European Railway Agency

Dissemination on CSM on monitoring , CSM on risk assessment and certification of ECMs

- **ERA Team involved in the dissemination workshop:**

  - Nathalie DUQUENNE (Management System Sector / Safety Unit)
  - Esteban COITO GONZALEZ (Management System Sector / Safety Unit)
  - Aleksandra PERKUSZEWSKA (Safety - Regulation & Safety Monitoring)
  - Marta LENARCIK (Secretariat / Safety Unit)

Objectives of European Union for railways

1°) Open the railway market to competition for the rail transport services and the railway supply industry!

2°) Remove historical barriers to free circulation of trains and make railways business oriented and competitive!

3°) Prevent the sector from using safety as a barrier to market access or an excuse to resist change!

- **Purpose of the workshop:**
  - Provide support to the concerned actors of the railway sector on both common understanding of different CSMs (Monitoring and risk assessment)
  - Provide support to the concerned actors of the railway sector on:
    - How Entities in Charge of Maintenance (ECMs) can develop a Maintenance System based on the requirements of the Regulation 445/2011/EU;
    - How railway actors have to understand their respective responsibilities regarding maintenance of freight wagons;
    - How the certification and accreditation processes are.

- **Presentations delivered both by the Agency (both days) and by the sector (2nd day)**
- **Time foreseen for open discussion with the participants:**
  - At the end of each presentation
  - Plenary session of questions/answers at the end of each day **(Debriefing)**.
- **Different level of knowledge in the audience - level of insight in the subject**

Please fill out your evaluation sheet before leaving for each day…

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Agenda

- **1st day: 09:30 to 18:00**
  - 09:30 – 10:00: Registration and welcome
  - 10:00 – 10:15: Opening of the workshop
  - 10:15 – 10:45: The concept of SMS and where the SMS fits into regulatory Framework
  - **10:45 – 11:00: Coffee Break**
  - 11:00 – 11:30: CSM Risk assessment
  - 11:30 – 12:30: Putting the CSM Risk assessment into practice (Group exercise)
  - **12:30 – 13:30: Lunch Break**
  - 13:30 – 14:30: Questions/discussion and feedback from the exercise
  - **14:30 – 14:45: Coffee Break**
  - 14:45 – 15:30: ECM maintenance system

- 15:30 – 16:00: Scope of ECM certification
- 16:00 – 16:40: Allocation of responsibilities
- 16:40 – 17:20: ECM certification scheme
- 17:20 – 17:40: Summary of the first day and preparation of the second day

English	Polish
Infrastructure Manager (IM)	zarządca infrastruktury
Railway Undertaking (RU)	przedsiębiorstwo kolejowe
National Safety Authority (NSA)	władza bezpieczeństwa
Common Safety Method (CSM)	wspólne metody oceny bezpieczeństwa
Risk assessment	ocena ryzyka

English	Polish
Monitoring	monitorowanie
Safety Management System (SMS)	system zarządzania bezpieczeństwem
Entity in Charge of Maintenance (ECM)	podmiot odpowiedzialny za utrzymanie
Maintenance System	system utrzymania
Maintenance workshop	warsztat utrzymaniowy

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Introduction to the concept of SMS and the role of rules in the SMS

1. What is the general purpose of having a SMS?
2. What are the benefits of having a SMS?
3. How do rules fit into the SMS?
4. Is the use of rules inconsistent with the management of risk requirements in a SMS?

From the Directive 2004/49/EC:

Art. 3.(i) – Definition on Safety Management System

Art. 4.3 – Development and improvement of railway safety

Art. 9 – SMS general requirements

Art. 10.1 / Art. 10.2 – Safety certification*

Art. 11.1 – Safety authorisation*

Annex III – Requirements and elements of the SMS

* NSAs assess the SMS in order to grant safety certificates and safety authorisations

General benefits from having a SMS

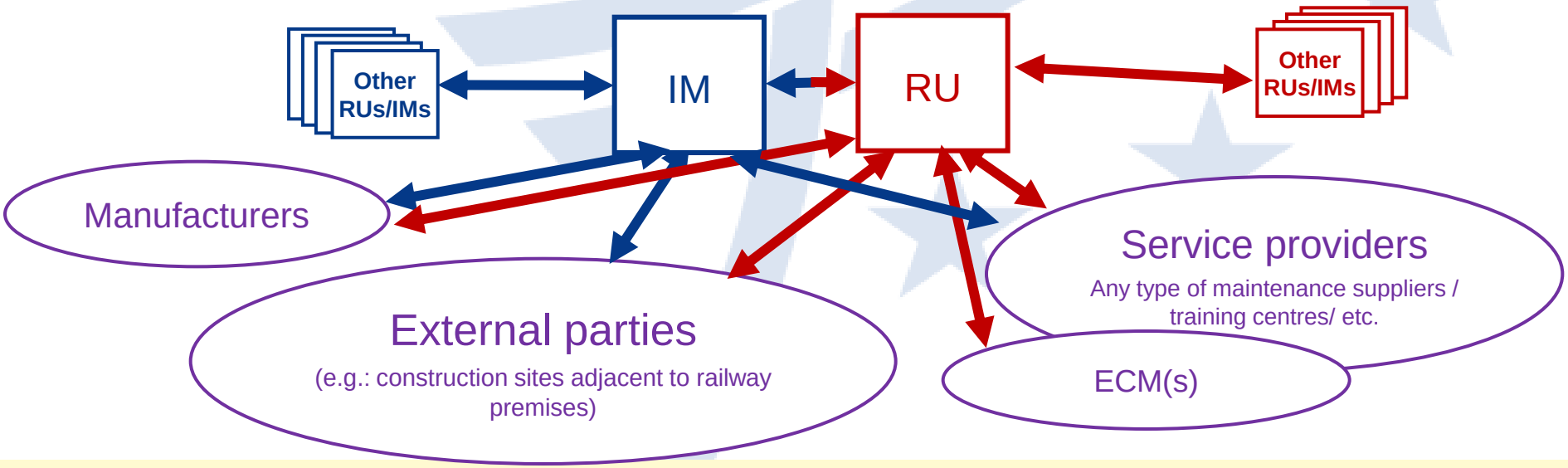
- **Compliance** with European Legislation and NSR(s), including technical and operational standards and internal provisions
- **Structured approach** to the implementation of safety related tasks based on processes and procedures
- Systematic use of processes and procedures which allows **traceability** and **auditability** of all the activities, from decision making to operations
- Decision making process supported by a **risk management**, which can foresee risks, leading to a **reduction of accidents and incidents** and, as consequence, to the **protection of the business**

Safety Culture

Safety Certification

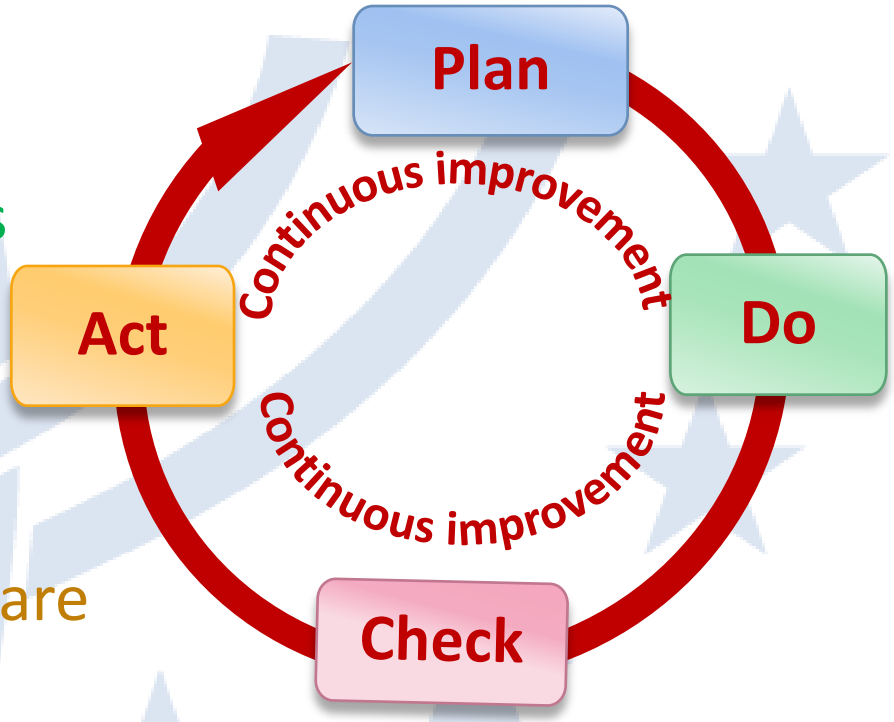
RUs and IMs have to manage all operational-organisational-technical risks

- Related to their specific activity
- Inherent at **interfaces** and shared risks within parties involved in the railway activities
- Originating by external parties



SMS provides a structured framework to ensure that :

- the organisations is designed to deliver operation in a safe way
- Operational and support processes are deployed
- Effectiveness of processes is monitored
- Preventive or corrective measures are taken



SMS is **not an alternative** to the existing set of safety related **technical and operational rules**. It's a structured way to apply them **taking into account** the risks related to the specific activities of RUs and IMs.

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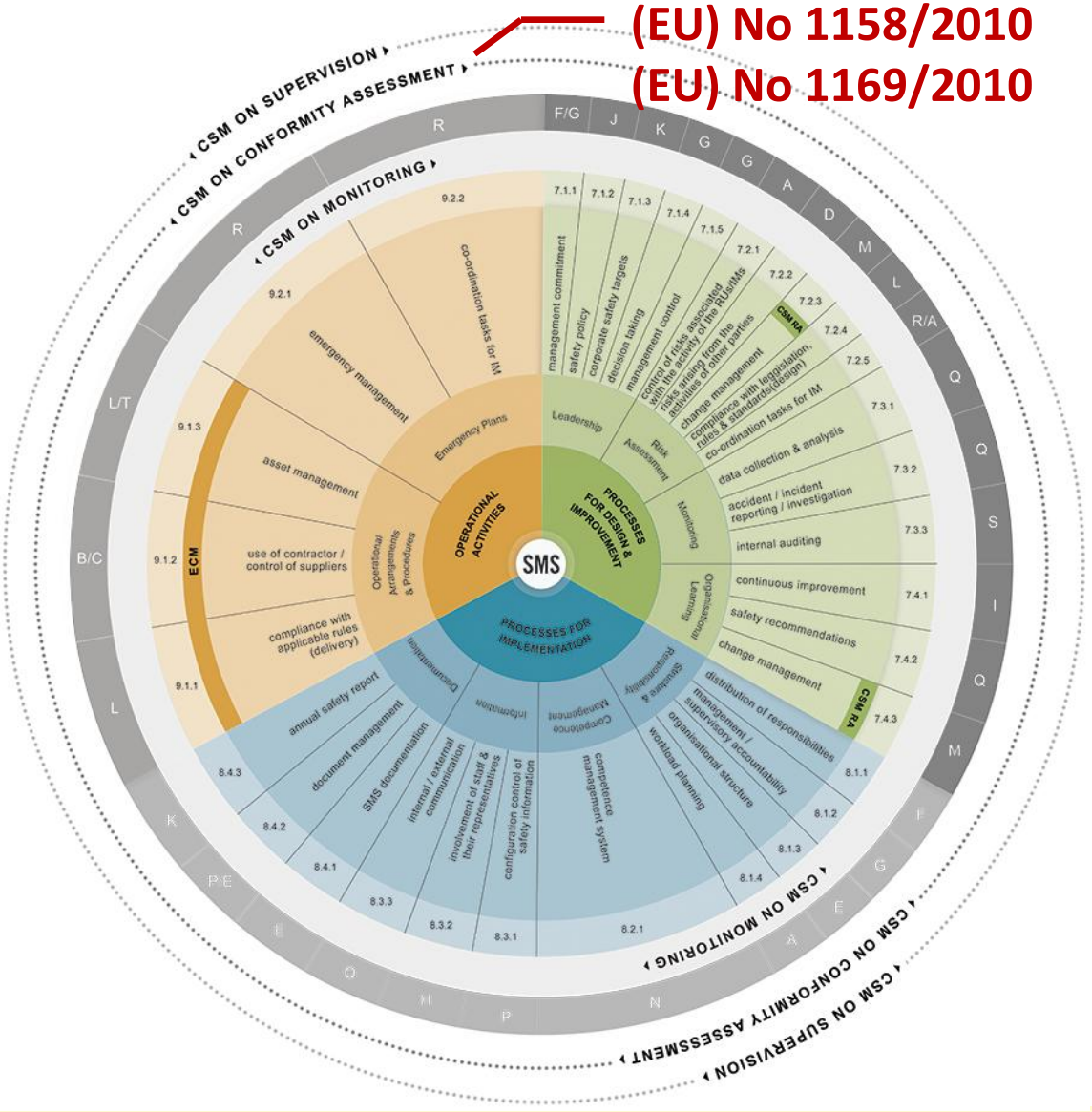
Where the SMS fits into the regulatory framework

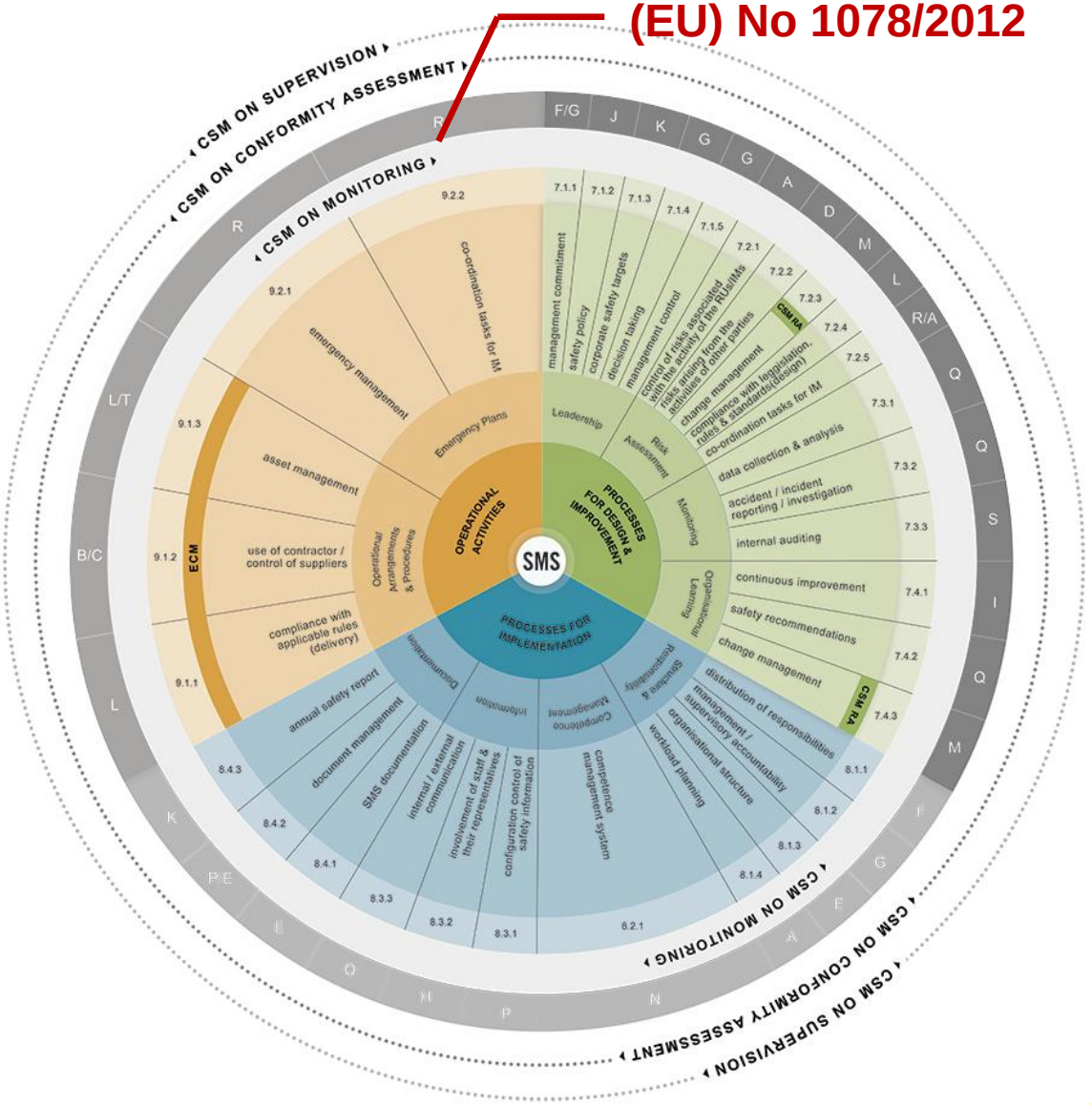
The SMS is the key to managing the safe operation of the Railway System by both the RU/IM

