Regulation 402/2013 on the CSM for risk assessment and independent safety assessment by an assessment body (AsBo)

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EUROPEAN UNION AGENCY FOR RAILWAYS

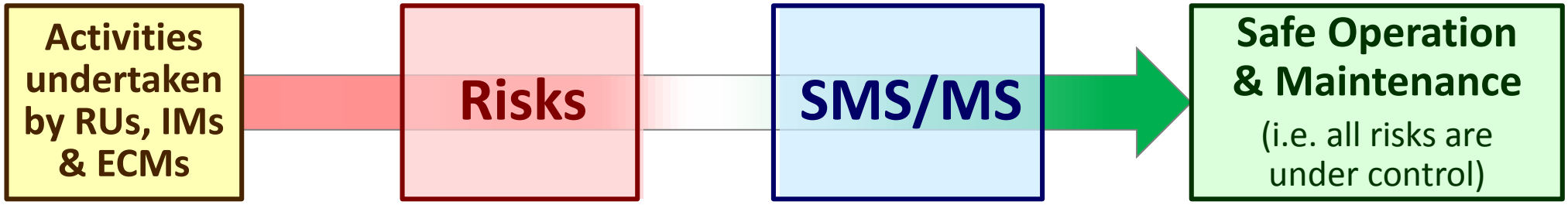
CONTENTS

CONTEXT - EU railway market opening legislation
Introduction of a harmonised way of thinking

For many railway stakeholders, this is a major shift in manner to manage safety of railway operation, traffic management and maintenance activities

- Past: it was sufficient to comply with well-established national rules, standards and legislation → technical differences, and approach to safety, among countries
- International traffic was made possible only thanks to (voluntary) international or multilateral agreements (COTIF, RIV, bilateral agreements,…)
- The new EU legal framework requires the stakeholders to take fully themselves the responsibility for the safe management of their activities through a **risk based approach**

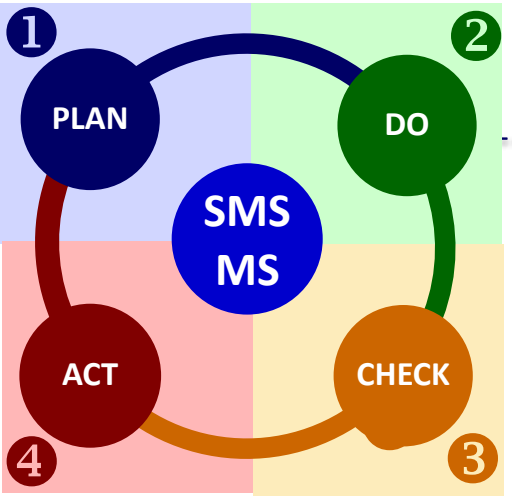
→ New concepts and new obligations/responsibilities generate many fears



- Instead of **«reacting and fixing»** only the events that occurred in past, the Safety Directive requires RUs, IMs & ECMs to put in place:
  - **(Safety) Management System (SMS/MS),** and;
  - **proactive** way of thinking in **«predicting and preventing»** possible unwanted events (risks) that may happen;

- To ensure safe **Operation & Maintenance** of railway system, **SMS/MS** shall look both FORWARD and RETROSPECTIVE in order to control (all) risks associated with RU, IM & ECM activities. This implies to:
  - **«predict»** unwanted events that can happen during operation & maintenance;
  - **«identify and implement»** risk control measures [i.e. SMS processes, procedures, & rules] in order to **«prevent»** them to happen or to **«protect»** against the consequences of those unwanted events;
  - **«monitor»** continually the effectiveness of predictive and preventive measures

What is an SMS/MS?



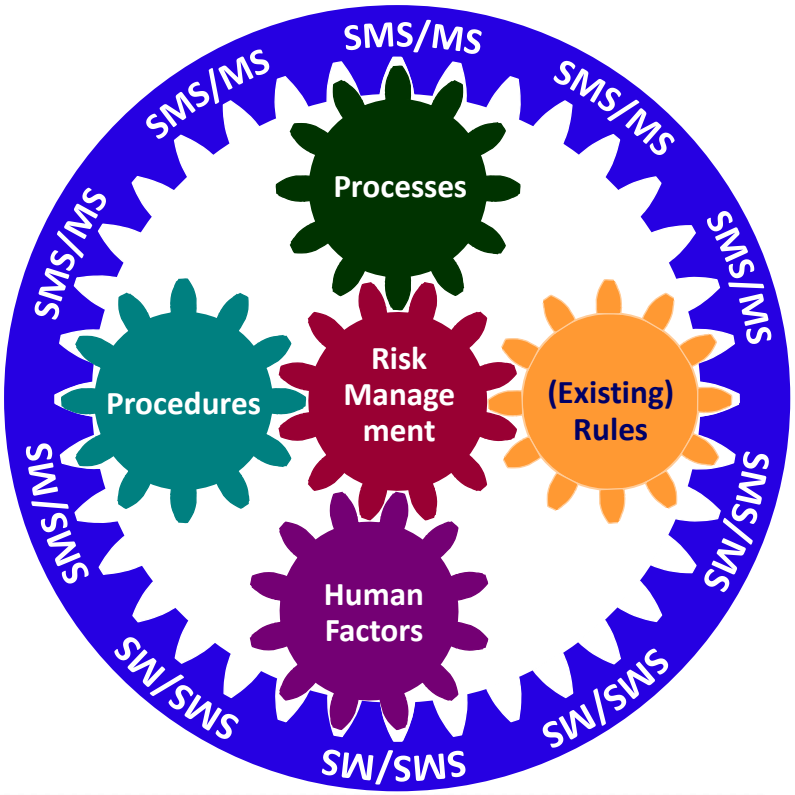
SMS/MS is **a structured & documented set of tools,** specific to activities of every RU-IM-ECM, used for safe management of company risks. It ensures that:

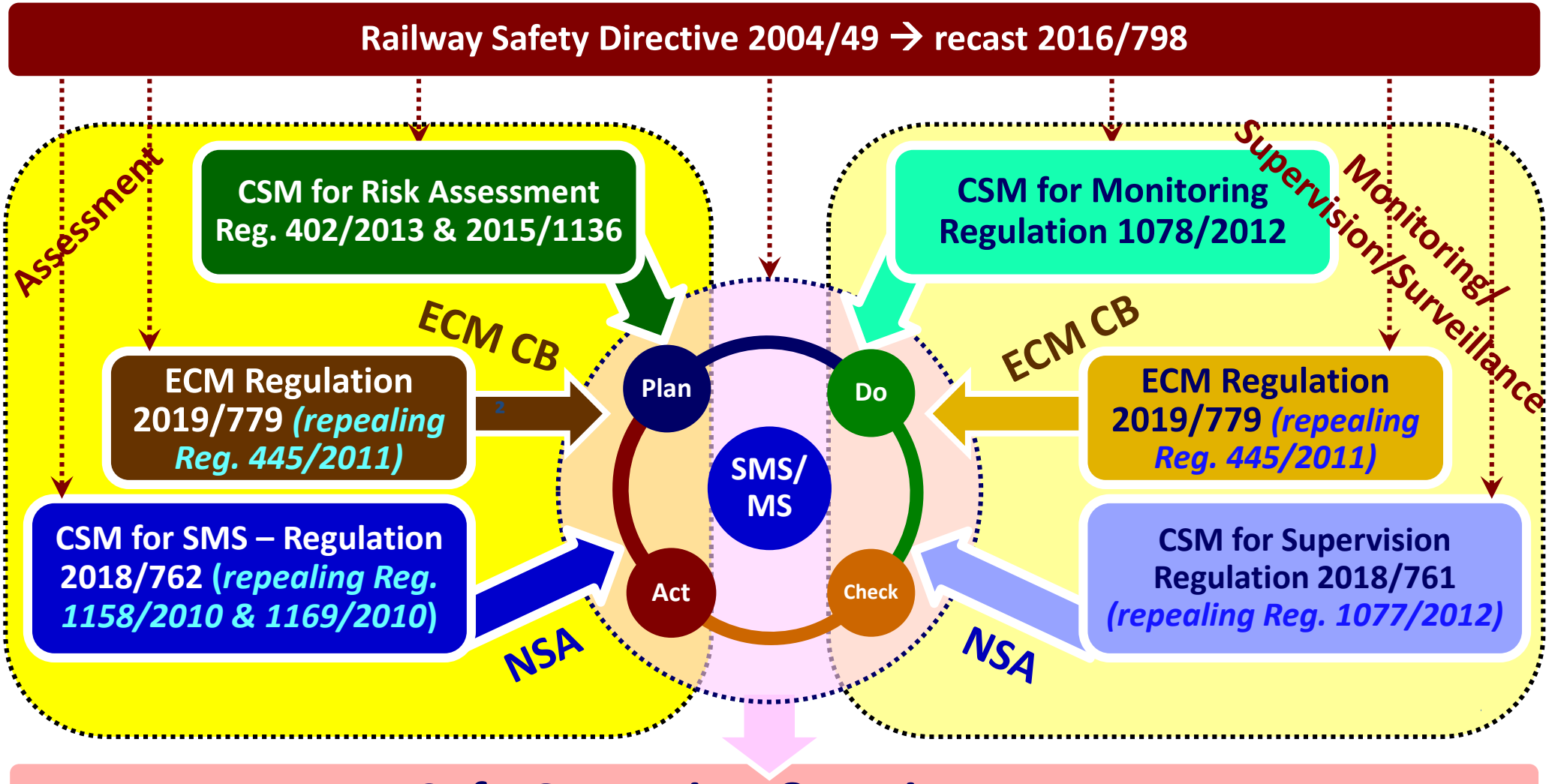
1) **PLAN**: the company is organised (designed) to deliver safely the operation through appropriate **processes, procedures & rules**

2) **DO**: the company actually deploys the operational and supporting processes

3) **CHECK**: the company measures the effectiveness of the processes (monitoring)

4) **ACT/ADJUST**: the company takes preventive or corrective measures on detection of non-compliances *(→ i.e. continuous management of company risks with aim of preventing accidents)*




Railway Safety Directive 2004/49 → recast 2016/798
Assessment
CSM for Risk Assessment Reg. 402/2013 & 2015/1136
ECM CB
ECM Regulation 2019/779 (repealing Reg. 445/2011)
CSM for SMS – Regulation 2018/762 (repealing Reg. 1158/2010 & 1169/2010)
NSA
Plan
Do
Check
Act
SMS/ MS
CSM for Monitoring Regulation 1078/2012
Supervision/Monitoring/Surveillance
ECM CB
ECM Regulation 2019/779 (repealing Reg. 445/2011)
CSM for Supervision Regulation 2018/761 (repealing Reg. 1077/2012)
NSA
Safe Operation & Maintenance

Why a CSM for risk assessment?

