoring and measurement is the process by which the safety performance of the Organization is verified in comparison with the safety policy and safety objectives.

Safety data collecting is a centralized task on SM and one of the subjects discussed at SAG and SRB.

### 1) Indicators

The Organization has to develop and maintain appropriate safety-related indicators **to measure its performance and its level of maturity.**

**Safety Performance Indicators (SPIs)** shall be simple, measurable and reliable. In order for them to be used for safety management they need to be a mix of:

- outcome indicators, also known as **Lagging Indicators.**
- process indicators, also known as **Leading Indicators.**

Indicators can be used in two ways:

- to **identify hazards derived from potential accident scenarios** and apply them to the development of safety performance indicators where no accident or major incident has yet happened,
- or **for measuring the effectiveness of risk mitigation measures**



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## Safety Performance Monitoring and Measurement (cont.)

### How to measure safety

- Due to multiple contributors in the chain of circumstances leading to a safety event (e.g., aircraft manufacturer, operators, maintenance, training - with each one playing their part in safety escapes), **data collected for processing by the Organization's SMS is by nature partial and limited.**
- Safety performance monitoring may need to consider **potential precursors, near misses and weak signals (events which could, potentially, lead to accidents or incidents but didn't)** due to factors such as the declining number of accidents and small number of actual recognizable safety events being offset by the continuing growth in the number of flights.

### How to build a SPI

- An SPI cannot be a simple raw number of incidents being processed, it should include an assessment aspect reflecting the criticality. The **results may be expressed in ratios, averages, rates or trends.**
- One recognized issue is the time needed for observing the effects of mitigating measures, again due to the low probabilities of actual events occurring. An **indicator will need to reflect a rather long observation time** (e.g. rolling averages over five years), which makes it inconvenient for short term management and measurement of the SMS.



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## Safety Performance Monitoring and Measurement (cont.)

### Typical Safety Performance Indicators

- Each Organization will need to define the category of events to be considered for data collection and analysis and the criteria for assessment, depending on its own activity, e.g.:
  - in-service events on aircraft or equipment for design organizations (DO) or
  - quality escapes or stability of the processes for manufacturing organization (PO)
  - quality escapes for maintenance organizations (MO).
  - number of pilots and crews licenses released with a rating less the "Good"
  - operational Occurrences vs Technical Occurrences (Training flights)
- So the above examples fall within the following categories :
  - Accidents and Incidents
  - Fleet Events
  - Climate SMS
  - Internal Occurrence, VOR

### Typical SMS Operation Indicators

- The monitoring of the operational performance of the SMS may require an adaption of the indicators to the current status of the SMS implementation, e.g. Level 1\_ Ramp up SMS activities, Level 2\_ Operating and effective, etc.



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## Safety Performance Monitoring and Measurement (cont.)

### 2) Monitoring and measurement process

- **safety reporting**, addressing also the status of compliance with the applicable requirements;
- **safety reviews (SAG/SRB)** including reviewing trends which would be specifically useful during the introduction of new products and components, new equipment or technologies, the implementation of new or modified procedures, or in situations of organizational change that may have an impact on safety;
- **safety audits** focusing on the integrity of the organization's management system, and periodically assessing the status of safety risk controls;
- **safety surveys**, examining particular elements or procedures of a specific area or bottlenecks in daily maintenance activities, perceptions and opinions of maintenance management personnel, and areas of dissent or confusion.
- **safety studies/SWG** examining a scenario or a specific issue after an event.

- The measured SPIs are communicated by a **dashboard**.
- The performance indicators are intended to measure **the progress against the Safety Objectives** defined by the Organization. They should be subject to **recurrent reviews to ensure their continued relevance**.