(EU) No 1158/2010
(EU) No 1169/2010



Fundamental principles:

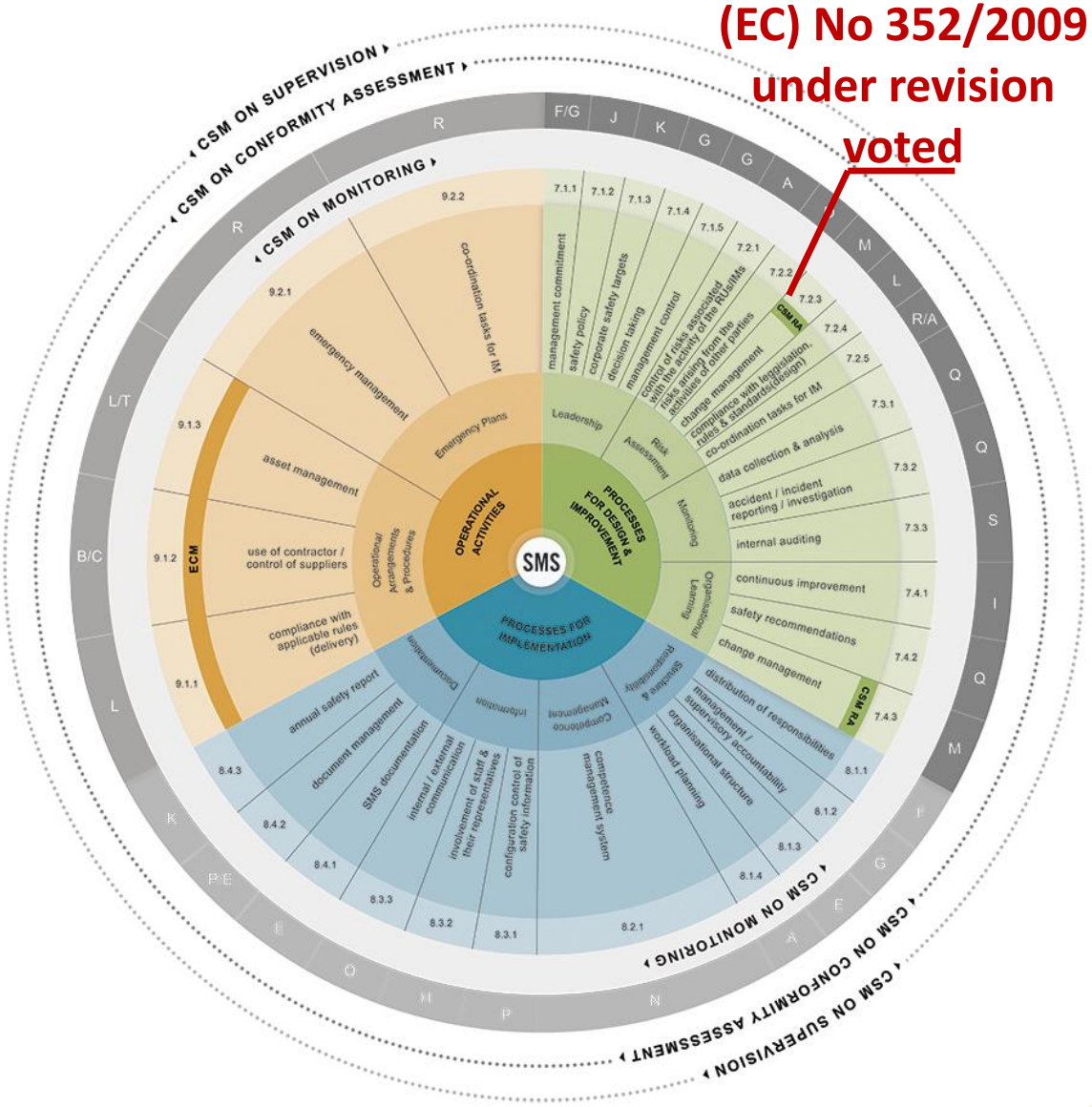
- *CSM provides further detail on how to monitor the SMS*
- *Harmonised process*
- *Helps ensure that the SMS continues to be effective*



Fundamental principles:

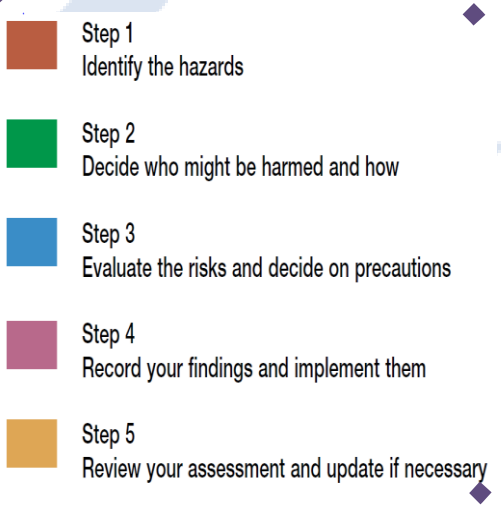
- *CSM is process for managing change*
- *It is not the key risk control – <u>that is for SMS</u>*
- *Harmonisation of the process – mutual recognition*
- *Risks must still be managed under the SMS, the only key difference is that CSM covers:*
  - *Significant change*
  - *Must be independently assessed*

(EC) No 352/2009 under revision voted



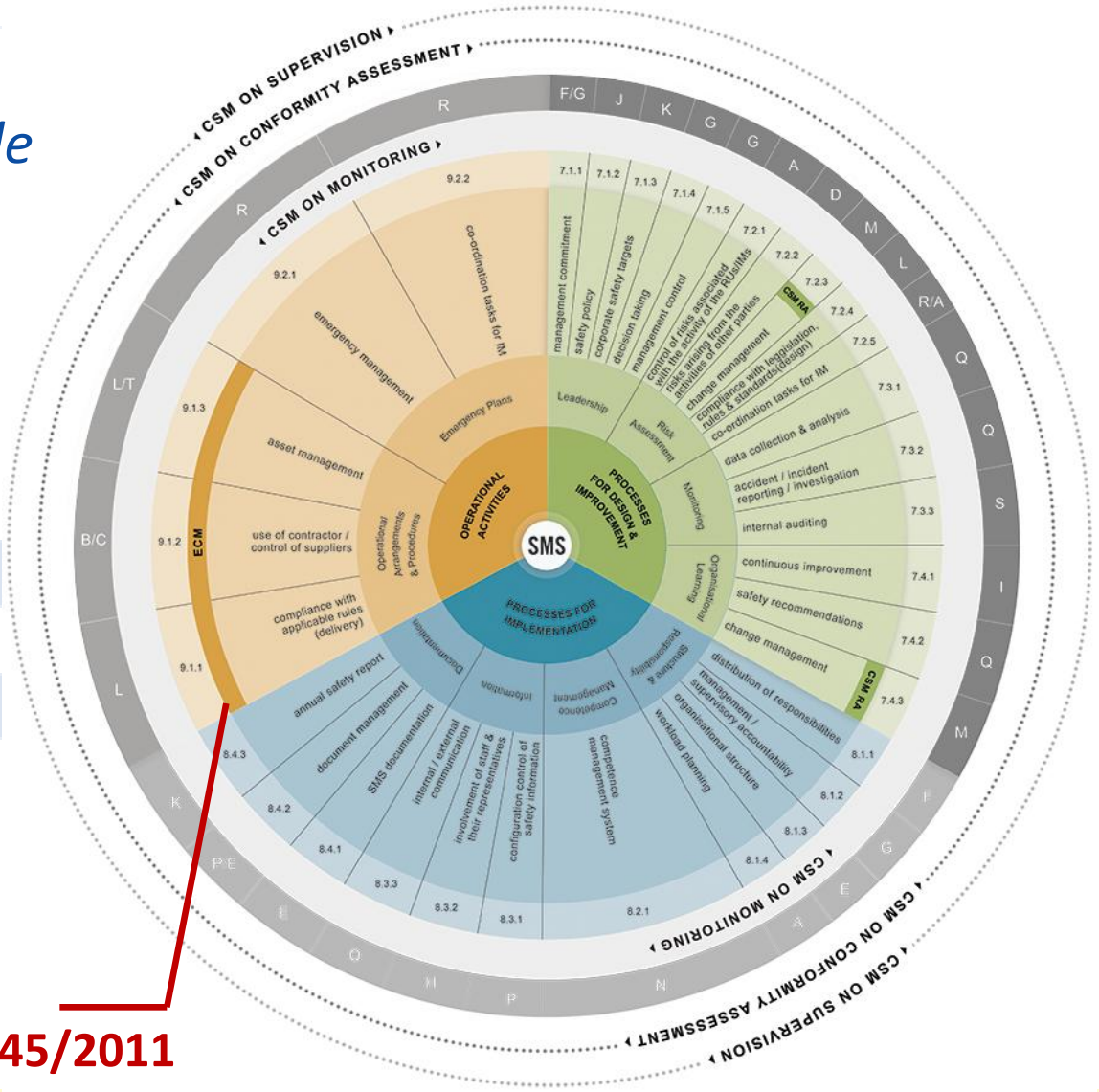
Steps: CSM → SMS

1. *CSM does it apply? → Significant change???*
2. *Now - Structural sub-system; 2012 – operational and organisational change*
3. *Define the system*
4. *Hazard identification/classification*
5. *Risk acceptance principles*
6. *Demonstration of compliance with safety requirements*
7. *Independent assessment*



Fundamental principles:

- *ECM – structured and auditable approach to maintenance management*
- *SMS – RUs/IMs*
- *ECM certification (freight wagons) to control risks associated to the supply of maintenance*
- *Exchange of info*