[Legal text(s) and Guidance material]

CSM for risk assessment expected to help Mutual Recognition of modifications

Art. 6(3)(a) of Directive 2004/49/EC requires development of a Common Safety Method (CSM) which defines "*procedures and **methods** for carrying out **risk evaluation** and implementing risk control measures **whenever a change** of the operating conditions or new material **imposes new risks** on the infrastructure or on operations*"

CSM for risk assessment is thus a harmonised legal framework which:

- based on existing practices in EU, sets out a **common process for risk assessment**
- **does not constraint** any specific manner on **HOW** to comply with the process (CSM application guides privilege use of standards and reference systems)
- highlights importance of careful management of shared risks at interfaces underlying the Roles & Responsibilities of the different involved actors

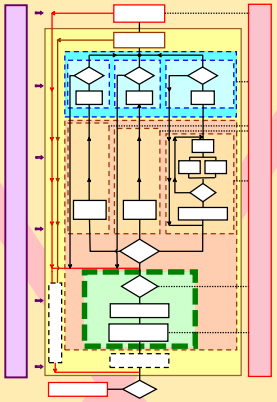
Supports **MUTUAL RECOGNITION** of results from risk assessments thanks to harmonised:

- risk management process;
- exchange of safety related information for the shared risks at the interfaces between;
- documentary evidence resulting from application of risk management process

Successive versions of CSM for risk assessment
Dates of application of the methodology

2005 to 2007

19/07/2010 Technical changes
01/07/2012 TOO changes



RAC-TS [10^{-9} h^{-1}]

Regulation 352/2009
(+ 2 existing Guides)

2010 to 2012

21st May 2015
(*Repealing Reg. 352/2009*)

R&R CSM AB

Regulation 402/2013

~~**More categories of RAC-TS**~~

2012 to 2014

3rd August 2015
(*Amending Reg. 402/2013*)

Regulation 2015/1136

CSM DT
[10^{-9} & 10^{-7} h^{-1}]

Regulation 1078/2012 on
CSM for monitoring
applicable since 7th June 2013

Associated guides for application of CSM for risk assessment
Complementarities between Guides and Standards

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WHAT shall be done?

Regulation 402/2013 on CSM for risk assessment (repeals Regulation 352/2009)

Reg. 2015/1136 on CSM Design Targets (CSM DT)

Existing material

HOW to comply with CSM?

Application Guide on Reg. 352/2009 on CSM for risk assessment

Explanatory Note Roles & Resp. CSM Assessment Body

Application Guide on CSM DT

Examples on **HOW** to apply the CSM

Collection of Examples of risk assessment and Some possible supporting tools

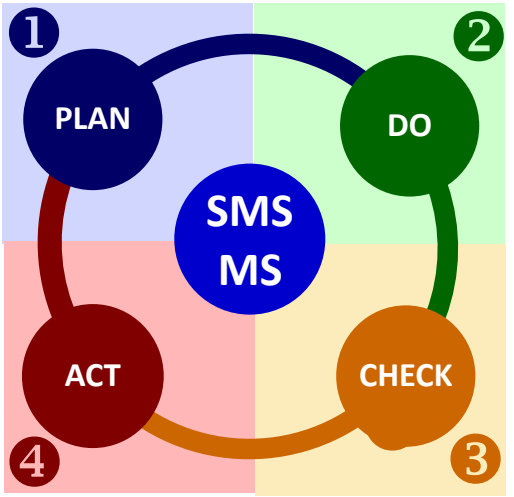
Supporting Standards

IEC61508, IEC/ISO 31000 & 31010
CENELEC 50126, 50128 and 50129 Standards
+ Other Standards (FMECA, FTA, ...)

CENELEC 50126 & 50129 revised in 2017

IEC/ISO 31000 & 31010
CENELEC 50126, 50128 and 50129 Standards + Other Standards (FMECA, FTA, etc.)

Place of CSM for risk assessment within the Safety Management System



CSM for risk assessment to be used for a "safe and controlled" **management of changes** to the railway system

What is place of CSM for risk assessment within Management System (SMS/MS)?

SMS/MS is **a structured & documented set of tools,** specific to activities of every RU-IM-ECM, used for safe management of company risks. It ensures that:

CSM for risk assessment

1) **PLAN**: the company is organised (designed) to deliver safely the operation through appropriate **processes, procedures & rules**

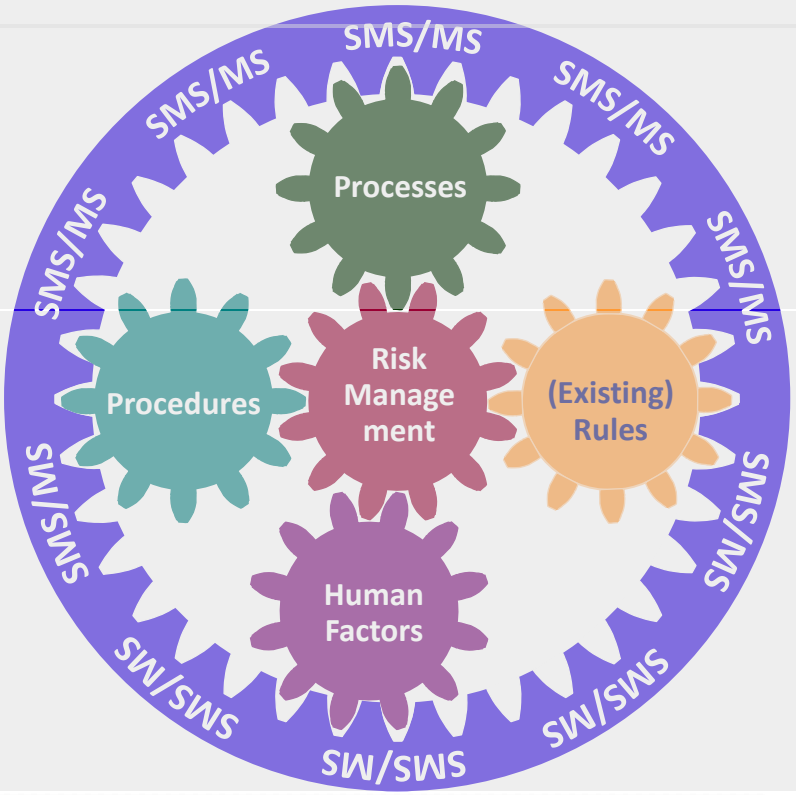
2) **DO**: the company actually deploys the operational and supporting processes

CSM for monitoring

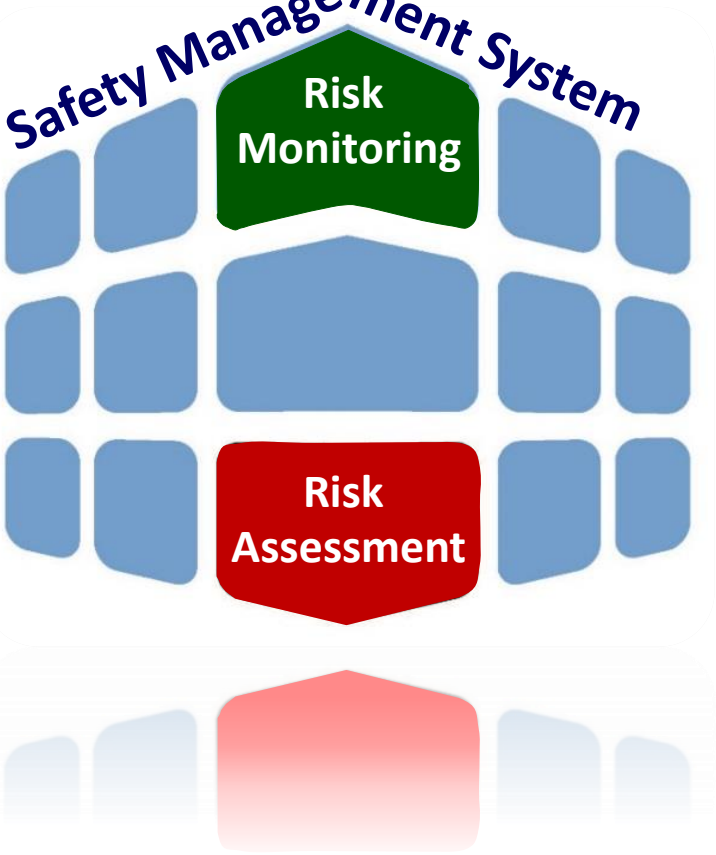
3) **CHECK**: the company measures the effectiveness of the processes (monitoring)

CSM for risk assessment

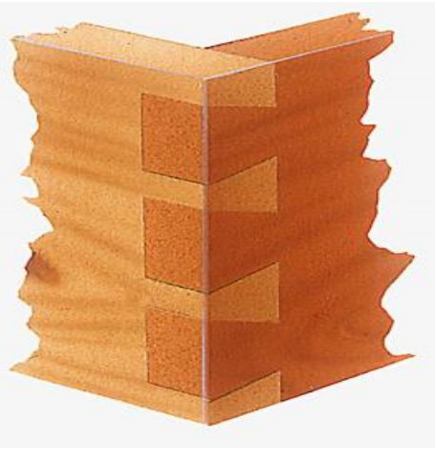
4) **ACT/ADJUST**: the company takes preventive or corrective measures on detection of non-compliances (→ *i.e. continuous management of company risks with aim of preventing accidents*)



Cornerstones/Pillars of an effective Risk Management and Safety Management System



CSM for risk assessment

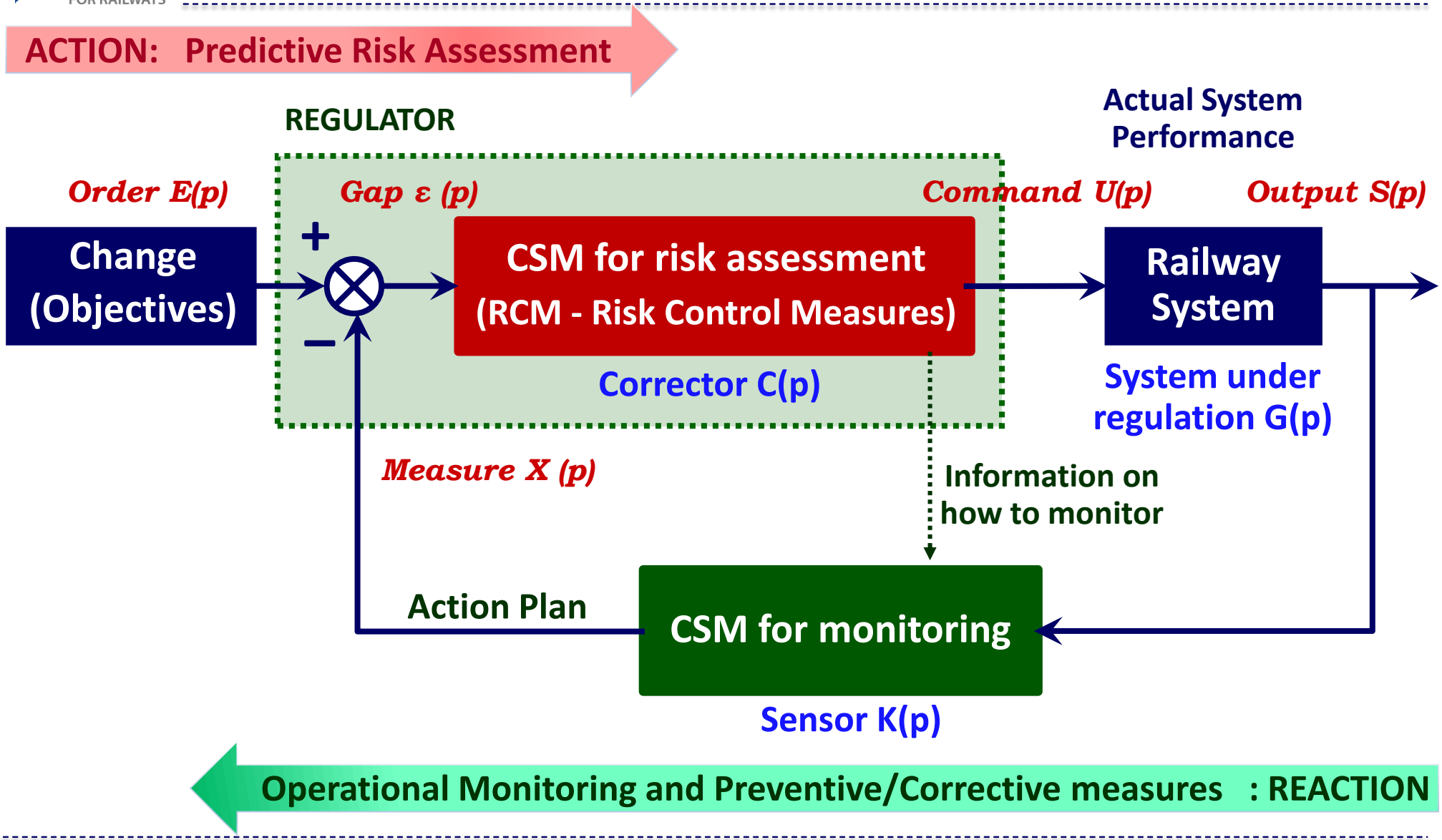


CSM for monitoring

cannot be separated from each other

The implementation of Technical, Operational & Organisational changes can be safe & effective only if the **Change Control Management** process of the RU/IM SMS is based on a continual and combined use of the CSM for risk assessment & CSM for monitoring