SMS Operational Performance					Status DD/MM/YYYY
Performance Indicator	Objective	Actual	Status	Trend	Recovery Action
Nomination of Key Personnel	All by end of 2023 (12 positions identified)	5	🟢	📈	NA
Communication on department level	Amber 10% below target line	28 of 30	🟡	📉	Planning & Commitment by departments
SMS Training deployment	Amber 10% below target line	58 of 85	🟡	📉	Solve budget Problem with TNG department
# of safety hazards by voluntary reporting	No consecutive decrease for more than 2 months	Stable	🟢	📈	Remain on the organization
# of new open risks vs # of mitigated risks (monthly)	Red 40%, Amber 35%	36%	🟡	📈	Observe trend
Authority audits: # of open Corrective Action Requests vs total #	Amber > 0%, Red > 10%	12%	🟡	📈	Authority approval on dedicated CAR
SMS Product Safety Performance					Status DD/MM/YYYY
Performance Indicator	Objective	Actual	Status	Trend	Recovery Action
# of incidents per 100 KPH with root cause within organization	< 10% of all incidents last 12 month rating	36%	🟢	📈	NA
Average time to put risk mitigation action in place after confirmation of safety impact (significant consequence)	Green < 2 month, Amber < 3 month	1.8	🟢	📉	Communication to departments to reverse trend
Average time to put risk mitigation action in place after confirmation of safety impact (non-significant consequence)	Green < 4 month, Amber < 6 month	5,5	🟡	📈	Observe Trend
New products Entry into Service (12months) - # of incidents above product range (average)	Amber > 0%, Red > 10%	Product X 12%	🟡	📈	Observe Trend



# The Company Safety Assurance



## The Management of Change (MOC)

Any Approved Organization within the Company shall have a **process to identify changes which may affect the level of safety risk** associated with its aviation products or services and to identify and manage the safety risks that may inadvertently arise from those changes. When significant, the change management is detailed below.

*Note: “change” shall be understood as a change to the system (e.g. organization, responsibilities, processes) and its associated operating environment and not directly to the product. Changes to the product are already controlled by other regulatory requirements (DOA Part.21 J), including acceptance of such changes by certificate/approval holders when initiated by suppliers.*

- It is neither possible nor desirable to implement Safety Risk Assessment process for all changes to the system.
  - **Only changes that potentially have a substantial impact on safety are subject to the SRM process.**
- **The safety performance assessment includes the evaluation of significant changes.**



# The Company Safety Assurance

## The Management of Change (MOC) (cont.)



Changes in the Company organizational structure, facilities, scope of work, personnel, documentation, policies and procedures, etc., **can result in the inadvertent reduction of the efficacy of the safety barriers in place or in the inadvertent introduction of new hazards**, which can expose the organization to new or increased risks.

Effective organizations seek to improve their processes, with conscious recognition that **changes can expose the organization to potentially latent hazards and risks if they are not properly and effectively identified and managed.**

The management of safety risks resulting from changes shall consider the following:

- criticality of systems and activities, including impact on external organizations;
- stability of systems and operational environments;
- past performance.



**The introduction of new risk controls/barriers may add other risks to be considered**

# The Company Safety Assurance



## The Management of Change (MOC) (cont.)

A systematic approach ensures that the **impact of the change is assessed, proactively planned and tailored before implementation.**

- During the MOC process, previous risk assessments, and **existing hazards shall be reviewed** for possible effect.
- MOC could rely on the **support from tools or methods (e.g. 8D, PPS, 5M, PFMEA)** documented within Industry standards and chosen by the Organization as best fitting its characteristics.
- **Availability of Subject Matter Experts (SME).** It is important that key stakeholders are available and involved in MOC. This may include individuals from external Organizations.

Effective MOC, when the change is significant, is supported by the following steps:

### 1) Preparing for change

- identify the objective of the change;
- identify the interested parties;
- appoint the change management team;
- carry out Safety Assessments: the process for formal hazard identification/risk analysis and assessment for major change;
- identify the mitigating measures;
- develop an Implementation Plan which shall also include setup of procedures and relevant training.



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## The Management of Change (MOC) (cont.)

### 2) Managing change

- inform the interested parties of the proposed schedule for change including the implementation dates, major milestones, and follow-up required to measure the success or failure of the change process;
- implement the change, following the Implementation Plan;
- provide the required training;
- provide regular communication to all interested parties.

### 3) Monitoring change

- collect and analyze feedback;
- identify discrepancies and “lessons learned”.