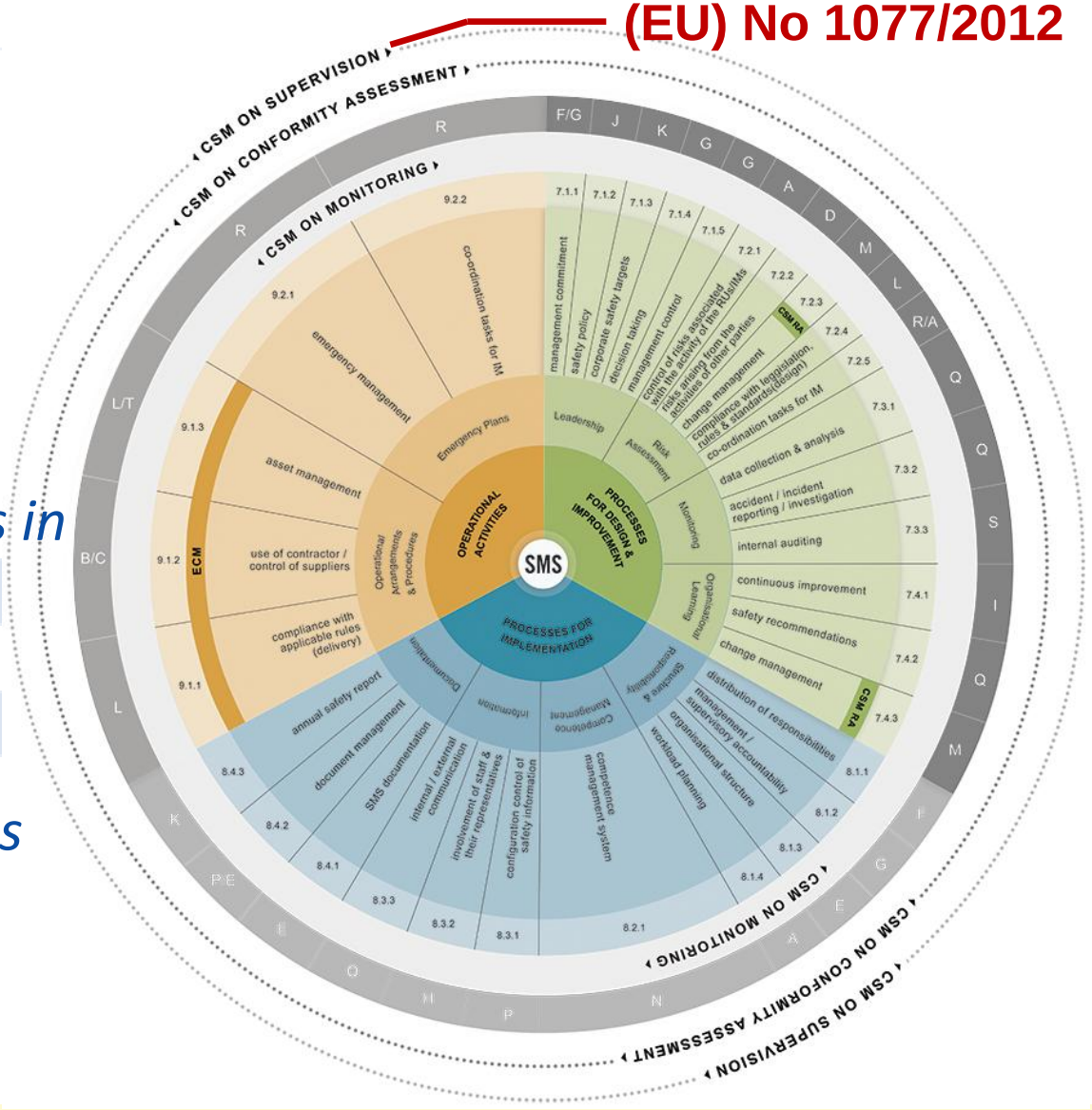


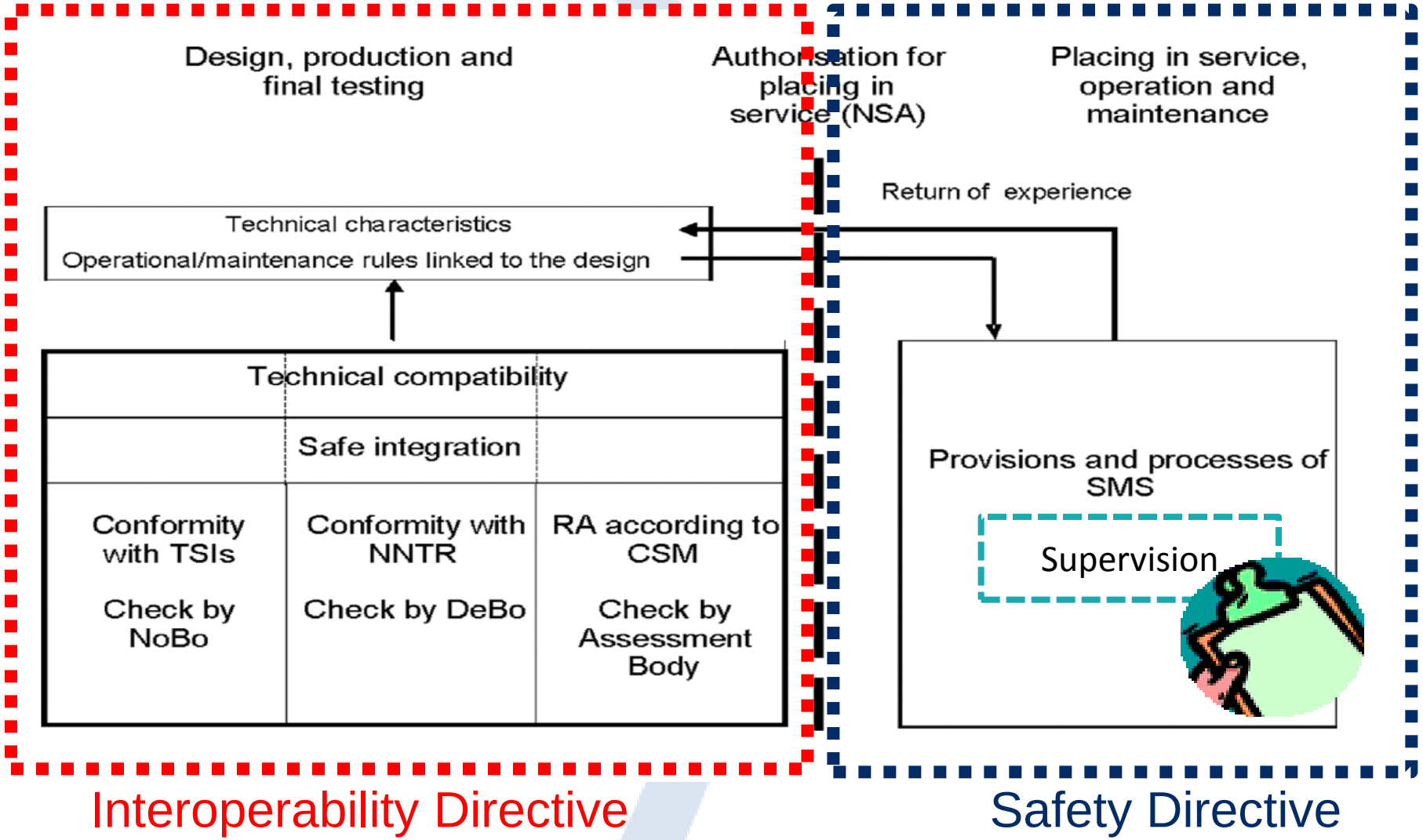
(EU) No 445/2011

(EU) No 1077/2012

Fundamental principles:

- *CSM supervision of the SMS*
- *Aim - ensure that safety performance is managed by RUs/IMs*
- *Further detail on the principles in the CSM on conformity assessment*
  - *Focus of the NSA activities*
- *Harmonisation – of the process*
  - *Install cross NSA trust*




Design, production and final testing
Authorisation for placing in service (NSA)
Placing in service, operation and maintenance
Return of experience
Technical characteristics
Operational/maintenance rules linked to the design
Technical compatibility
Safe integration
Conformity with TSIs
Check by NoBo
Conformity with NNTR
Check by DeBo
RA according to CSM
Check by Assessment Body
Provisions and processes of SMS
Supervision
Interoperability Directive
Safety Directive


COFFEE
BREAK

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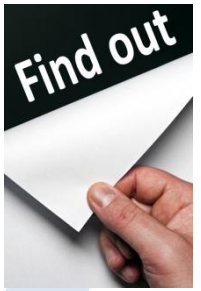
What is "Risk Management"?
CSM Risk Assessment

Risk Management and Risk Assessment
"Hazard" and "Risk" Concepts

- Discovery of "theory of probability" during XVII century, and later on its mathematical refining, have actually laid down the mathematical instruments for the decision making process



- During XVIII century, shipping insurance companies first use those mathematics and probabilistic tools for assessing risks and taking decisions

- Risk Management and Risk Assessment, as used nowadays, originate from 1960'

- Motivated by financial benefits, insurance companies first introduce **"concept of risk"** in their **"process of taking decisions"**

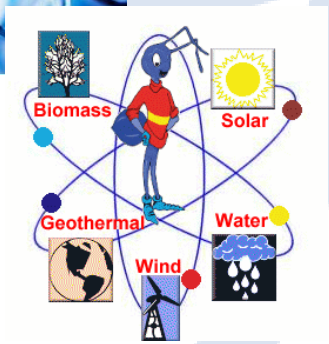
Domains of application of Risk Management and Risk Assessment Tools

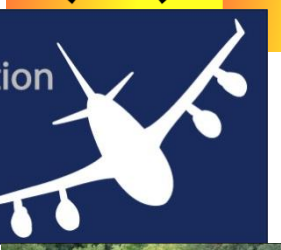
Considered as a necessary **modern and proactive instruments** for controlling safety and taking decisions

- Finance, banking, capital investment
- Telecommunications
- Public Policy Research
- Energy
- Medicine
- Petrochemical industry
- Nuclear Power
- Aviation
- Railways

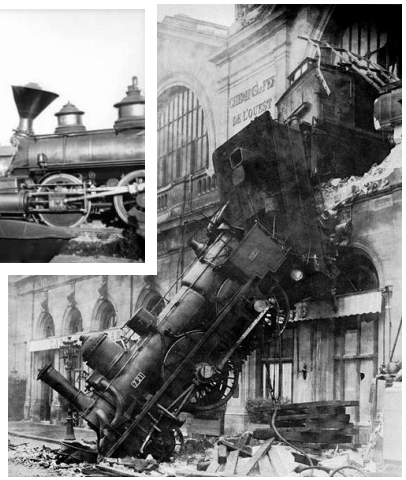


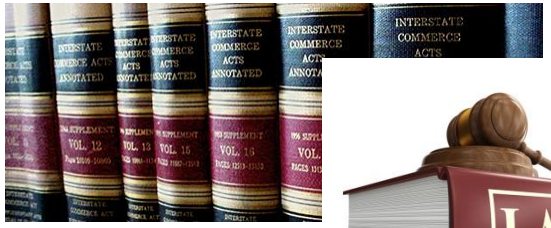





Prevention of accidents in the past & Modern Risk Management

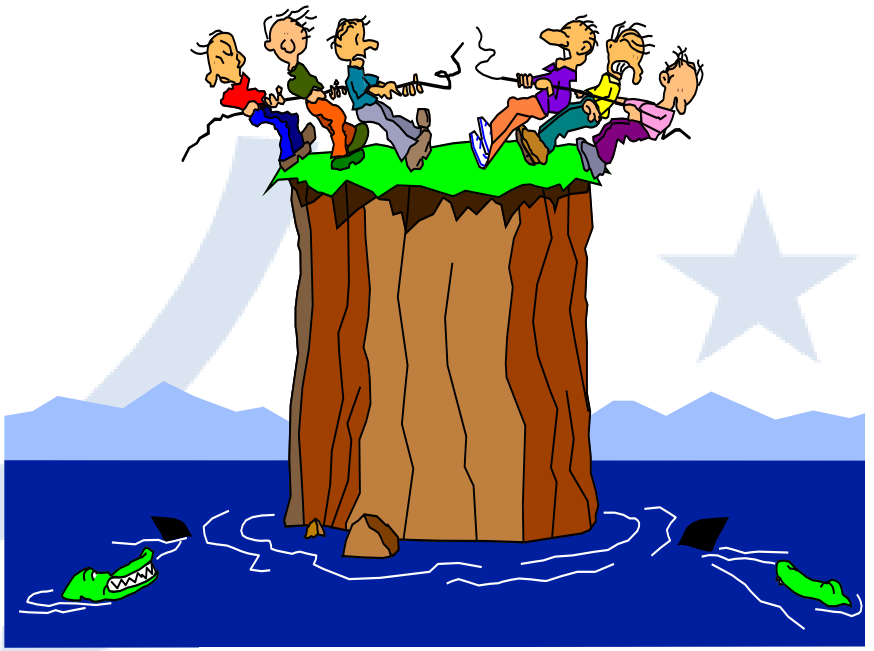




- For long, in many domains, gradual improvement of safety resulted from costly experiences and lessons learned from accidents
- Prevention of similar events was regulated reactively by state authorities and establishment of new laws, codes of practice, rules or standards
- Development of modern and scientific methods for "Risk Assessment" and "Risk Management" enabled to substitute those reactive ways of controlling safety by a **proactive and systematic** approach to manage safety

What is "Risk Management"?

- **Risk Management** is the name given to a **logical and systematic method** of identifying the **hazards** and analysing, treating and monitoring the **associated risks** involved in any activity or process of a company



- The Risk Management methodology shall be an integral part of the company business planning that helps the managers to **make the best use of their available resources**

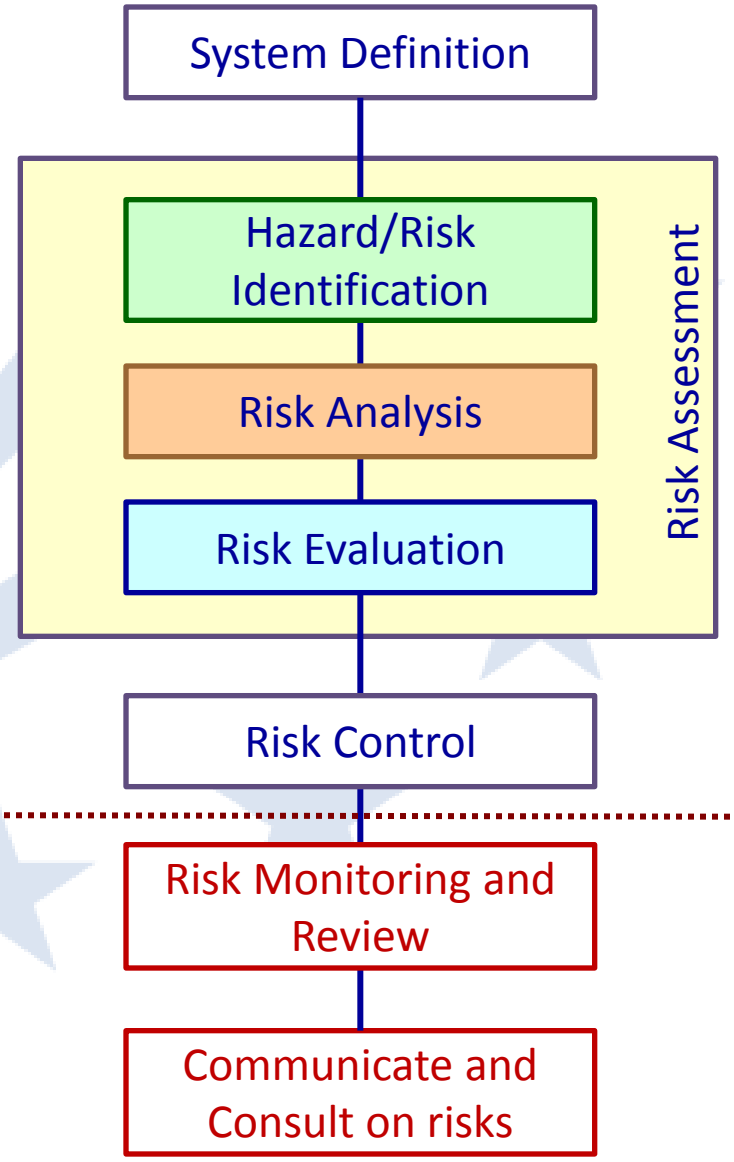
Overview of Risk Management Basic Steps

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

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

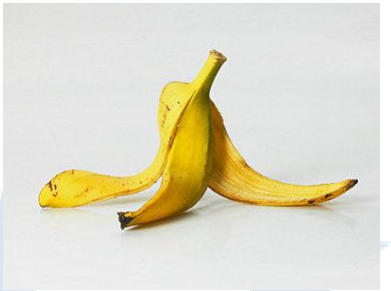
Basic Process Steps

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



What is a HAZARD?

It is a source or situation or act with a **potential** for harm in terms of human injury or damage to environment or both *(e.g. Toxic or flammable substances, electric energy, working at heights etc.)*



→ **Hazard is something that has a potential to cause harm or injury**

What is a RISK?

Combination of the likelihood of an occurrence of a hazardous event and the severity of injury, damage to environment or damage to property that may be caused by the event

→ **Risk is the likelihood of harm resulting from a hazard**

Basic principles for assessing the risk

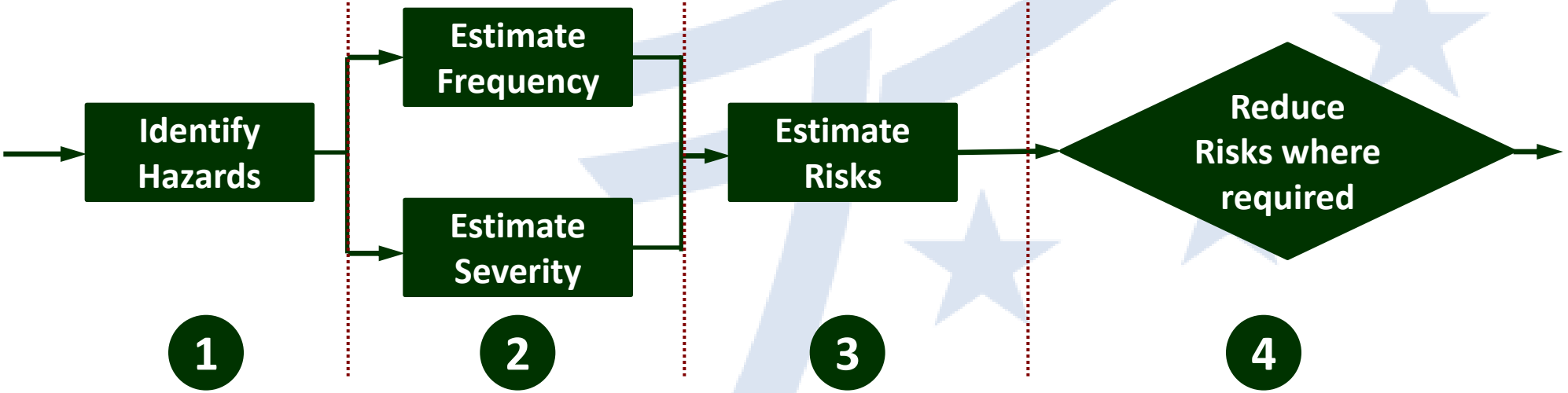
Independently on whether complex or simple, Risk Assessment follows a common 4 step process