Relation between predictive Risk Assessment and Operational Monitoring similar to engineering disciplines of Automatic Regulation Systems



Overview of the CSM for risk assessment

(Regulation 402/2013 & Regulation 2015/1136)

CSM for risk evaluation and assessment

(Regulations 402/2013 & 2015/1136 replacing Regulation 352/2009)

- **Method:** tool to be applied for controlling risks and taking decisions transparently and in a harmonised way.
  It is <u>not replacing</u> the technical railway knowledge
- **Common and harmonised** method at the European level ensuring equal treatment for all railway actors
- **Safety:** it is to be used by railway actors to manage and control safely changes of the European railway system

CSM for risk assessment is a European regulation ➔ it is legally binding and there is no need for national transposition

Who shall apply the CSM? ➔ the Proposer

- IMs, RUs, ECMs;
- Actors requested to apply CSM by law (TSIs, directives,…)
  (*e.g. an applicant for the Authorisation for placing a vehicle on the market*)
- Other actors when defined through contractual arrangements

How should the CSM be applied?

- CSM describes a process or framework for risk assessment to be integrated within the SMS of RUs/IMs/ECMs
- CSM does not constraint any detailed tool/instrument for risk assessment
- Tools/instruments on how to comply with CSM can be found either in Agency guidance material or in international and European Standards

When should the CSM be applied?

- When making changes to the railway system
- Indifferently to "Technical, Operational or Organisational" changes
- **Always** → for **evaluating** at least the **"significance of the change"**

BUT

- Annex I must be applied only when change impacts safety performances **AND** when it is assessed as being a **"significant" change**

When change is non significant, method for risk assessment is not imposed
But RISK CONTROL IS MANDATORY, e.g. ISO 31000 standard could be used

Who is deciding if the change is significant?

- If there is no Notified National Rule, **Proposer decides** whether the change is significant → national safety authority (NSA) does not decide

Controls of the correct assessment of the significance of the change

WHO is checking, **WHEN** and **HOW** **risks** of both Significant and Non Significant changes are adequately **controlled?**

- For RUs and IMs → **NSA during supervision activities** of RU/IM SMS
- For ECMs → **ECM Certification Bodies during surveillance activities** of ECM System of Maintenance
- In the cases foreseen by the national legislation (notified rules)
- **Supervision/Surveillance are not expected to be done systematically on all changes but on a sampling basis, having knowledge of the key risks**
- RUs and IMs (respectively ECMs) are requested to keep and document a list of changes they do to enable such a supervision by NSA (respectively such a surveillance by ECM Certification Body)

Decisions made by Proposers can be questioned by NSAs and by ECM Certification Bodies if they can demonstrate existence of substantial safety risks

Benefits of application of CSM for risk assessment

- Common tool used by all railway actors
  Common language supporting mutual recognition of results of Risk Assessments and the exchange of information between stakeholders

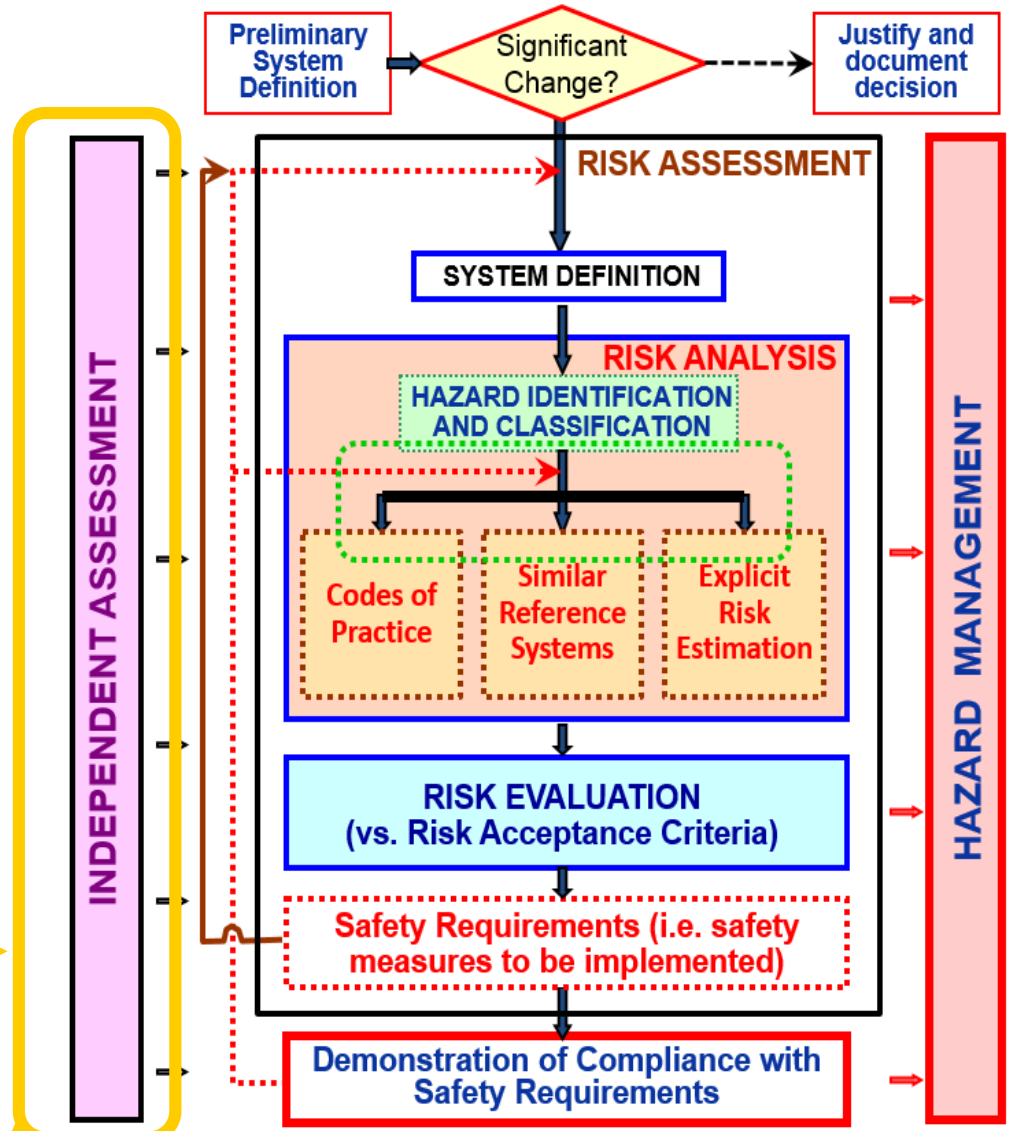
- Enables traceability of decisions and provides Company Management with criteria to help them taking consciously and safely decisions
  Memory of the company

- Decisions of the NSA/ECM Certification Body are based on objective evidences
  Equal treatment for all RUs/IMs and ECMs

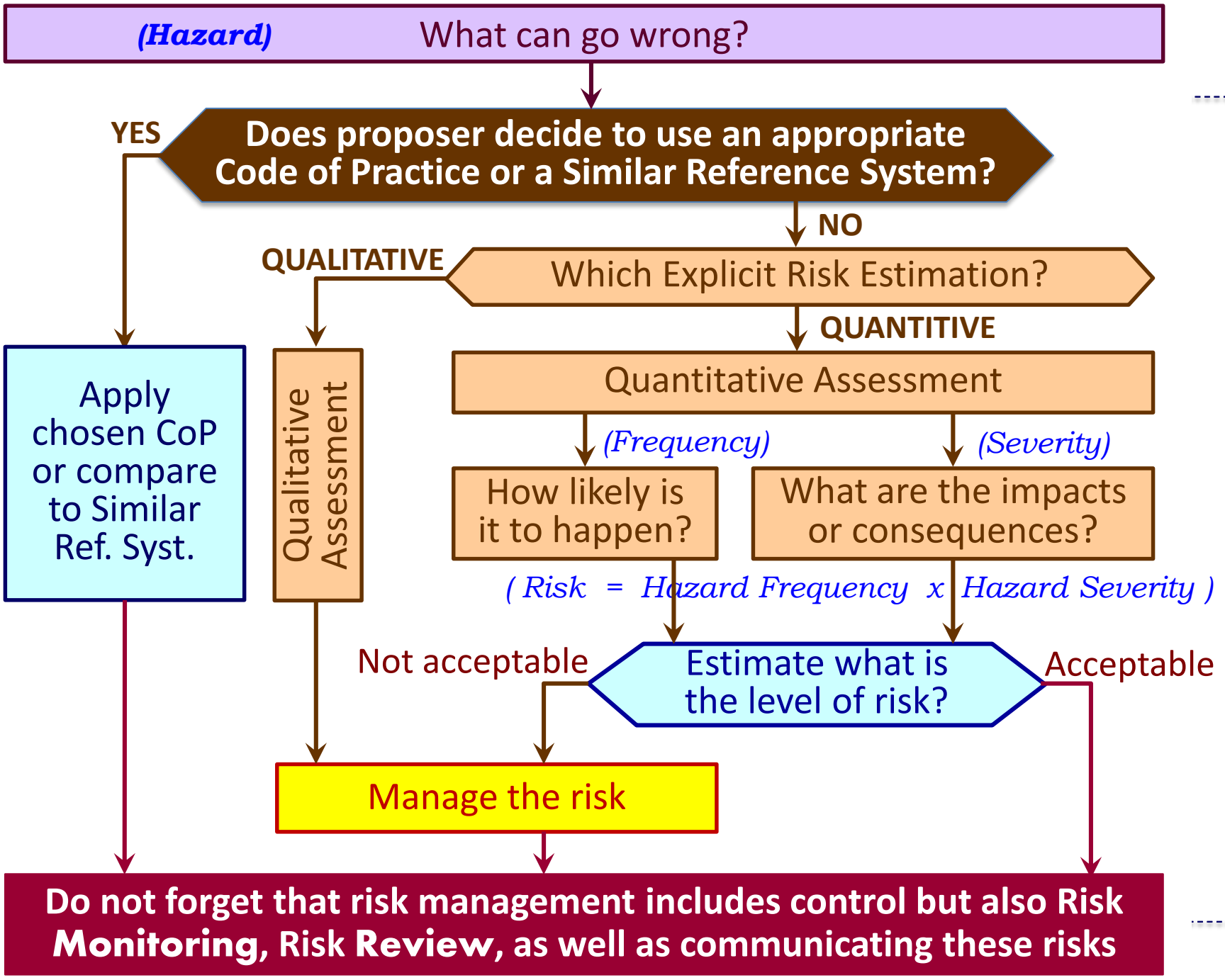
CSM supports logical and rational approaches rather then emotional behaviours based on doubts and fears

Overview of the CSM for risk assessment
Risk assessment flowchart - Process in Annex I

- A common risk assessment process with:
  - (a) System definition
  - (b) Identification of hazards/risks & associated safety measures
  - (c) Risk analysis based on exiting risk acceptance principles (**CoP, Ref. Syst, Explicit Risk Estimation - no priority**)
  - (d) Risk evaluation for checking acceptance of risk(s)
  - (e) Definition of safety requirements from identified safety measures
- Demonstration of system compliance with identified safety requirements
- **Requirements for mutual recognition:**
  - (a) Hazard Management via a Hazard Log
  - (b) **Independent Assessment (Body)**



Iterative Risk Management Process "triggered" by a Significant Change



No order of priority

Why is Independent Safety Assessment necessary?