# The Company Safety Assurance

## The Management of Change (MOC) (cont.)



A good guideline to ensure success of the management of change process is the KUBA approach:

### KUBA – Know, Understand, Believe, and Act

- **K(now)** - Informing the interested parties so that they know why the change is necessary, they are aware of the implementation of the change and the outcome of the change that will affect them.
- **U(nderstand)** - The interested parties should understand the reason and implications for them regarding the change. This includes understanding the rationale and the benefits expected from the change
- **B(elieve)** - The interested parties move through knowledge and understanding to the point that they will believe, or will buy into the change. Once the stakeholder believes in the change the implementation will have a greater chance of success
- **A(ct)** - The implementation of the change can be successfully realized once the interested parties have moved through the previous steps



# The Company Safety Assurance



## The Management of Change (MOC) (cont.)

The Management of Change (MOC) process consists of the following three types of changes:



The table on the right illustrates the general stages for each MOC type.

Technical	MOC Stages Administrative	Organizational
Initiate	Initiate	Initiate
Verify		
Coordinate	Verify/ Coordinate	
Review	Review	Review
Pre-Approval Actions	Pre-Approval Actions	Pre-Approval Actions
Approve	Approve	Approve
Pre-Startup Actions	Implementation Actions	Post-Approval Actions
Pre-Startup Safety Review		
Authorization		
Post-Startup Actions		
Temp Assurance/ Closure	Closure	Closure



# The Company Safety Assurance



## Continuous Improvement of the SMS

**SMS Continuous Improvement is a gradual and continuing process that focuses on increasing the effectiveness and efficiency of an Organization** to fulfil its safety policy and objectives.

Continuous Improvement shall enhance performance with action plans that are based on safety performance monitoring and measurement so that the results of the safety performance measurement shall be considered when the Organization defines Continuous Improvement actions.

Based on the safety data collected the **Safety Manager will ensure that:**

- **a report (feedback) is provided on safety performance** (how well safety is managed) and on the SMS (how effectively the SMS works, the stage of implementation, any issues/challenges and any proposals for improvement) during the Safety Review Board. The feedback shall include a comparison with the levels achieved in previous years and status of indicators with respect to the target.



# The Company Safety Assurance



## Continuous Improvement of the SMS (cont.)

- **analysis of data** at the organizational level (Organization SRB and at Company Level: SGR and SSC) is performed to establish an action plan, jointly with the stakeholders in charge of the actions implementation. The action plan shall address the root causes of the failures or malfunctions at the system level where safety performance has not reached the expected level;
- **improvement actions** are implemented and the effects are monitored and reviewed;
- **best practices and the lessons learned** are taken into account to improve SMS. Furthermore, these best practices shall be disseminated across the Organization through safety promotion activities.

The **Organization shall continuously seek to improve its safety performance and effectiveness** of its management system even when the SMS seems to function satisfactorily . Continuous improvement may be achieved through:

- **Assessments on safety culture and management system effectiveness**, in particular to assess the effectiveness of safety risk management processes and the awareness of risk;
- **Surveys, including cultural surveys**, that can provide useful feedback on how engaged personnel are with the management system and to fix improvements on promotion/communication;
- **Evaluation of safety performance indicators** and review of all available safety performance information;
- **Monitoring the recurrence of incidents and occurrences.**



# The Company Safety Assurance



## Continuous Improvement of the SMS (cont.)

- **VOR process maturity**
- **Reporting and analysis tools**, level of maturity of Safety Studies (i.e. SWG), Safety Reviews, Internal Safety Audits
- **Audits** carried out by external independent Organizations;
- **Relations with the subcontractors, suppliers and customers** regarding safety
- **Identification of lessons learnt.**
- **Open workshops and brainstorming** on improvement areas with stakeholders at all levels

During the **Safety Review meetings**, the **continuous improvement will be assessed** with a frequency and format commensurate to the level of risks and the complexity of the Organization.

Result of this processes will give inputs for the SRB and SGR/SSC SMS performance monitoring.

Continuous improvement of the SMS may target **any component of the SMS** with the objective of increasing the effectiveness of the system over time.





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