You 1st **identify hazards**

… for each hazard you **estimate risk** by estimating frequency and severity

… you then **evaluate acceptability** of risk and prioritise …

… If necessary you then **take action to mitigate/control** risk



Most important concepts to remember about hazards & risks

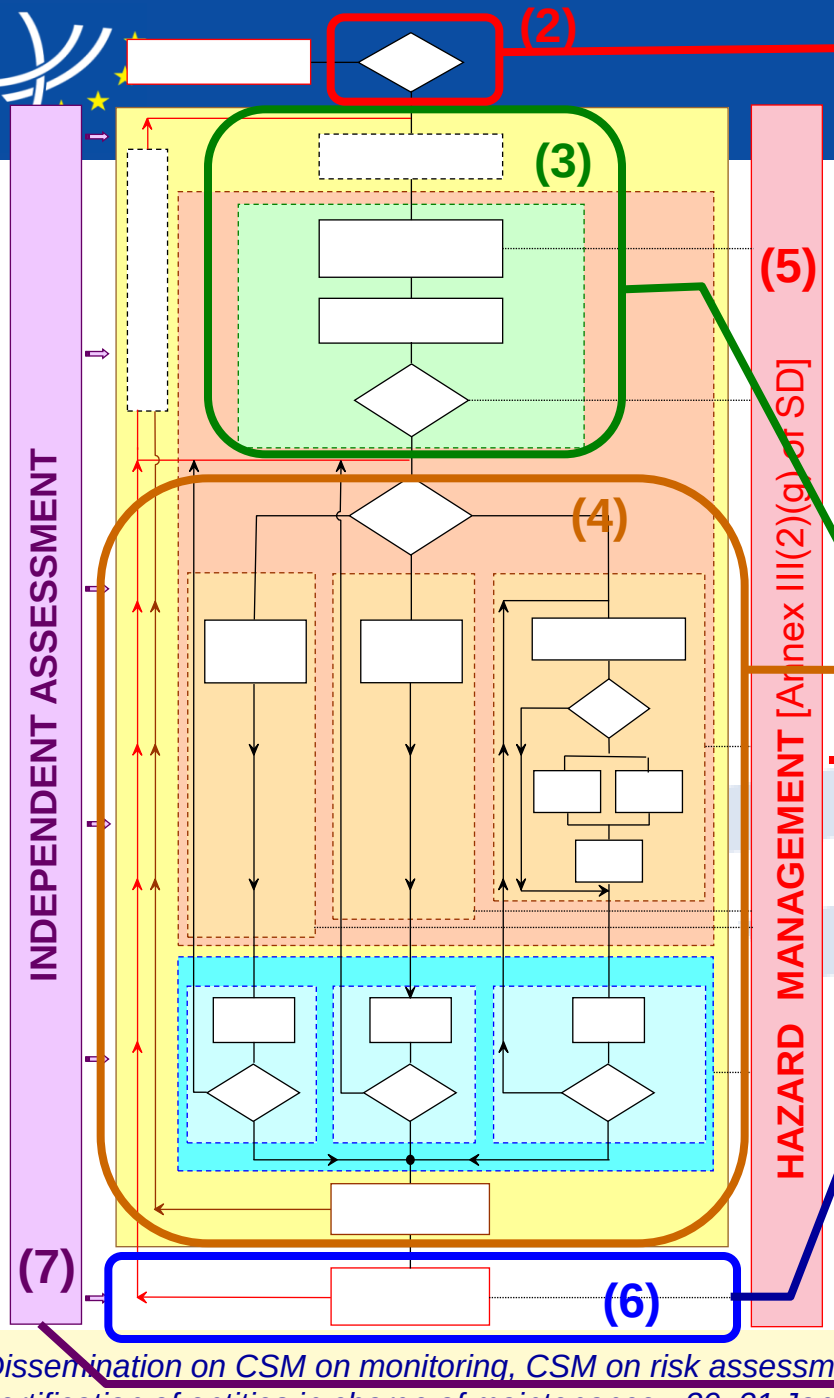
Do not forget that risk management includes control but also monitoring of risks, as well as communicating these risks

Remember these

Risk Assessment		Risk Management
What can happen?	⟷	What can be done?
How likely is it to happen?	⟷	What are the benefits, costs and risks of each option?
What are the consequences if it happens?	⟷	What are the impacts of each option on future options?

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

Go through different steps of CSM Process



For presentation purposes, CSM Process split into 7 topics (see questionnaire)

(1) **Introduction**

(2) **What is a significant change?**

(3) **Hazard Identification phase;**

(4) **Risk analysis and evaluation**

(5) **Hazard Management and Hazard Records;**

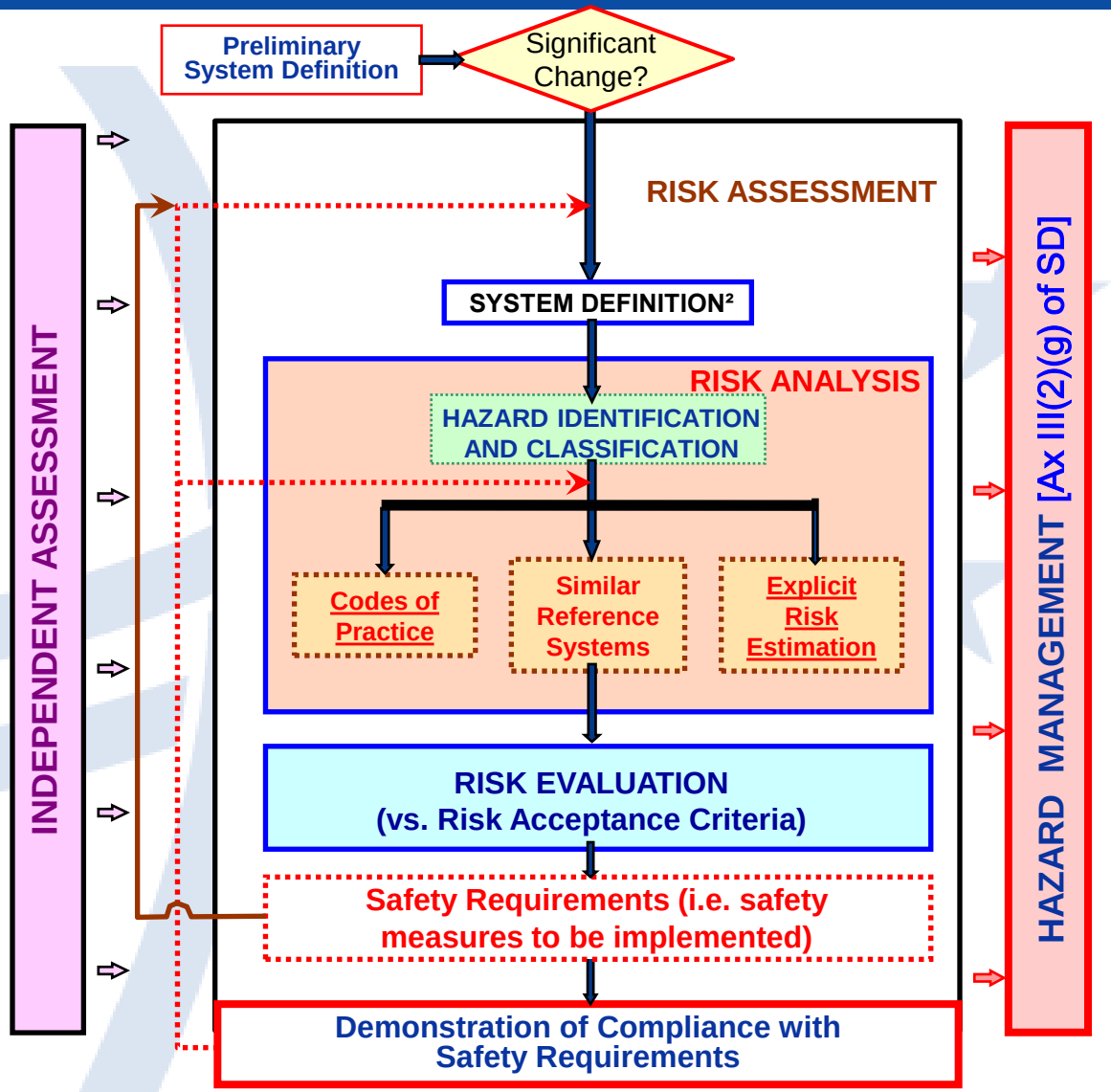
(6) **Demonstration of system compliance with the safety requirements**

(7) **Independent assessment of correct application of CSM Process by an Assessment Body**

B – Overview of Commission Regulation on CSM on Risk Assessment

Risk Management Process and Independent Assessment

- Basically CSM is an iterative process made of 3 steps:
  - (a) Identification of hazards, associated safety measures and resulting safety requirements
  - (b) Risk analysis and risk evaluation based on exiting risk acceptance principles
  - (c) Demonstration of the system compliance with the identified safety requirements
- Necessary requirements for mutual recognition:
  - (a) Hazard Management
  - (b) Independent Assessment (Assessment Body)



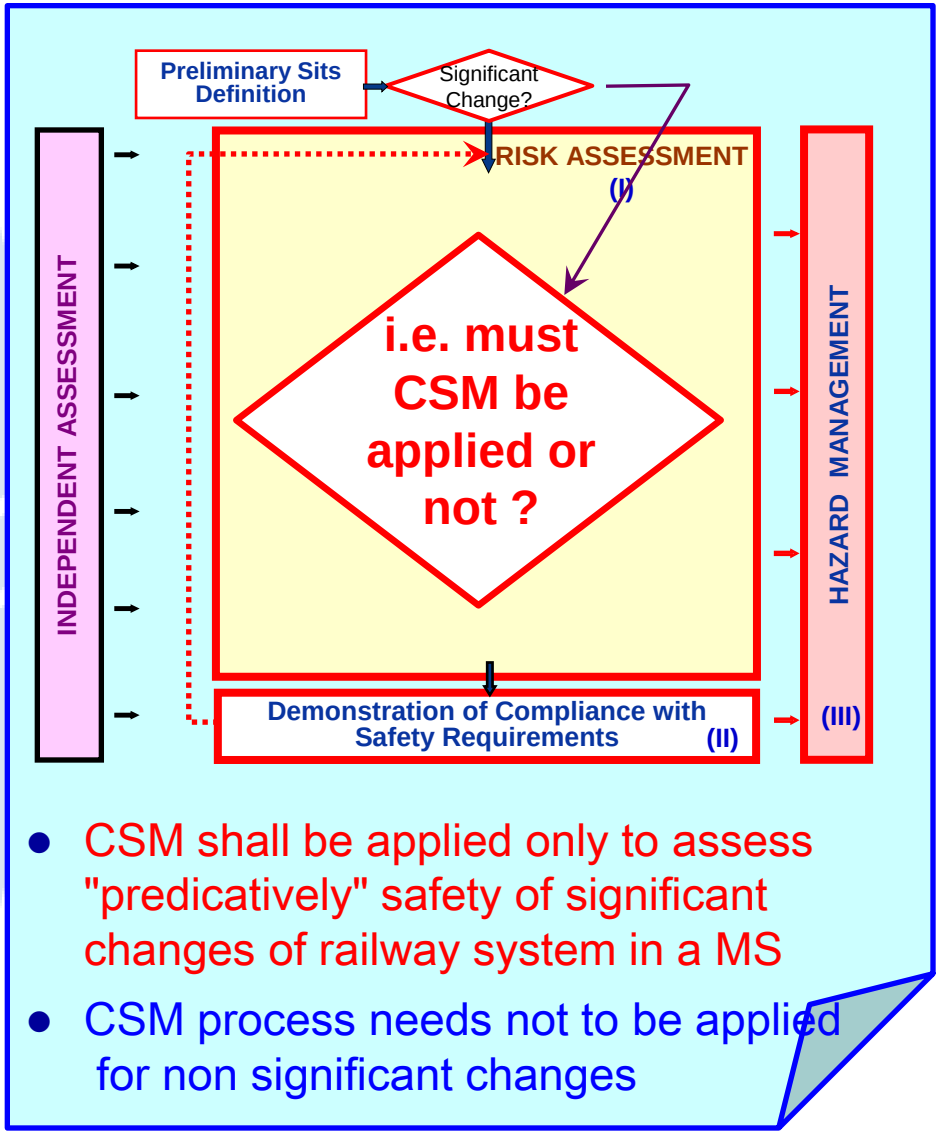
Iterative Risk Management Process "triggered" by a Significant Change

WHEN shall the CSMs be applied [Article 2]?

- Applies to any change of the railway system in a Member State, as referred to in point (2)(d) of Annex III to Safety Directive 2004/49/EC, which is CONSIDERED TO BE SIGNIFICANT

Annex III(2)(d): requires that RU/IM SMS has *"procedures and methods for carrying out risk evaluation ... whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations"*

➔ Such changes may be of technical, operational or organisational nature.



- CSM shall be applied only to assess "predicatively" safety of significant changes of railway system in a MS
- CSM process needs not to be applied for non significant changes

WHAT is a significant change? ➔ NR (if any) or expert judgement based on criteria

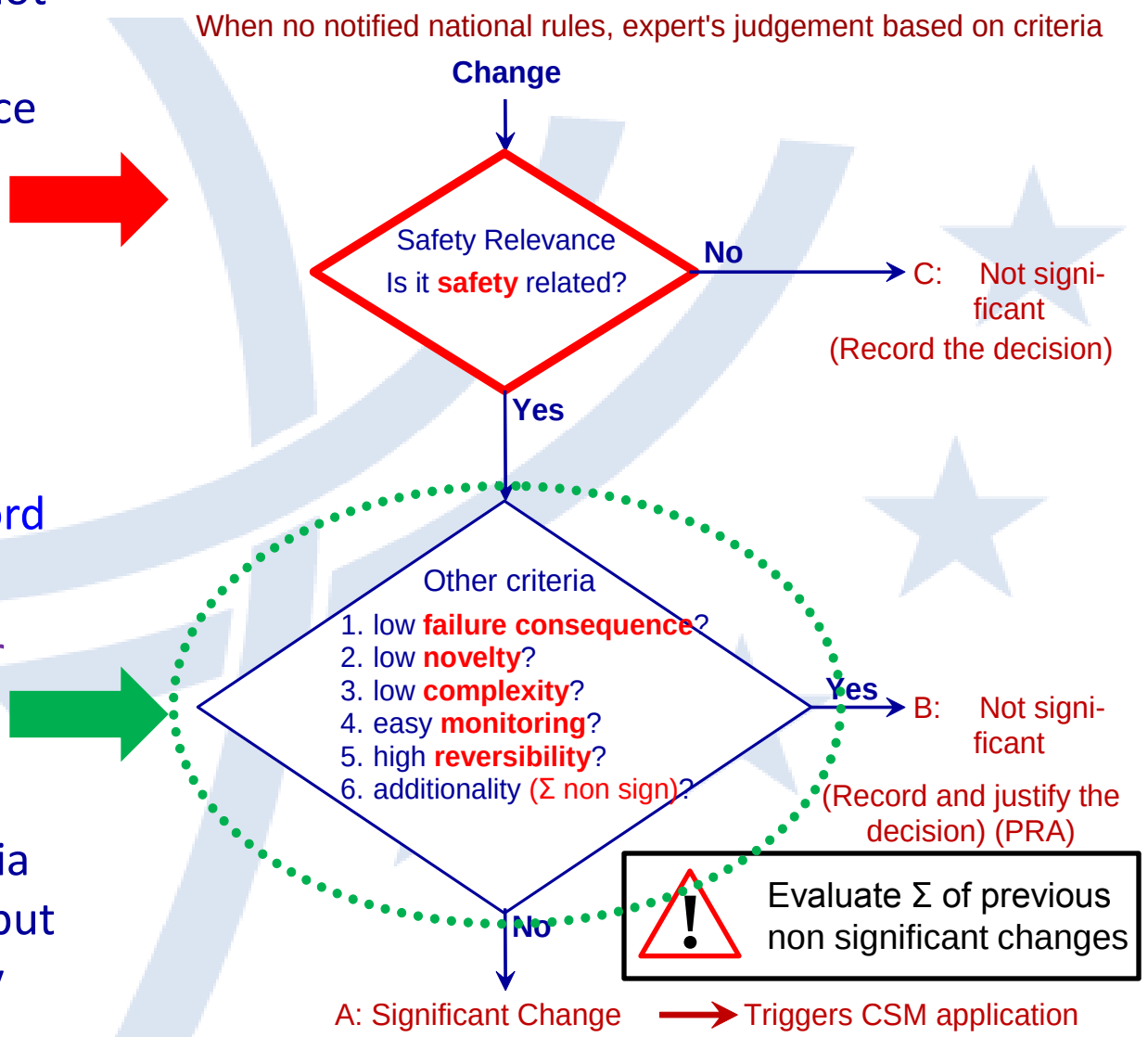
- When notified national rules do not define what is significant change, proposer evaluates the significance of change based on expert's judgement and criteria in CSM

- 1st check whether change safety related?