What are the AsBo Roles & Responsibilities?

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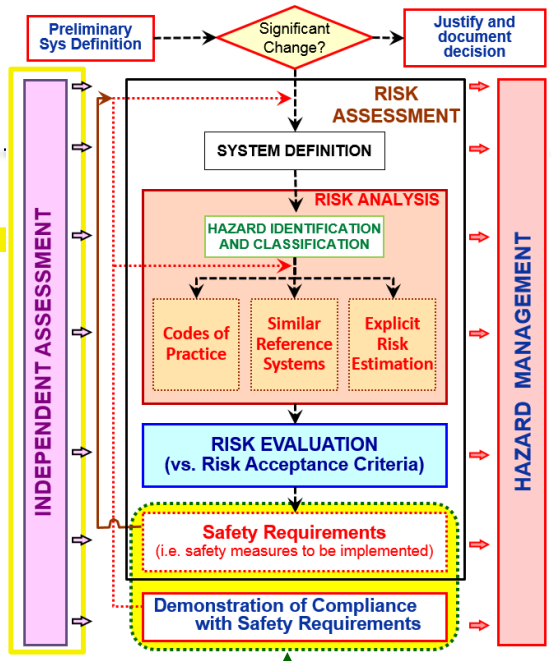
Significant Change

Article 6 → an AsBo must be appointed



… in order to provide the necessary reasonable assurance to an Authorising Entity who must take a decision based on the results from the application of the CSM

AsBo is a **reliable second pair of eyes** who through independent assessment of:

- **correct application** of risk management **process** in Annex I of CSM, and;
- **suitability of results** from the risk management process;

- gives **an expert judgement** on the confidence that the change under assessment can fulfil safely the intended objectives,
- enables to gain trust in an effective risk management and **allows the mutual recognition** of the results from the risk assessment

Pay attention not to mix the Roles & Responsibilities of the Proposer and of the AsBo

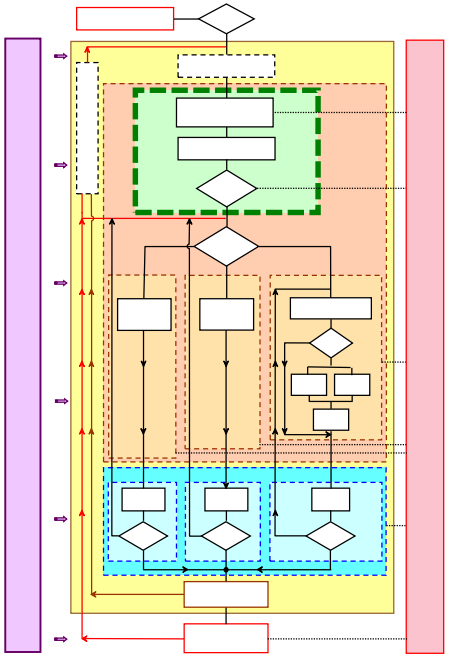
- Important to distinguish that:
  - Risk Assessment shall be done by the **Proposer**
  - Independent assessment shall be done by CSM Assessment Body to check:
    ① correct application of risk management process in Annex I of CSM, and;
    ② suitability of the results from that risk management process

- **CSM assessment body:**
  - does not independently assess the significance of change
  - **does not carry out risk assessment**
  - does not provide advices, recommendations or solutions on how to address detected non-compliances with CSM or any organisational concerns related to company safety and quality assurance processes

Otherwise there is a risk to compromise CSM AB independence in assessing appropriateness of corrective measures Proposer suggests to address issues

Responsibility of independent CSM Assessment Body
WHAT shall be assessed?

- **Correct application** of CSM → check of compliance with
  - the CSM **Regulation**, and;
  - the risk assessment **process** in that CSM
- **Suitability of results** of risk assessment → check that system under assessment can fulfil safely intended objectives of the change
- Assessment include all steps of CSM process:
  - system definition
  - hazard identification and risk analysis
  - risk evaluation and risk acceptance
  - demonstration of compliance with safety requirements
- **AsBo working method detailed in a Recommendation For Use [RFU 1] available on the Agency website**

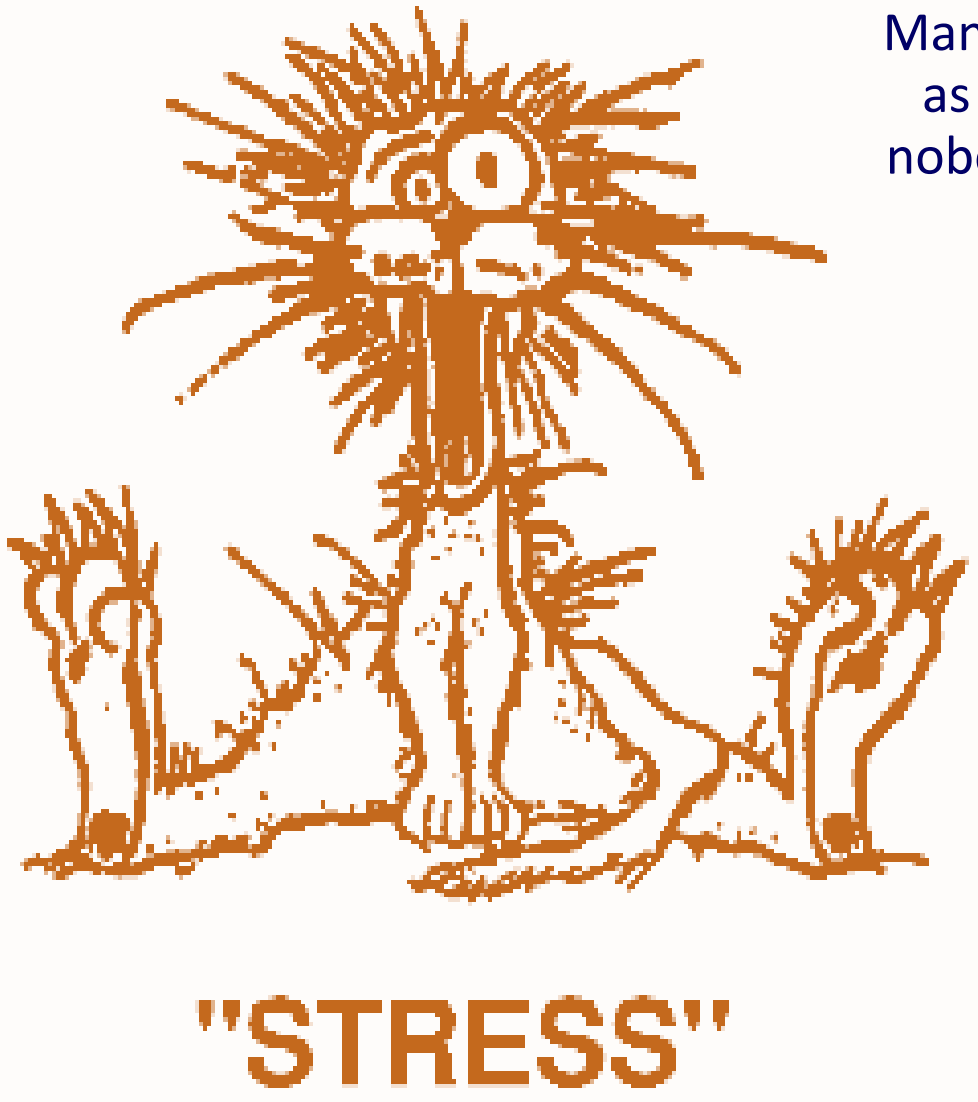


When shall risk assessment be done?

What is a change?

What is not a change?

Perception of the concepts of «risk», «risk identification» and «risk management»



Many people perceive risk and risk management as a **complicated and boring** task that almost nobody likes and nobody is happy to deal with it

shown by return ↓ of experience [REX]

Many stakeholders **misuse concept of significant change** in CSM to avoid:

1) application of Annex I of CSM
2) appointment of an AsBo

In practice, no matter we like or dislike it, proper **Risk Identification, Risk Control and Risk Management must be done for both Significant and Non-Significant** changes

Legal requirements
Where is risk assessment necessary/required?

Safety Directive 2016/798

Art. 6(1)(a) → **Reg. 402/2013 on CSM RA** → Manage safely the changes [Art. 4 & 2(2)]

Safety related changes

- Risk assessment **must be done**
- Documentary evidence must exist

Non-safety related

- Risk assessment not needed
- Keep traceability of changes to justify a proper management of changes

Art. 9 → RU/IM SMS

Art. 14 → ECM MS

Interop. Directive 2016/797

Art. 10 → 'EC' decl. of conformity or suitability for use of ICs

Art. 15 & 20 → 'EC' decl. of verification of a subsystem

Art. 18 → Auth. for placing in service of fixed installations

Art. 15 → 'EC' declaration of verification of onboard and trackside CCS (Reg. 2019/776 which amends Regulation 2016/919

Art. 21 → Vehicle authorisation for placing on the market (Reg. 2018/545)

Non-significant

Justification **must be done by Risk Assessment** (next slide examples of process)

(AsBo optional)

Significant or by law application of

Risk Assessment in **Annex I of CSM is mandatory**

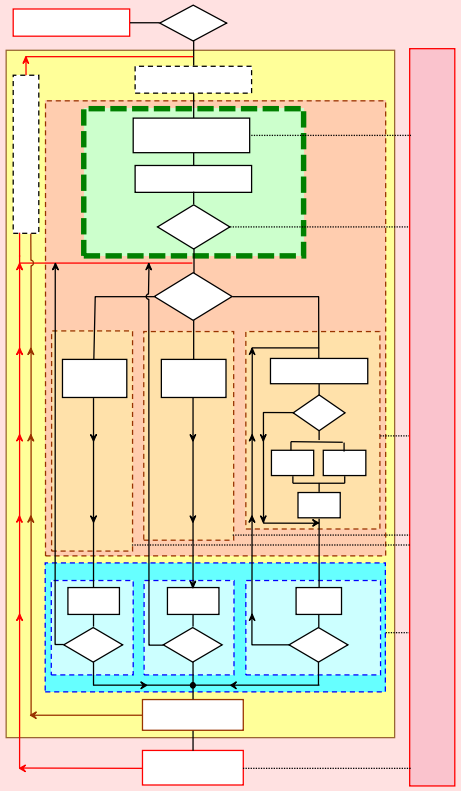
+

AsBo mandatory

Possible “processes for risk assessment” and control of **risks arising from safety-related non-significant changes**

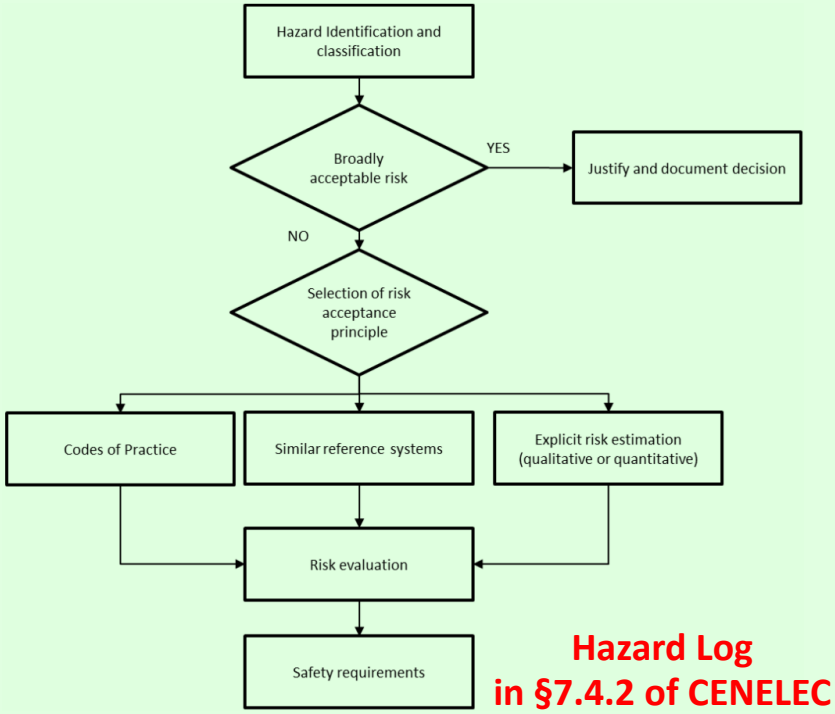
1

Annex I of Reg. 402/2013 without AsBo



2

Figure 8 in CENELEC 50126-1:2017 standard on the process for risk assessment (related to phases 3 and 4 of Figure 6)

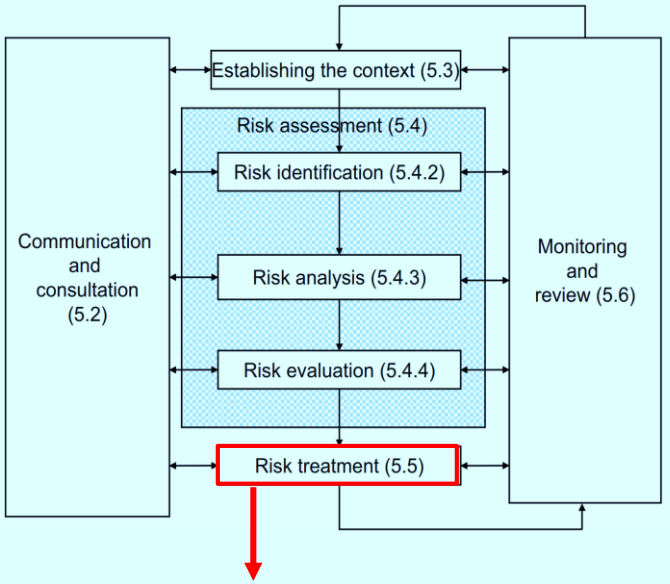


Hazard Log in §7.4.2 of CENELEC

Implementation and demonstration of compliance part of Figure 6 of 50126-1:2017

3

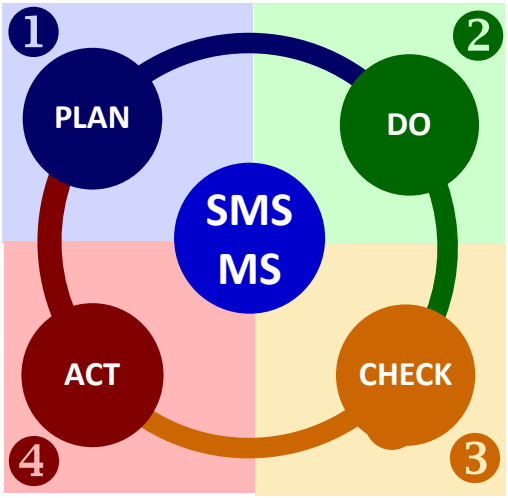
Figure 3 in ISO 31000 standard Risk management process



Includes implementation of control measures that make the risk acceptable/tolerable

Setting up and/or modification of a (Safety) Management System

Capability for safe railway operation, safe traffic management and safe maintenance are acknowledged through a certified **(Safety) Management System (SMS/MS)**



The development (or modification) of the SMS/MS must be based on a **risk assessment in order to**:

- identify all risks arising from the activities of the company;
- take into account all risks associated to the safe operation and maintenance of technical equipment/sub-systems;
- put in place an organisational structure and share roles and responsibilities across that structure in order to:
  - fulfil safely the company activities;
  - operate and maintain safely the technical equipment;

For that, independent Assessment by an AsBo gives a reasonable confidence that the company organisation, processes, procedures and working instructions of the SMS/MS enable to fulfil safely its activities **(i.e. safe operation and safe maintenance of the railways)**

Vehicle authorisation for placing on the market

The applicant for the Authorisation for placing a Vehicle on the market must apply **risk assessment in order to**:

- identify/capture, understand and analyse all reasonably foreseeable hazards;
- identify and implement risk control or mitigation measures reducing the risks to an acceptable level;

- Identify, and export through the Technical File of the Vehicle, all necessary Safety-related Application Conditions in order to ensure that the vehicle can be safely integrated within the network, and safely operated and maintained

The independent assessment by an AsBo gives the assurance to the Authorising Entity that:

- Applicant's risk assessment process is systematic, exhaustive & correct
- Vehicle can be safely integrated within the network, safely operated and safely maintained

Examples of changes where risk assessment must be done

- Placing in service, and integration into RU SMS, of an already authorised vehicle
- Design of a new vehicle or modifications to an existing vehicle
- Merging of two railway undertakings into a single company or an RU which integrates an external ECM into its company
- Modification of an existing process, a procedure or working instruction of the SMS
- Extension of the type of operation (e.g. a freight RU which wants to transport dangerous goods or to operate passenger transport)
- Outsourcing an activity previously done internally (e.g. an infrastructure manager which sub-contracts some parts or wholly maintenance of infrastructure
- Placing on the market of an on-board or trackside ETCS sub-system, or modifications to such an existing sub-system
- Reorganisation and re-structuring of the company with new roles and responsibilities
- etc.

Examples of activities which should not require risk assessment if those activities are already covered by either existing SMS arrangements or by existing risk assessment evidence

- Use of temporary speed restrictions (TSRs) for maintenance of infrastructure
- Application of a maintenance procedure/instruction of the SMS
- Replacement of a defective technical component/equipment by a healthy one in compliance with the manufacturer's installation prescriptions (which includes the necessary tests to be done)
- Change of supplier of an interoperability constituent (IC)
- Conformity of a New Vehicle to an already Authorised Type
- etc.

Structuring of Development, Verification, Validation and independent Conformity Assessments activities

between the Proposer, NoBo, DeBo & AsBo

Relationship between AsBo and other conformity assessment bodies (NSA, NoBo, DeBo, other ASBOs)

EU legislation requires to avoid duplication of independent assessment work between different conformity assessment bodies *(NoBo, DeBo, NSA, AsBo, etc.)*

Essential that the Proposer correctly structures the different development, verification and validation activities and independent conformity assessments

Compliance with applicable TSIs & National Rules

and

NoBo "EC Verification of conformity" & DeBo Checks

&

Compliance with CSM for risk assessment

and

Independent Safety Assessment by an AsBo

Compliance with applicable TSIs and national rules is mandatory

TSIs ≡ **EU law**
(Derogations in Art. 7 of ID 2016/797)

NR in force at time of request of Authorisation
≡ **National Law**

Independent Conformity Assessment by **NoBo**

DeBo

- TSIs contain essential requirements related to safety **as far as they are necessary for interoperability**
- Sole compliance with TSIs **does not ensure safety is fully covered** → additional risk assessment necessary
- **Only where necessary for interoperability purposes**, TSIs request application of specific part(s) of CSM RA
- TSIs do not question necessity to apply CSM RA for safe management of changes → **CSM RA must also be applied to demonstrate safety is fully controlled**

Compliance with Regulation 402/2013 is mandatory when carrying out a change

Regulation 402/2013 (CSM RA) ≡ EU law

(when making changes)

Independent Conformity Assessment

AsBo

Compliance is mandatory

BUT

Application of CSM RA shall not lead to requirements contrary to a TSI otherwise TSIs need to be revised or MS shall ask for a derogation

TSIs and Regulation 402/2013 are separate legal texts ➔ compliance with CSM Risk Assessment is also mandatory

TSIs ≡ **EU law** (Derogations in Art. 7 of ID 2016/797)

NR in force at time of request of Authorisation ≡ **National Law**

Regulation 402/2013 (CSM RA) ≡ EU law ***(when making changes)***

Independent Conformity Assessment by **NoBo** / **DeBo**

Compliance is mandatory

Independent Conformity Assessment by **AsBo**

Compliance is mandatory

- TSIs contain essential requirements related to safety **as far as they are necessary for interoperability**
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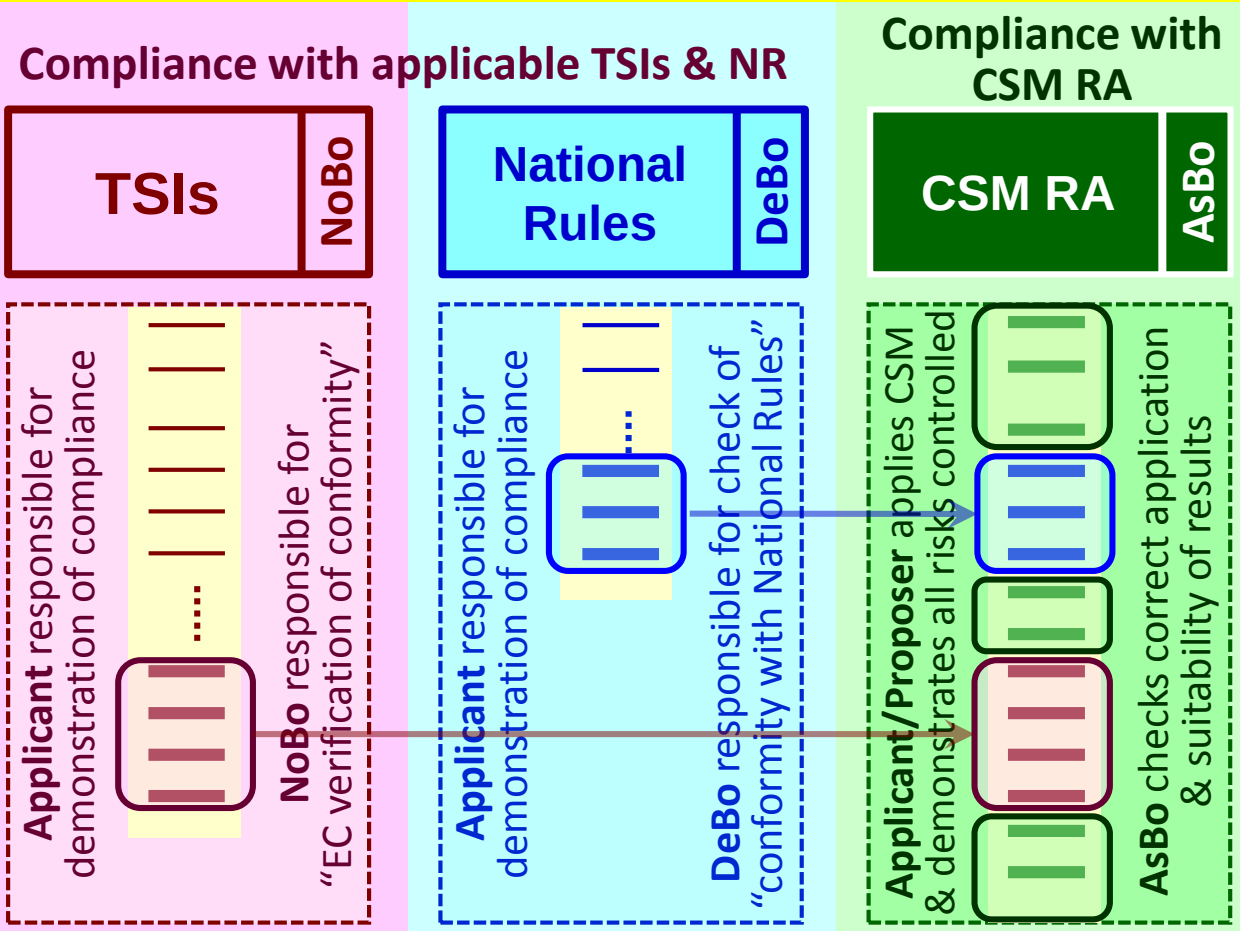
BUT