  1) NOT safety-related → not significant → no CSM, but record decision ;

  2) YES safety-related → use other criteria to evaluate whether change significant

- Proposer should analyse all criteria and decide on their importance, but could take decision based on only one or some of them

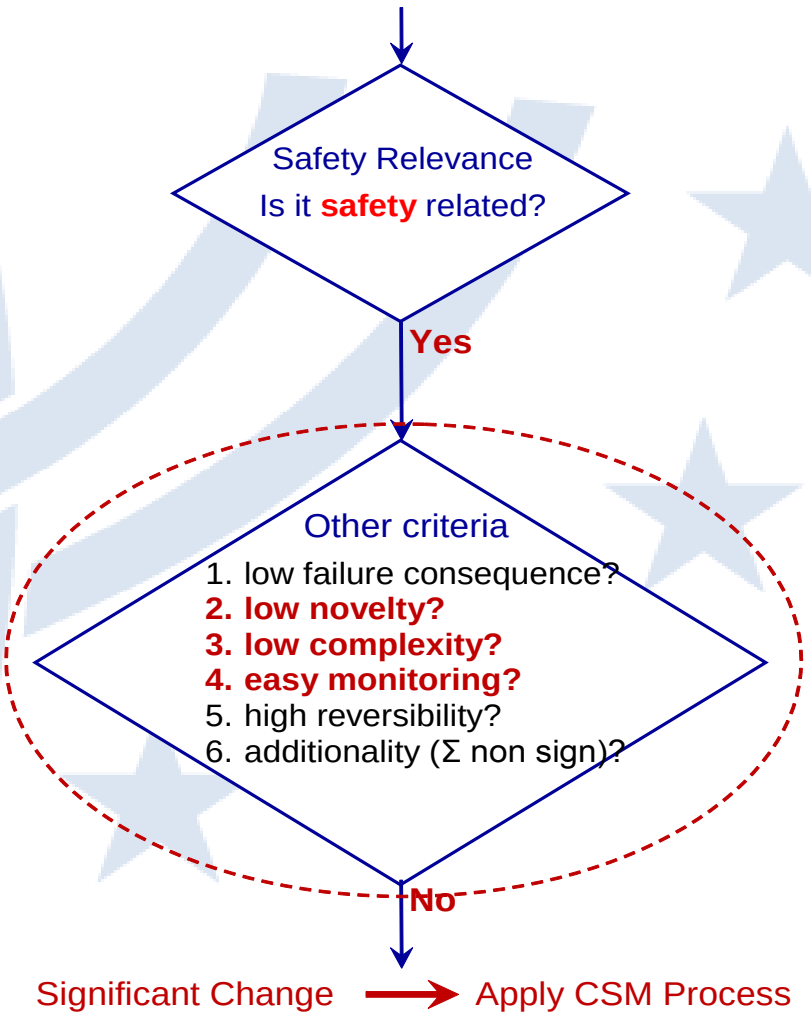


- The process of deciding change will be set out in the SMS
- Although a change is classified non significant, when it is safety related decisions need to be recorded (could be an SMS process)
- Help the NSA in their supervisory role

  [e.g. preliminary risk analyses, risk analyses, justifications, arguments proportionate to the risk need to be documented]

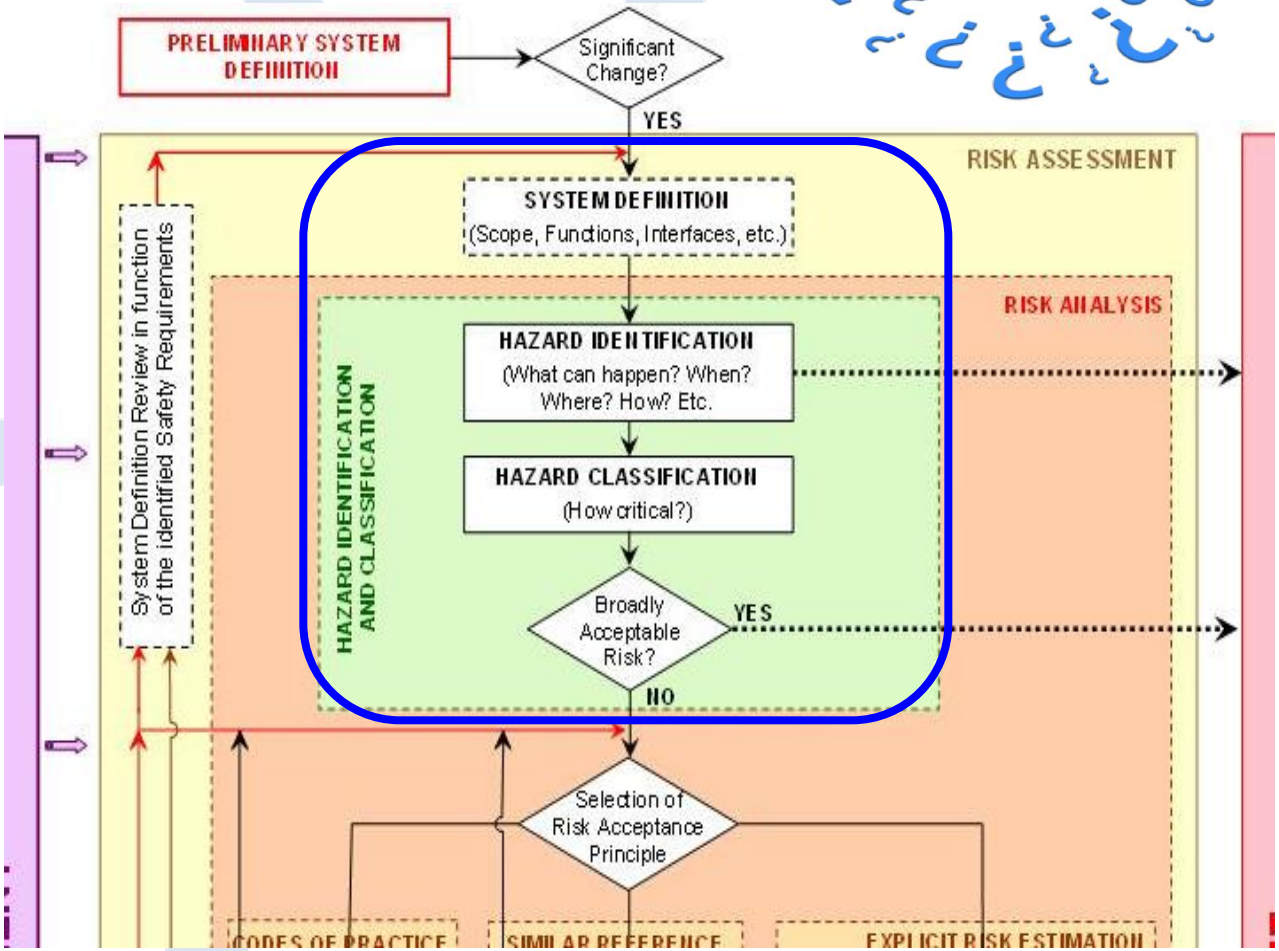
CSM Regulation does not require assessment body to check evaluation of significance

- Change description: outsource maintenance branch of an IM and put it in competition with other companies working in same field
- → significant change **(need to cover all questions)** :
  - Safety relevant? → YES
    Downsizing , redistribution of staff and tasks → same work with less staff
  - Low novelty? → NO
    Contractual relation and follow up
  - Low complexity? → NO
    New functions in IM remaining organisation to follow up subcontractor
  - Easy monitoring? → NO
    Not easy to check subcontractor efficiency
- Consequence: apply CSM Process



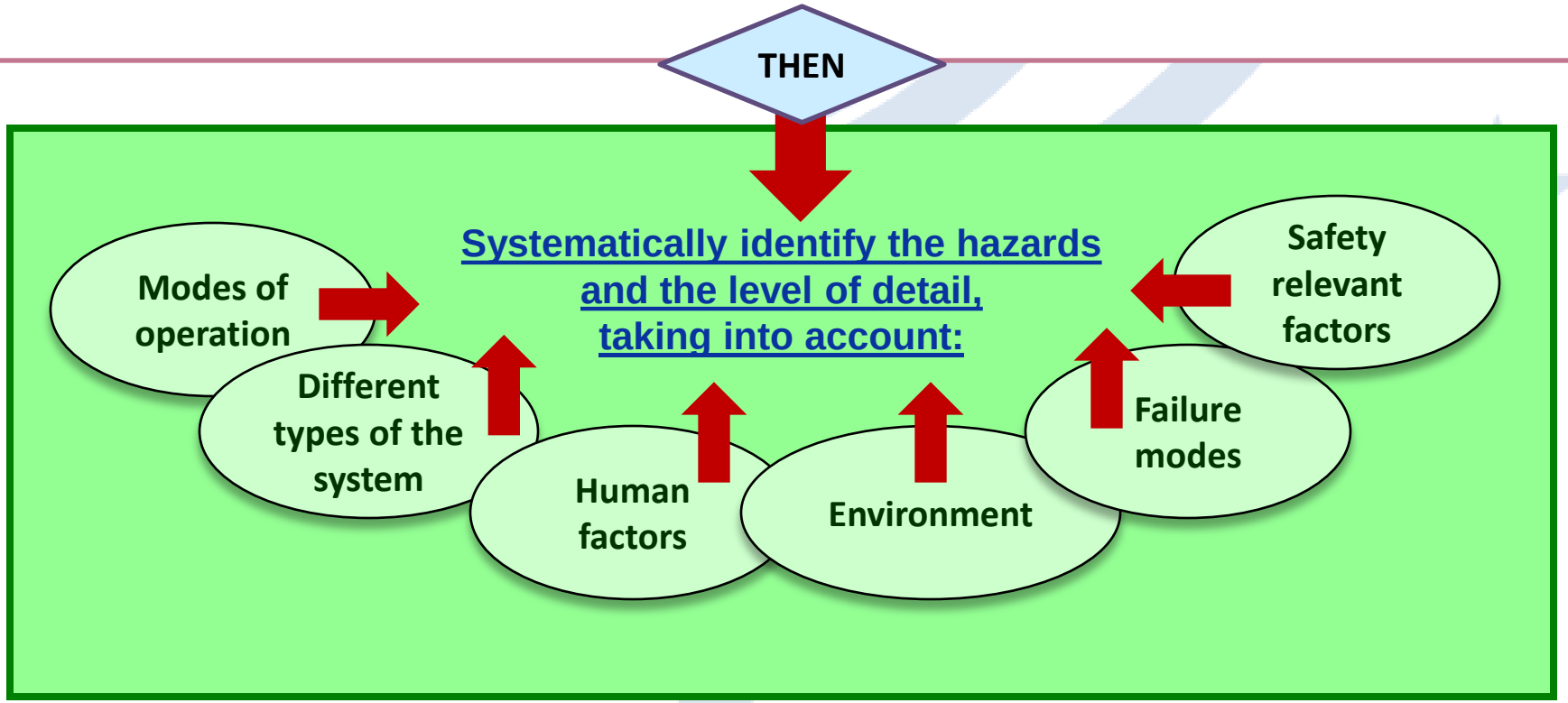
What is "Hazard Identification" and why is it important?

- Hazard Identification is first step in risk analysis process.
- HAZID process needs to be reiterated and completed until all reasonably foreseeable hazards have been identified correctly.
- It is important because, if hazards are not identified, they will not be assessed and covered by the risk management process.



What are the first steps of the "Hazard Identification"?

- System definition is important because it specifies functions and interfaces of the system. Based on it, also hazards could be identified properly.
- It is necessary to look at the hazards from all relevant contributors.



Hazard Classification or Risk Ranking

A very simple approach is to rank the risk severity based on individual experience of the expert performing the Risk Assessment

Risk ranking assessment based on experience

- Risk is ranked as high, medium or low
- The decision is purely based on experience and intuitive feeling without considering the actual frequency and consequence of the hazard
- No calculation or supporting evidence is required to justify decision

Example: Cycling in different areas may be deemed to have relatively different levels of risk

High Risk

On a motorway

Medium Risk

In a city

Low Risk

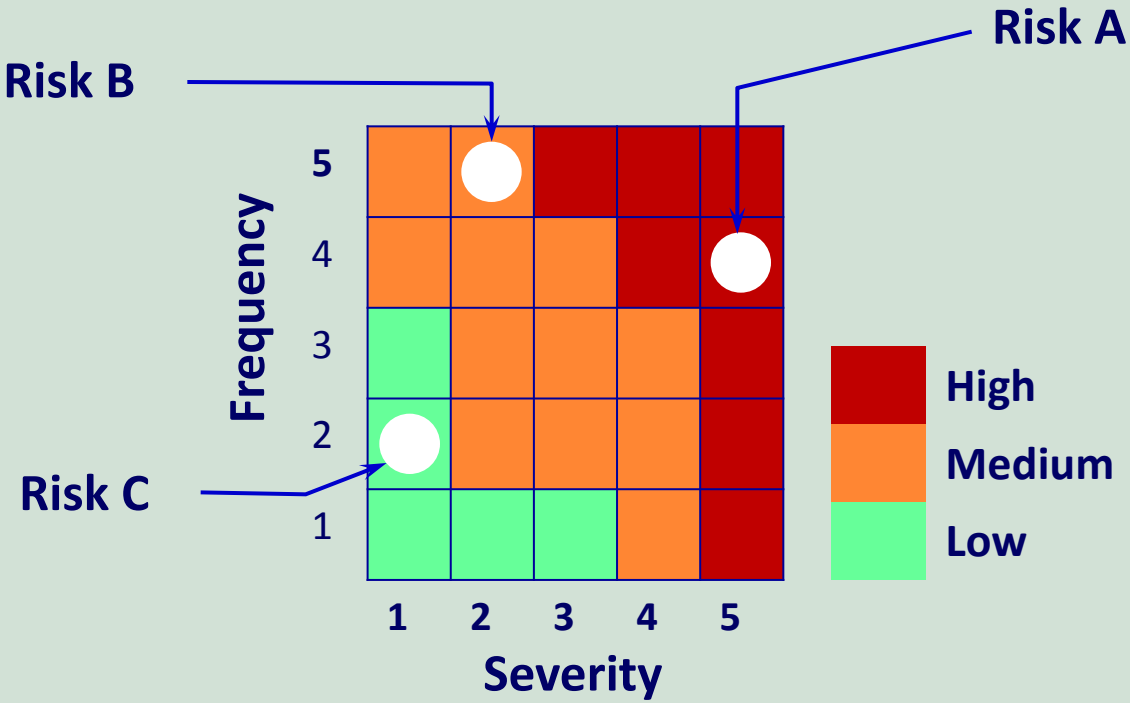
In a park

Hazard Classification or Risk Ranking

A more sophisticated way of ranking risks is by ranking with the aid of a risk matrix in which

Risk ranking using a risk matrix

- Risks are ranked based on frequency and severity



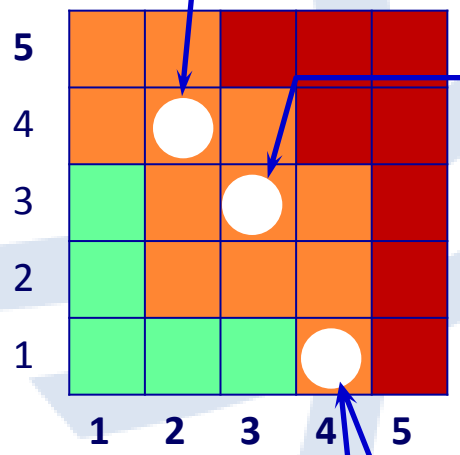
Ranking risks using a matrix provides a justification on making decisions

Hazard Classification or Risk Ranking

Exemple : Four hazards identified in a HAZOP study

	Frequency
1	Once in 10 years
2	Annually
3	Monthly
4	Weekly
5	Daily

	Severity
1	No or slight injury
2	Minor injury
3	Single major injury
4	Single fatality or multiple minor injury
5	Multiple fatalities



Passenger falls down stairs and sustains injuries

Priority 1

Passenger fall from platform onto track

(Assumption: typical accident does not involve a train striking person)

Priority 2

Passenger electrocuted

Priority 3

Passenger struck by train when crossing tracks

Priority 3

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Putting the CSM risk assessment into practice (Group exercise)

Group exercise

from predefined railway activity small/mixed groups are invited to identify how they follow the criteria defined in article 4 of the regulation 352 to decide the significance of the change.