Application of CSM RA shall not lead to requirements contrary to a TSI otherwise TSIs need to be revised or MS shall ask for a derogation

Compliance with TSIs – Compliance with CSM Risk Assessment
WHAT is the interaction of AsBo with other CABs?

Duplication of independent assessment work between different Conformity Assessment Bodies shall be avoided



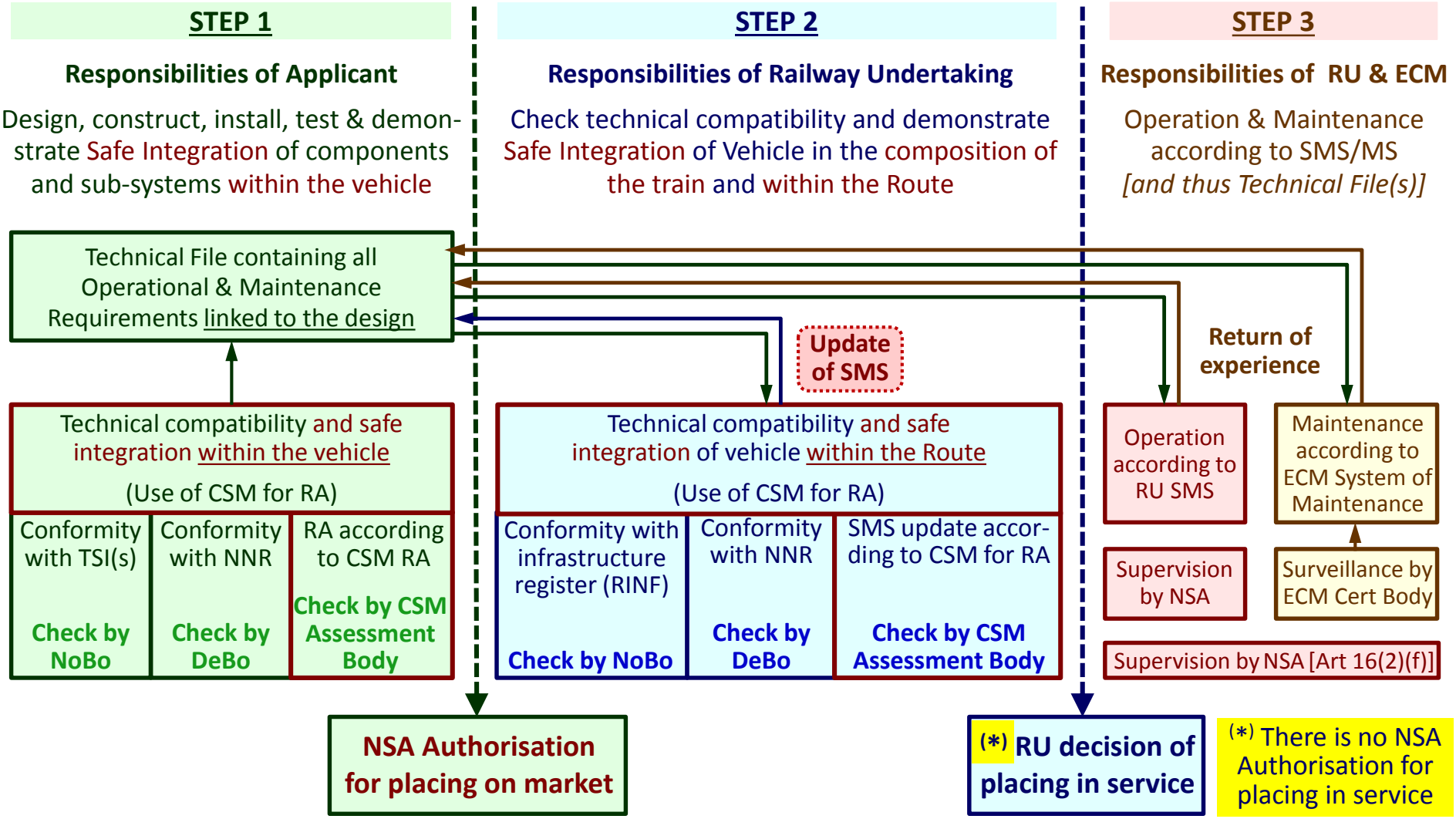
Applicant/Proposer applies its processes and demonstrates:

- compliance with TSIs, NNR & CSM
- all risks identified and controlled to an acceptable level **(Proposer's Declaration – Art. 16)**

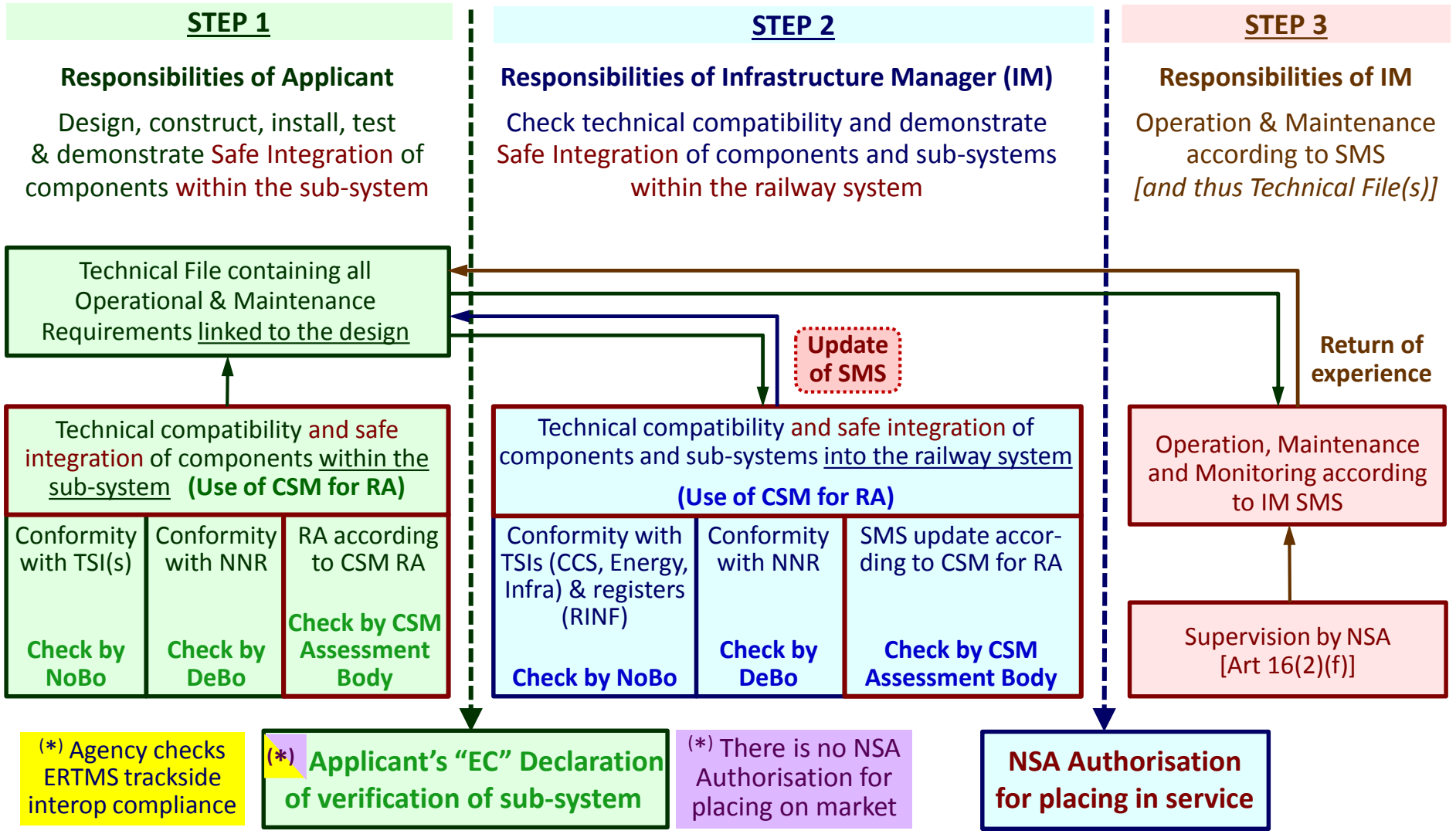
Authorising Entity (e.g. NSA) issues authorisation based on evidences of:

- NoBo EC Verif.ication of conformity with TSIs;
- DeBo verification of conformity with notified national rules;
- **Applicant's EC declaration of verification**;
- AsBo safety assessment report;
- Applicant's declaration of **Article 16 of the CSM RA**;

Roles and responsibilities of different Conformity Assessment Bodies within Authorisation for placing on market Vehicles - Safe Integrations



Roles and responsibilities of different Conformity Assessment Bodies within Authorisation for placing in service of fixed installations – Safe Integrations



Differences between Regulation 402/2013 on the CSM for risk assessment

&

CENELEC standards

In terms of Risk Assessment PROCESS

There is no difference in the process between:

- CSM for risk assessment
  (WHAT? i.e. High Level requirements)

&

- ISO 31000, CENELEC EN 50126, 50128 & 50129 Standards
  (HOW to comply with CSM?)

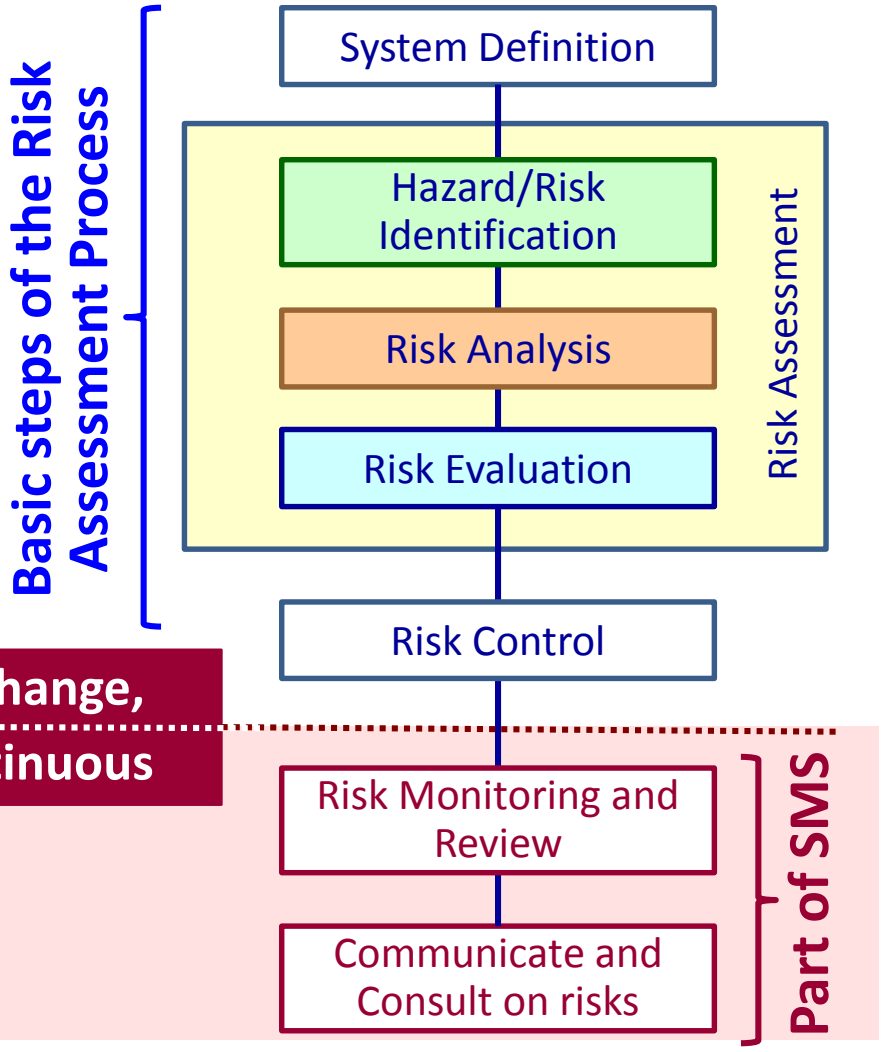
General overview of risk management in ISO 31000

Regardless of type of business, activity or function of company, Risk Management is **7 step based process**

- Defining context (System Definition)
- Risk Assessment
  - Hazard/Risk Identification
  - Risk Analysis
  - Risk Evaluation
- Risk Control

'Risk' is dynamic and subject to constant change, so Risk Management process includes continuous

- Risk Monitoring and Review
- Communication with and consult staff on company and their activity risks



In terms of independent safety assessment activities

A CENELEC ISA is not a CSM AsBo

A CENELEC ISA cannot work instead of a CSM AsBo

- **CSM Assessment Body (AsBo)**
  - **Mandatory** accreditation–recognition and supervision **by a competent authority**
  - Mutual acceptance of AsBo report mandatory

whereas

- **CENELEC Independent Safety Assessor (ISA)**
  - **Neither obligation** for accreditation–recognition **nor** for supervision **by any competent authority**
  - **Mutual acceptance of ISA report not mandatory**

BUT no difference of working method between AsBo & ISA

Levels of the railway system where the CSM for risk assessment applies

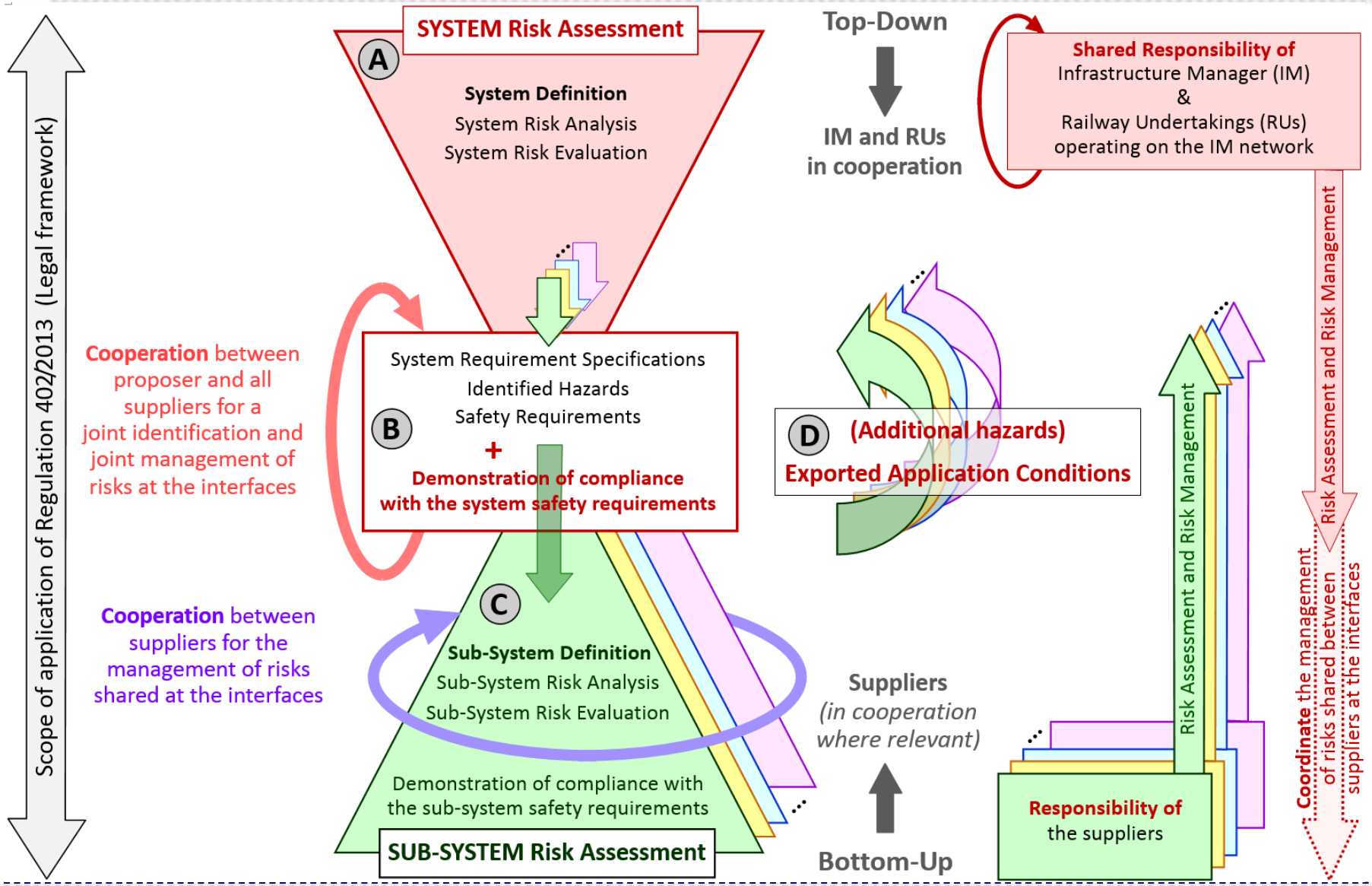
REMINDER: Who shall apply the CSM? ➔ the Proposer

- IMs, RUs, ECMs;
- Actors requested to apply CSM by law (TSIs, directives,…)
  (*e.g. an applicant for the Authorisation for placing a vehicle on the market*)
- Other actors when defined through contractual arrangements

➔ (CSM for) **risk assessment** must be done <u>at all levels</u> of the railway system architecture

System based approach required by Art. 4(1) of Safety Directive 2016/798 as well as by CENELEC 50126 2:2017 & 50129 2:2018 standards

Concepts from Figure 1 of CENELEC 50126 2:2017 and Figure A.2 of CENELEC 50129 2:2018 adapted to the process in Annex I of Regulation (EU) 402/2013.

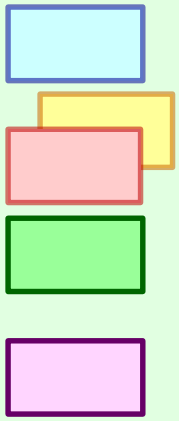


At the level of the railway system, systematic top-down "system based approach":

- Joint System Risk Assessment by IM & RUs
- **System AsBo**

At level of every sub-system (i.e. sub-contractor)

- Sub-System Risk Assessment (jointly with other sub-contractors **for shared risks**)



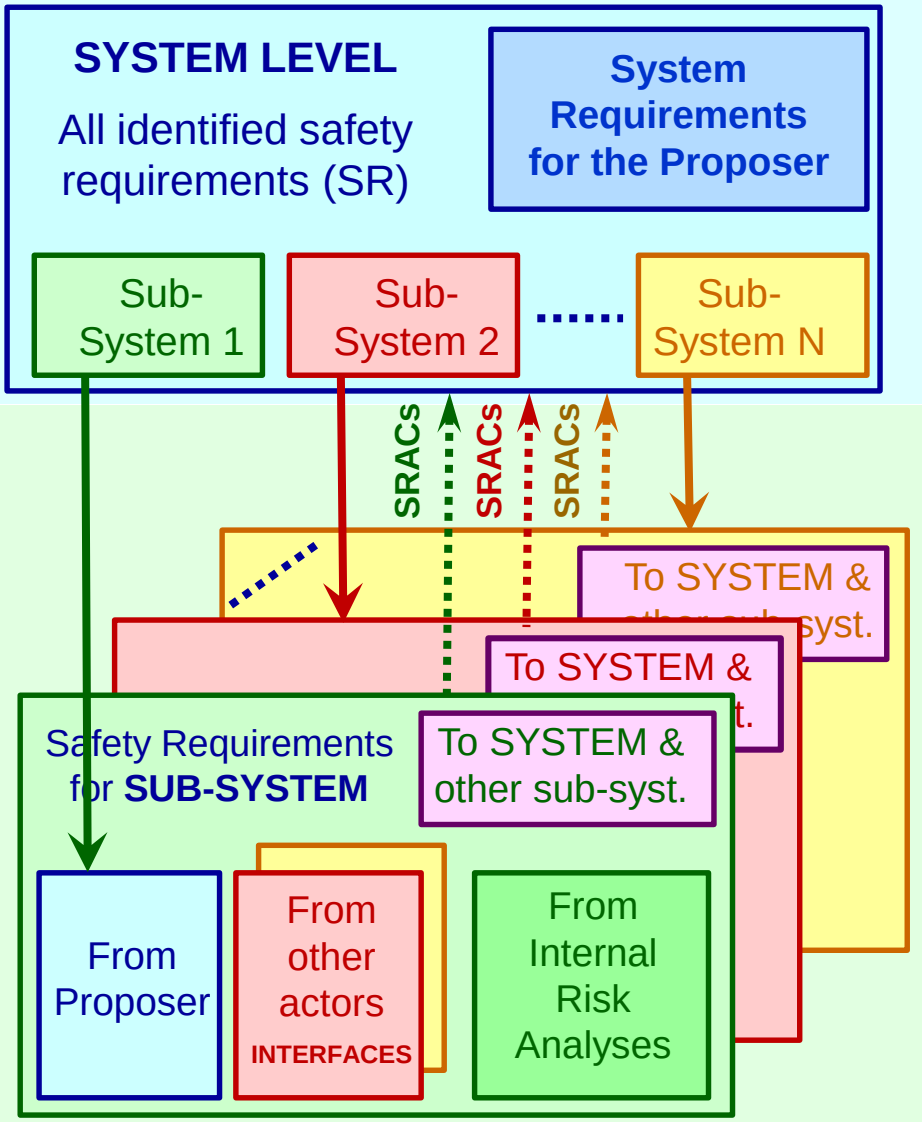
Requirements allocated to sub-system from the SYSTEM