Group session (60 min.) - Small/mixed groups

- *Example study:*
- *Read carefully the instructions*
- *Nominate a rapporteur*

Plenary session (60 min.)

- *Feedback from the exercise (rapporteurs+ERA)*
- *Discussion/questions*

GROUP 1	GROUP 2	GROUP 3	GROUP 4
Baczyński - Krzysztof	Brzeziński - Mirosław	Chajęcka - Barbara	Cieślikiewicz - Marek
Bogdan - Seweryn	Dąbrowski - Marcin	Kalman - Leszek	Czernik - Adam
Ciszewski - Maciej	Dereziński - Piotr	Kogelheide - Rainer	Faliński - Zdzisław
Gil - Zdzisław	Habel - Dariusz	Krassowski - Władysław	Janiec - Łukasz
Maciąg - Mirosław	Iwański - Rafał	Lyra - Gregor	Karasiewicz - Iwona
Marchel - Danuta	Jeleń - Rafał	Madeja - Rafał	Naperty - Aneta
Solski - Jan	Mandryka - Robert	Majewski - Krzysztof	Osiak - Tomasz
Tabaszewski - Antoni	Musiał - Cezary	Nalewajko - Barbara	Śmiechowska - Maja
Węcławik - Ryszard	Polczak - Wojciech	Stefanowicz - Aleksander	Walczak - Robert
Wydmuch - Dariusz	Tetla - Józef	Urban - Tomasz	Zalewska - Magdalena
Wysocki - Bogumił	Turkot - Krzysztof	Wójcicki - Paweł	Zubilewicz - Krzysztof

GROUP 5	GROUP 6	GROUP 7	GROUP 8
Brudny - Grzegorz	Boratyński - Jarosław	Bogdziewicz - Małgorzata	Chruzik - Katarzyna
Cybulski - Andrzej	Fac - Michał	Darsznik - Sebastian	Czech - Paweł
Glapa - Grzegorz	Folgart - Inez	Jabłoński - Adam	Częstochowski - Łukasz
Grabowski - Marcin	Gójski - Ireneusz	Jarosz - Andrzej	Kroc - Mirosław
Gryciuk - Marek	Kaleta - Józef	Kiełbowicz - Piotr	Kula - Alicja
Kuźmicki - Grzegorz	Kusior - Andrzej	Klugiewicz - Waldemar	Ptaszek - Magdalena
Nejman - Jerzy	Macioszek - Piotr	Kruszewski - Krzysztof	Salamon - Grzegorz
Pińkowski - Jarosław	Olesiński - Jacek	Piotrowski - Janusz	Sitarz - Marek
Śmieszek - Maciej	Stępniewicz - Hubert	Pipke - Sławomir	Zawadzki - Paweł
Świerk - Przemysław	Zagubieniak - Marek	Rzońca - Artur	Zdebik - Anna
Wachowicz - Zbigniew	Zdrojewski - Sylwester	Zgrzebnicki - Henryk	Ziółkowska - Aneta
Zasadni - Jacek			

LUNCH BREAK

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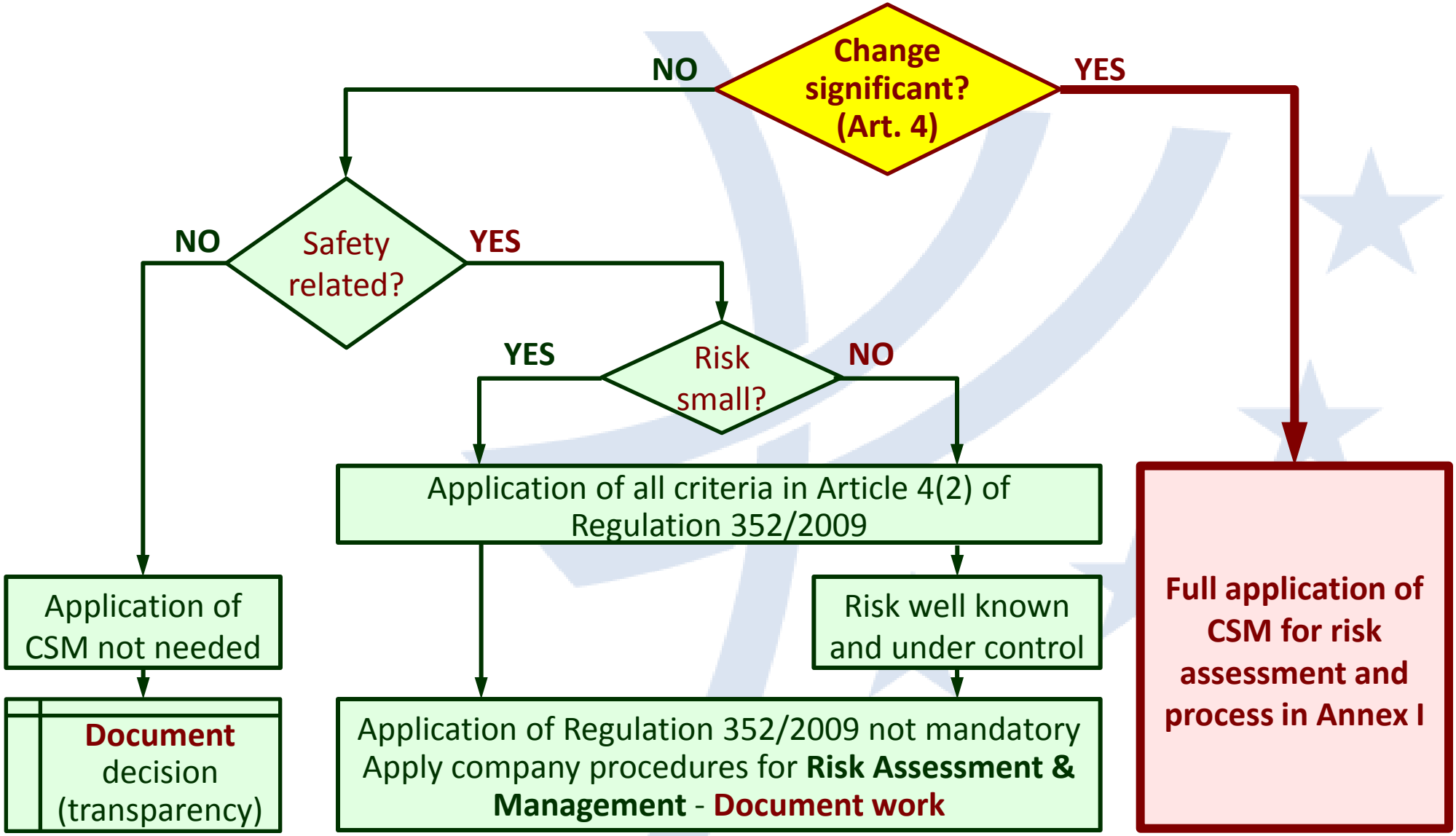
Questions/discussion and feedback from the exercise

Reasonable use of CSM for risk assessment

Significant – Non Significant in Regulation 352/2009



When making a **change** ask yourself whether change is significant [Article 4]

1) Not significant:

   a) because not safety related: document for transparency reasons;

   b) safety related but not significant because activities well known and under control

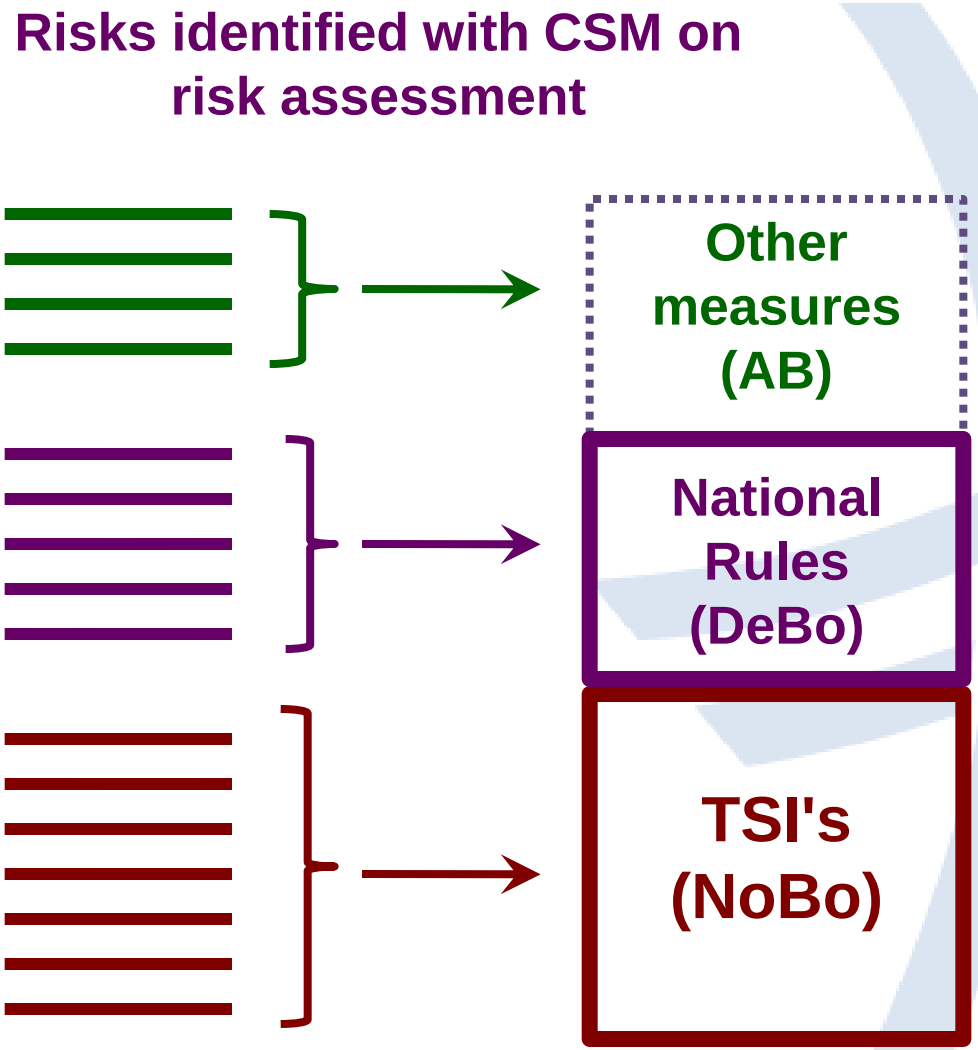
      → SMS obligation to demonstrate that all risks related to change are managed. Proposer applies his procedures/process for risk management

2) Significant → apply Regulation 352/2009

Tasks of different involved BODIES (avoid duplication of work)

- Assessment Body in CSM: check correct application of CSM risk management process and suitability of results
- NSA delivers Safety Certificates &Safety Authorisations for RUs/IMs SMS
- NSA delivers Authorisations for placing in service structural subsystems based on
  - NOBO's "EC verification of conformity with TSI requirements" applicable to structural sub-systems
  - Applicant "EC declaration of conformity with TSI requirements" applicable to structural sub-systems
  - Designated Body's check of conformity with national rules applicable to structural sub-systems,
  - check by Assessment Body of correct application of the CSM regulation on risk assessment.