Requirements imported from other actors through shared interfaces

Internal requirements from own sub-system risk assessment

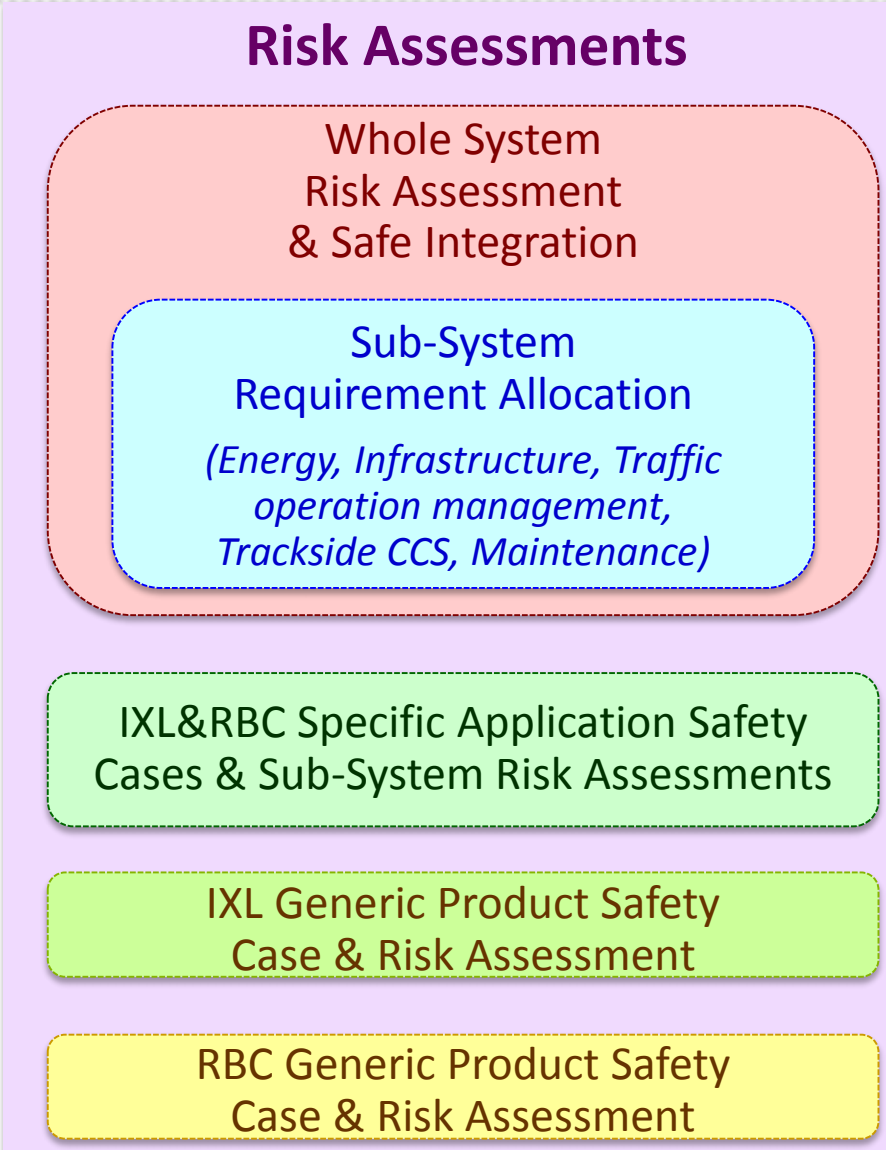
Requirements exported to SYSTEM (SRACs) and to other sub-systems (/actors) through shared interfaces

- **Sub-System AsBo**



System: build a new line fitted with ERTMS

- **Structural sub-systems:**
  - Energy,
  - Infrastructure
  - Traffic operation management
  - Trackside CCS
  - Maintenance
- **Existing products on the market:**
  - RBC
  - Interlocking
  - etc.



System Architecture

Independent assessment

SYSTEM AsBo →

- System: new line to be fitted with ERTMS – Structural sub-systems:
  - Energy,
  - Infrastructure
  - Traffic operation management
  - Maintenance
  - Trackside CCS
  - Sub-System req^{mnt} allocation

Whole System Risk Assessment (including sub-system requirement specification) & Safe Integration

RBC Sub-System AsBo / **IXL Sub-System AsBo** →

- Interlocking + RBC (Level 2) parametrisation (configuration)

Specific Application Safety Cases & Risk Assessments

IXL Product AsBo (ISA?) →

- Interlocking Product

Generic Product Safety Case & Risk Assessment

RBC Product AsBo (ISA?) →

- RBC Product

Generic Product Safety Case & Risk Assessment

Mutual recognition of the Independent Safety Assessment Reports from the different CSM Assessment Bodies (**AsBo**)

Independent Safety Assessment Reports

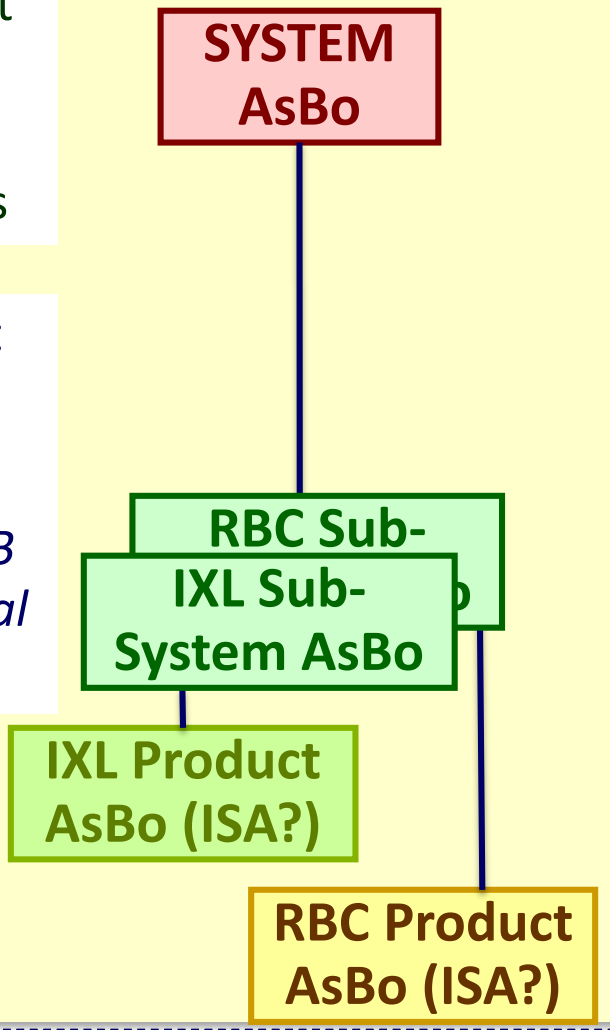
SYSTEM AsBo Report

Mutual recognition obligatory for sub-system AsBo reports

CENELEC ISA Report

Mutual recognition non-obligatory

(Possible but CSM AB can request additional checks)



Independent assessment

Whole System Risk Assessment & Safe Integration

Sub-System Requirement Allocation

(Energy, Infrastructure, Traffic operation management, Trackside CCS, Maintenance)

IXL&RBC Specific Application Sub-System Safety Cases & Risk Assessments

IXL Generic Product Safety Case & Risk Assessment

RBC Generic Product Safety Case & Risk Assessment

AND MOST IMPORTANT

Principles of a proactive Risk Management

- Railway operation, traffic management and maintenance are risky businesses. It is therefore mandatory for Top Managers to have a good understanding of the concept of risk and to engage in proper, continual & proactive Risk Management

- Rather than only reacting to events from the past, proactive Risk Management, **based on risks**, ensures that before any problem appears:

  - a proactive and systematic risk assessment of all reasonably foreseeable problems is done,
  - their causes and consequences are analysed
  - acceptable risk control measures are defined and implemented:
    - either to prevent the hazard (cause), or
    - to mitigate the consequences severity ,or to reduce probability

- So, it facilitates managers taking consciously decisions (**responsibility**)
- As the process is consistent and traceable, it improves transparency within the organisation, to (external) independent assessors, as well as to Regulatory Bodies
- A proactive Risk Management builds mutual trust both within company and among business partners (e.g. insurance companies)

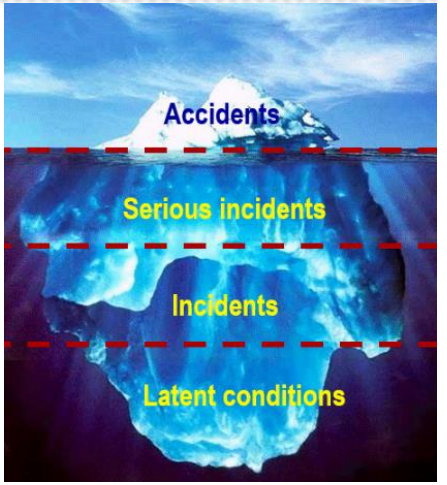
Reminder

Risk Assessment		Risk Management
What can happen? *(Identify Hazards)*	⟷	What can be done?
What are the consequences if it happens? *(Estimate severity)*	⟷	What are the impacts of each option on future options?
How likely is it to happen? *(Estimate frequency)*	⟷	What are the benefits, costs and risks of each option?
Are consequences acceptable? *(Risk acceptability)*	⟷	Are the impacts of each option affordable?
Reduce the risks where required *(Risk control)*	⟷	Risk monitoring and risk review *(i.e. check effectiveness + improve)*

Risk assessment is a means to an end, not an end in itself - The aim is to keep people safe, not only to have good paperwork

The method alone does not lead to successful Risk Management

- The most important step in any risk assessment is that **hazards can only be controlled if they are IDENTIFIED**



- Risk assessment is a **means to an end**, not an end in itself. The aim is to **keep people safe**, **not only to have good paperwork**

- The risk analysis process depends on:
  - the experience,
  - the knowledge,
  - the imagination,
  - the creativity, and,
  - the integrity

  of the individuals doing the analysis

The only application of risk assessment and risk management techniques without appropriately talented/competent staff does not ensure a proper and thorough risk analysis result

Useful links

ERA guidance material on the CSM for risk assessment, and additional relevant documentation can be found on the Agency website under the link https://www.era.europa.eu/common safety methods for risk evaluation and assessment

- Regulation 402/2013 and Regulation 2015/1136
- Agency guide for the application of the CSM for risk assessment
- Agency collection of examples of risk assessments and some possible tools supporting the CSM
- Agency guideline for the application of harmonised quantitative design targets for technical systems (CSM-DT) defined in Regulation 2015/1136
- Agency explanatory note on the CSM assessment body roles and responsibilities
- Recommendation for use 01 on the working method of the AsBo
- Agency clarification note on safe integration

Making the railway system work better for society.

Follow us on Twitter: @ERA_railways

Questions? → Send e-mail on: CSM.risk_assessment@era.europa.eu