Role in Authorisation for placing in service a structural sub-system



Safety demonstration + NSA authorisation based on evidences of:

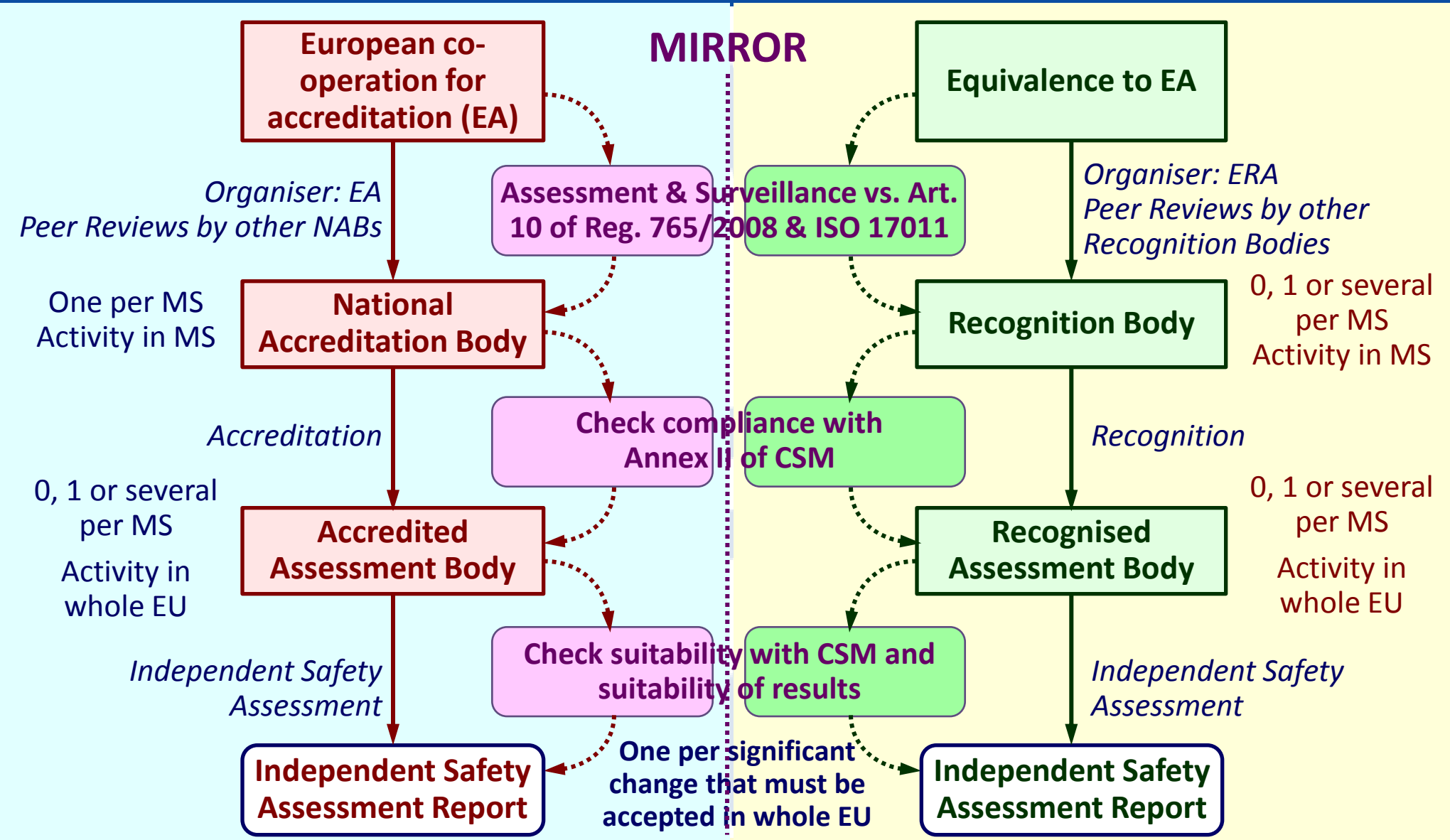
- Safe integration (AB]
- Check of technical compatibility
- Compliance with TSI's [NoBo] & National Rules (law) [DeBo]

Examples of Technical, Operational & Organisational Changes

OPERATIONAL	ORGANISATIONAL	TECHNICAL
• New operational procedures (e.g.: driver only operated train; implementation of centralised traffic control system) • Procedures adapted in relation to: ❑ deployment of a new signalling system / CCS / … ❑ new /changed services ❑ new interfaces ❑ Contract services ❑ Etc. • Change to standards / new standards • Change / new maintenance rules and/or practice • Change / new routes	• Incorporation/ separation of companies • Changes in services provided (e.g.: freight>passengers) • New services • Outsourcing activities • Change/New contractors	• New infrastructure • Upgrade of infrastructure • New control-command • Upgrade of control-command • New signalling system • Upgrade of signalling system • New rolling stock • Upgrade of rolling stock (e.g. for on board signalling system) • New products (constituents)

See guidance on Reg. 352/2009/EC + collection of examples http://www.era.europa.eu/Document-Register/Documents/Collection-of-RA-Ex-and-some-tools-for-CSM-v1-1-PT.pdf

Accreditation and Recognition scheme




Coffee break
sample text sample text

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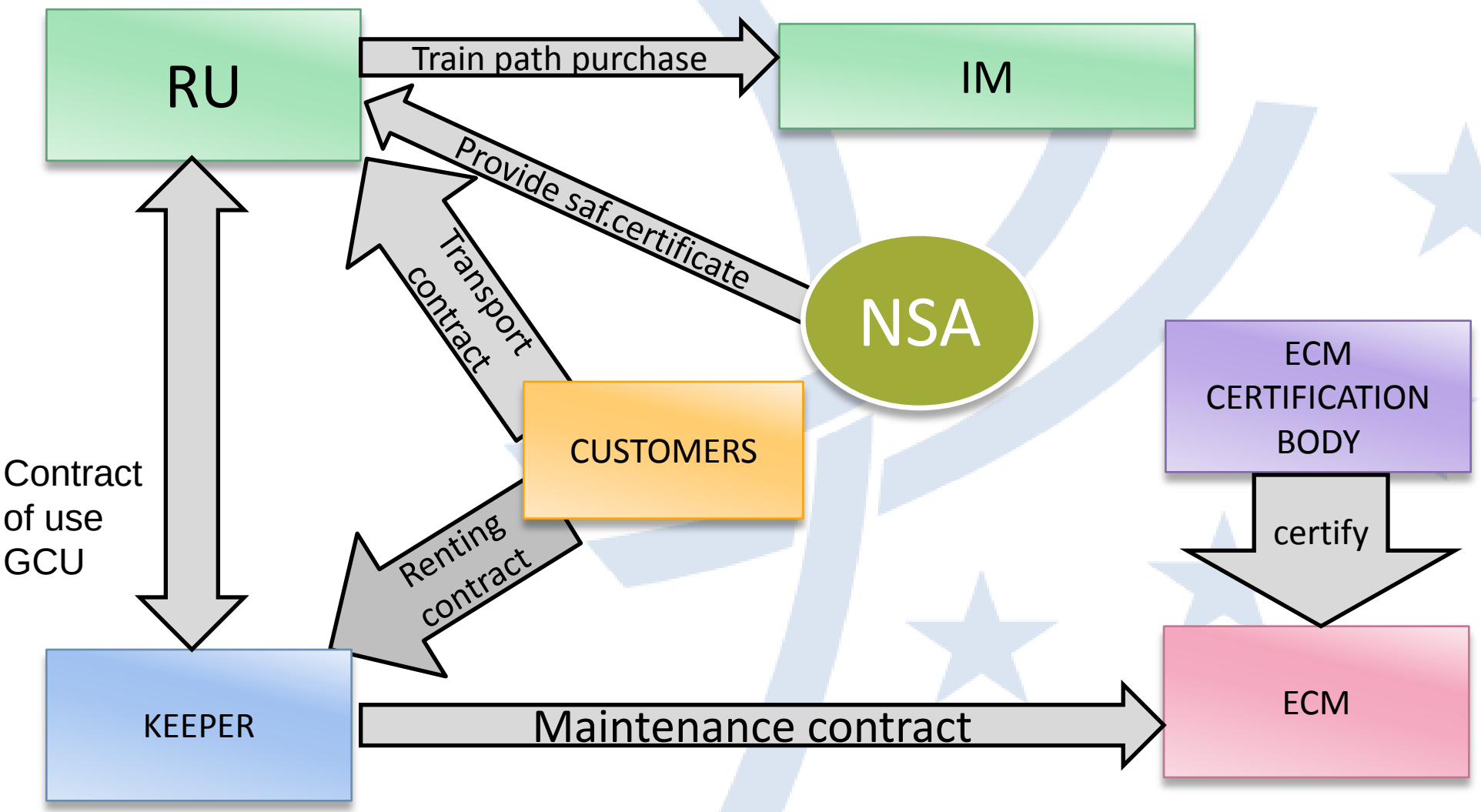
ECM maintenance system


RU
Train path purchase
IM
Provide saf.certificate
Transport contract
NSA
ECM CERTIFICATION BODY
CUSTOMERS
Contract of use GCU
Renting contract
certify
KEEPER
Maintenance contract
ECM

Legal framework of ECM certification

- **Railway Safety Directive 2004/49 (Article 14a)**
- **Commission Regulation 445/2011 - maintenance system and certification of ECM and maintenance workshops**
  - Implementation documents: guidelines, accreditation and certification schemes **mandatory** (Art. 6 of EU Regulation 445/2011)
  - Cooperation of certification bodies (Art. 6 of EU Regulation 445/2011)
  - Public database of ECM certificates (Art. 10 of EU Regulation 445/2011)
- **OTIF rules (ATMF annex A) = identical to Commission Regulation 445/2011**

- **Dissemination:**
  - (National) workshops organised by NSAs
  - (Sectoral) workshops organised by Sector Associations
  - Trainings to accreditation bodies and certification bodies
  - Guidance
- **Feedback process** related to implementation of ECM certification (Article 14a of Safety Directive)
- **Public database of ECM certificates** (Art. 10 of EU Reg. 445/2011)
  Includes also certificates of maintenance workshops
  Update of ERADIS in force on 01 June 2012.

ECM certification = European certification

Transitional provisions

Article 10(1)

30/11 Member States

↓

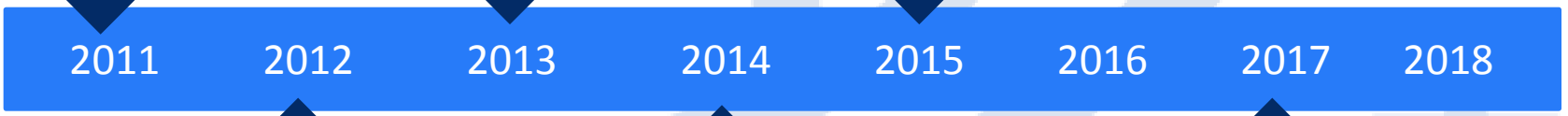
- Accreditation
- Recognition
- NSA

Article 12(6)

31/05 ECM
All self-declared ECM are certified according to 445/2011/EC

Article 12(3)

31/05 ECM
End of validity of any ECM MoU certificate



Article 12(2)

31/05 ECM

- Start validity of ECM certificates 445/2011/EC
- Certification according toECM MoU no longer accepted

Article 12(4)

31/05 ECM
Certifications according to national rules no longer accepted

Article 12(5)

31/05 Workshops
End of validity of any certificate granted under national rules

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Scope of ECM certification

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Scope of ECM certification (Part I)

1. Role of ECM
2. Safe state of running
3. Maintenance functions
4. ECM and maintenance workshop

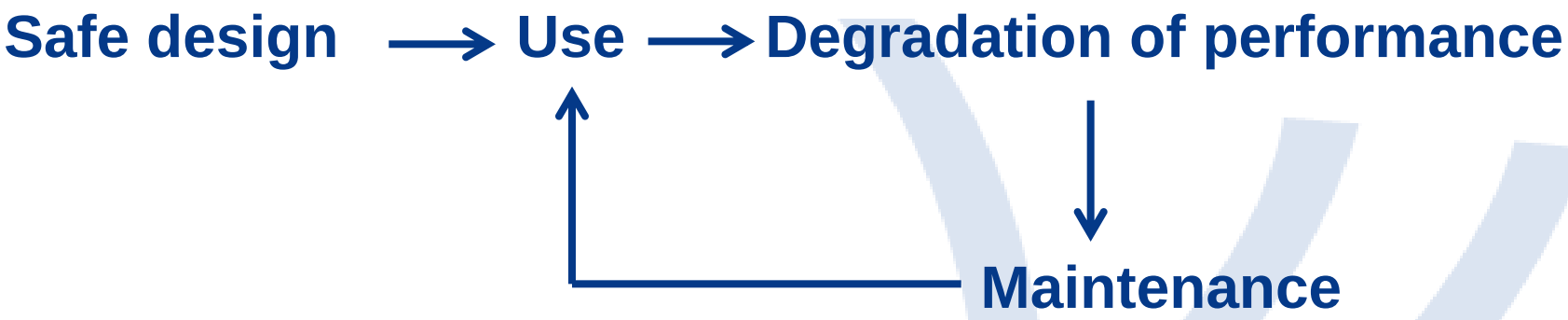
Safety Directive 2004/49, article 14a(3), 1st part

"the entity in charge of maintenance should ensure that the vehicle for which it is in charge of maintenance are in a safe state of running by means of a system of maintenance…"

Maintenance of freight wagon → 3 interrelated functions:

- ***Establish the maintenance technical instructions***
- ***Remove from operation and return to operation***
- ***Deliver the technical maintenance tasks***

All 3 interrelated functions must be organised → need of a MANAGEMENT PROCESS



Safe state of running by means of a system of maintenance
= restore the vehicle in its safe design
= the freight wagon can be used safely without any additional maintenance measures.

Degradation of performance = vehicle no more in its **safe** design.

Safe design = design that can provide a **safe** use of the freight wagon (operation)

Regulation 445/2011, Article 4

The maintenance system shall be composed of the following functions:

(a) the **management function**, which supervises and coordinates the maintenance functions referred to in points (b) to (d) and ensures the safe state of the freight wagon in the railway system;

(b) the **maintenance development function**, which is responsible for the management of the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return on experience;

(c) the **fleet maintenance management function**, which manages the freight wagon's removal for maintenance and its return to operation after maintenance; and

(d) the **maintenance delivery function**, which delivers the required technical maintenance of a freight wagon or parts of it, including the release to service documentation.

Establish the maintenance file

Remove from operation and return to operation

Deliver the technical maintenance tasks

MANAGEMENT PROCESS

Scope of ECM certification
ECM and maintenance workshop

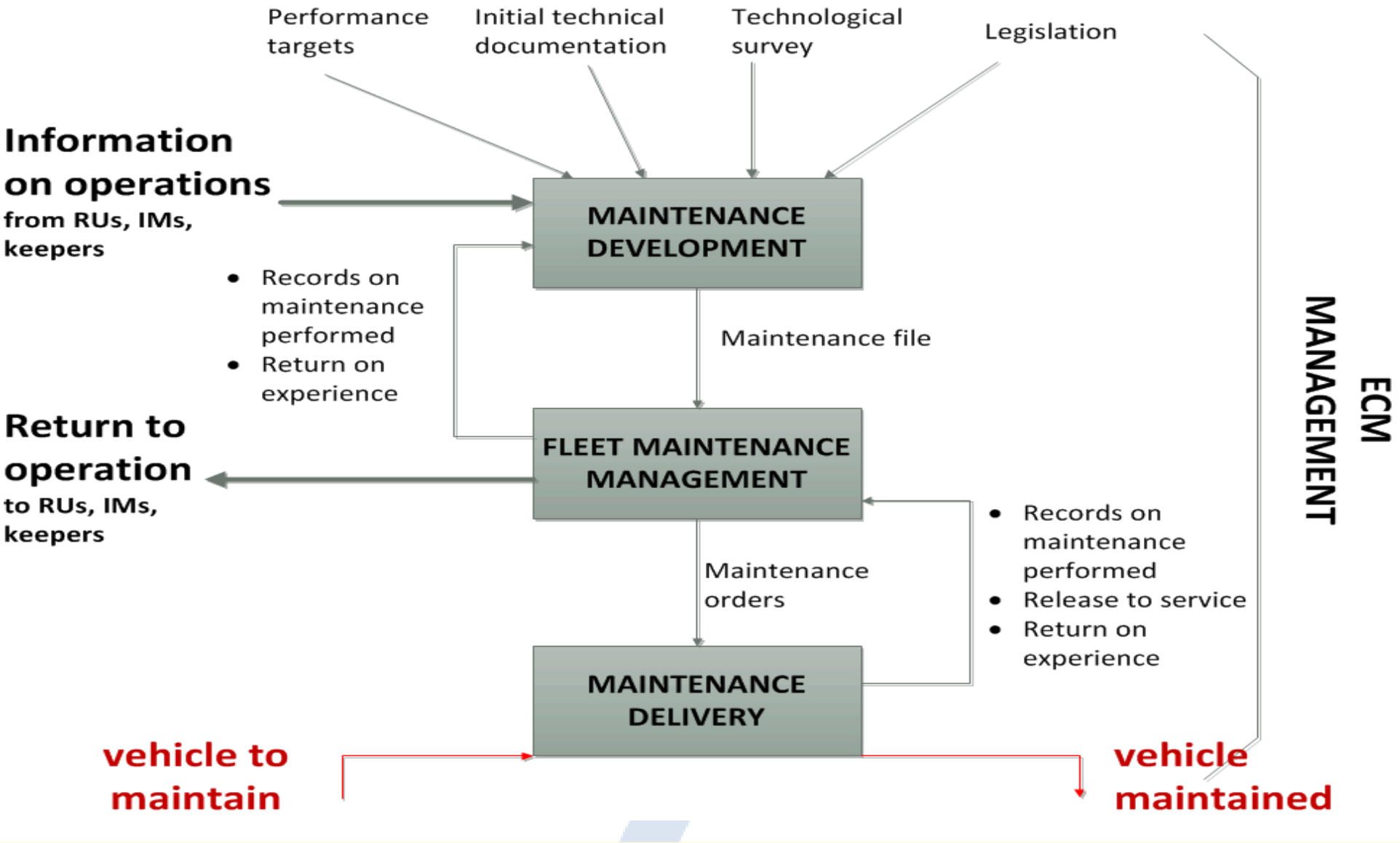
+

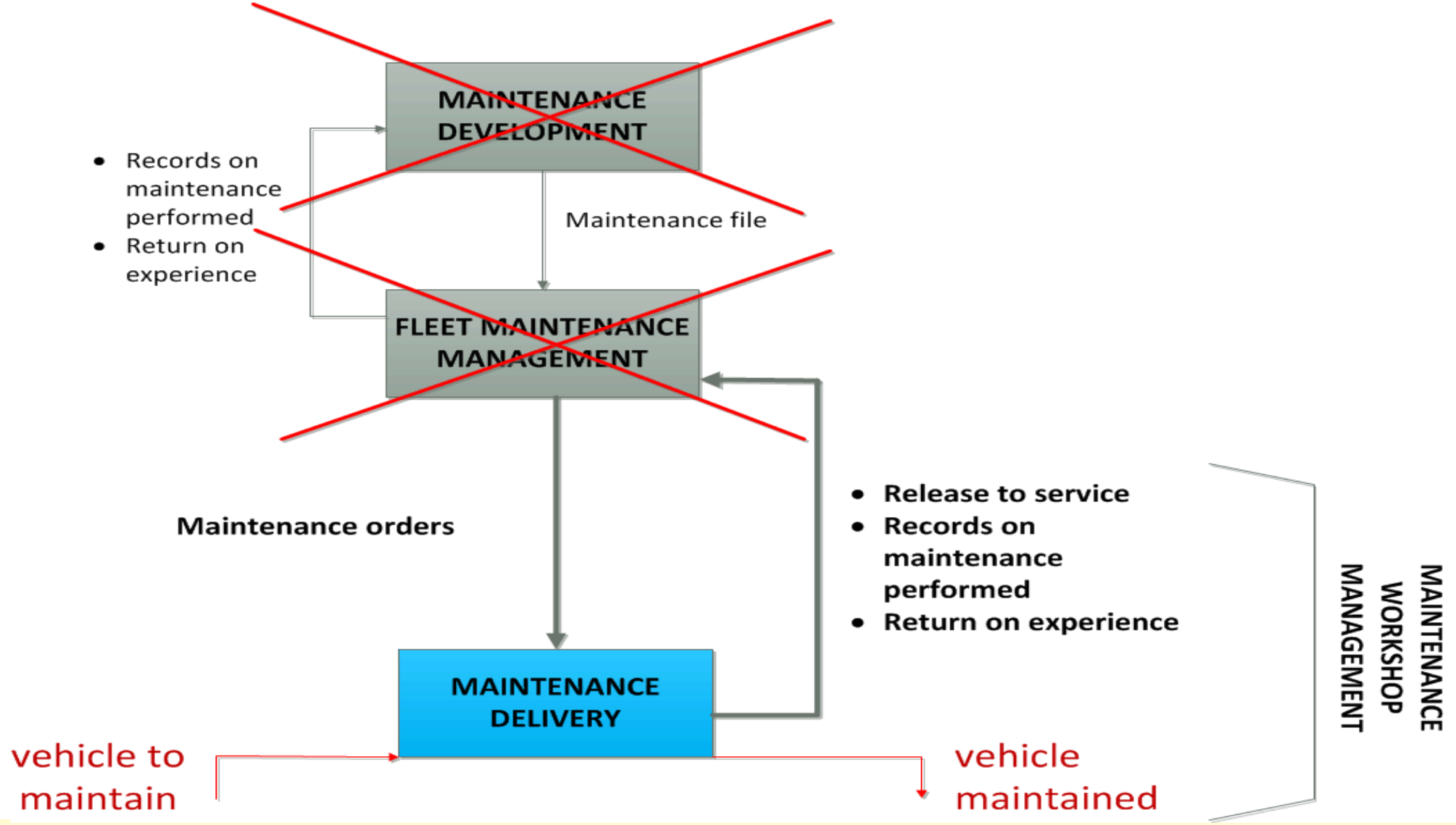
Entity in charge of maintenance

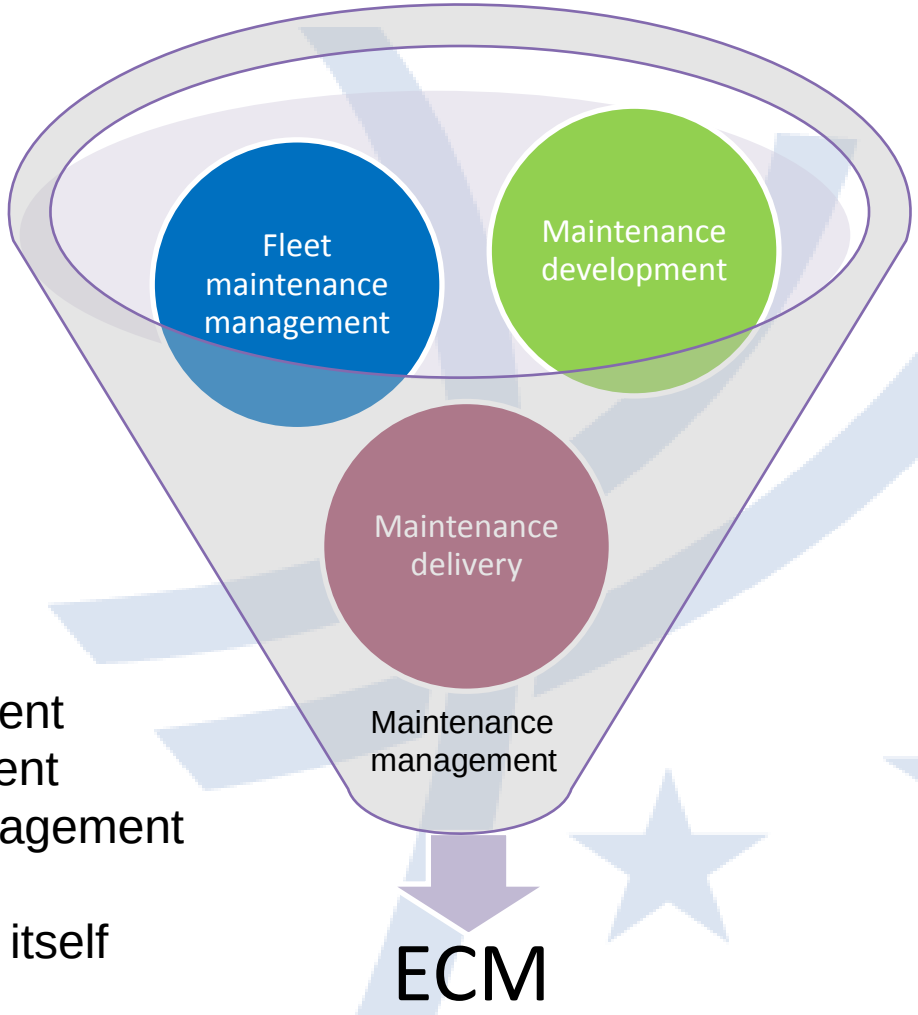
- Maintenance development
- Fleet management
- Maintenance delivery

Maintenance workshop

- Maintenance delivery


Performance targets
Initial technical documentation
Technological survey
Legislation
Information on operations
from RUs, IMs, keepers
MAINTENANCE DEVELOPMENT
Records on maintenance performed
Return on experience
Maintenance file
Return to operation
to RUs, IMs, keepers
FLEET MAINTENANCE MANAGEMENT
Maintenance orders
Records on maintenance performed
Release to service
Return on experience
MAINTENANCE DELIVERY
vehicle to maintain
vehicle maintained
ECM MANAGEMENT


MAINTENANCE DEVELOPMENT
Records on maintenance performed
Return on experience
Maintenance file
FLEET MAINTENANCE MANAGEMENT
Maintenance orders
Release to service
Records on maintenance performed
Return on experience
MAINTENANCE DELIVERY
vehicle to maintain
vehicle maintained
MAINTENANCE WORKSHOP MANAGEMENT

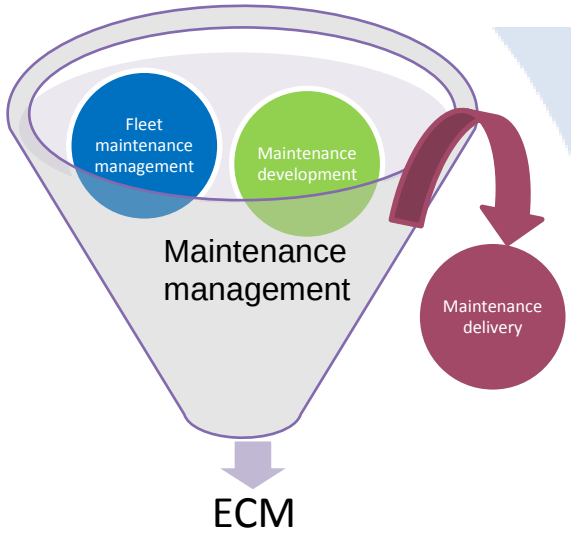


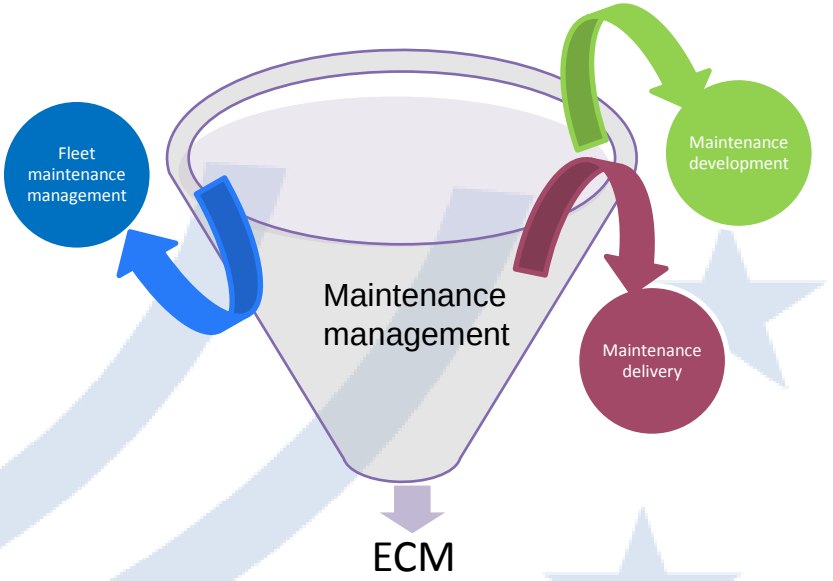
The 4 functions

- Maintenance management
- Maintenance development
- Fleet maintenance management
- Maintenance delivery

are carried out y the ECM itself

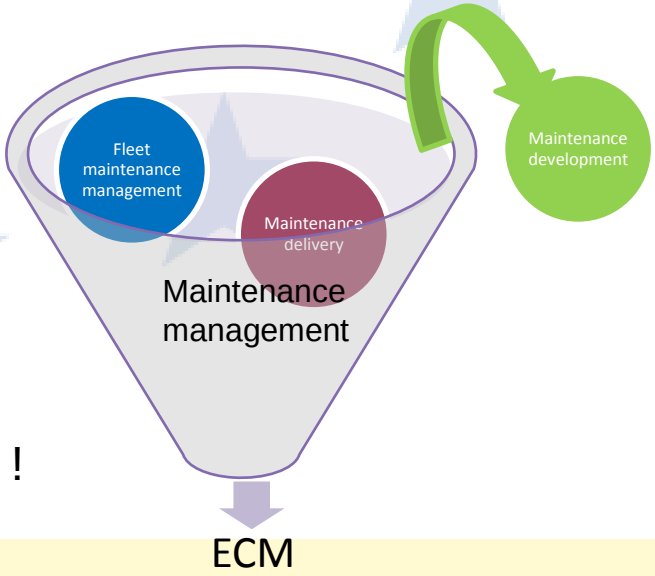
Scope of ECM certification
scenario 2- annex1- 445





The function
- Maintenance management

is carried out y the ECM itself (mandatory)
- the other functions may be outsourced



The ECM may outsource a function but not the responsability !

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Scope of ECM certification (Part II)

1. Legal bases
2. Exceptions
3. Geographical scope
4. Vehicle scope

- Article 9(2) of Safety Directive imposes to railway undertakings (RUs) to **control the risks related to maintenance of vehicles through their safety management system** (SMS).

- Article 16 of Safety Directive entitles National Safety Authorities (NSAs) to **assess SMS and deliver safety certificates**.

- Article 14a of Safety Directive imposes to Entity in Charge of Maintenance (ECMs) to **ensure that vehicles are in a safe state of running through a maintenance system**. ECMs have to control the risks related to maintenance of vehicles.

- ECM Regulation 445/2011 of 10 May 2011 imposes UNIQUE ECM certification in the EU for ECM maintaining freight wagons (since 1 may 2012 identical rules in OTIF-ATMF Annex A)

➔ Aim of ECM certification:

Assure RUs that vehicles are maintained by competent ECMs

- **Art 2.2 of the Safety Directive establishes the following possible exclusions (up to the MSs) in the implementation of this Directive, and consequently the obligations of Art. 14a and the NVR Decision:**
  a) metros, trams and other light rail systems;
  b) networks that are functionally separate from the rest of the railway system and intended only for the operation of local, urban or suburban passenger services, as well as railway undertakings operating solely on these networks;
  c) privately owned railway infrastructure that exists solely for use by the infrastructure owner for its own freight operations.

GEOPRAPHICAL SCOPE	VEHICLES	ENTITIES IN CHARGE OF MAINTENANCE
EUROPEAN UNION AND EEA	Vehicles operating in the UE (coming or not from 3rd countries): They must be registered in the NVR with an ECM (with residence in or out the UE) assigned	ECMs (with residence in or out the UE) maintaining vehicles that operate in the UE (coming or not from 3rd countries) • ECMs (with residence in or out the UE) must be identified in the NVR • In addition, ECMs (with residence in or out the UE) of freight wagons must be certified
THIRD COUNTRIES (members of OTIF: f.i north Africa, Croatia, Serbia, Macedonia, Bosnia, Switzerland, Turkey…) **It applies the ATMF – Annex A (from 01/05/2012) which is identical to ECM Regulation**	Vehicles operating in members of OTIF (coming or not from countries outside OTIF): They must be registered in the NVR with an assigned ECM	ECMs (with residence in or out OTIF) maintaining vehicles that operate in OTIF (coming or not from countries outside OTIF) • ECMs (with residence in or out OTIF) must be identified in the NVR • In addition, ECMs (with residence in or out OTIF) of freight wagons must be certified
REST OF THE WORLD	Applicable on a voluntary base For vehicles going to EU or third countries, application of EU legislation and OTIF rules	Applicable on a voluntary base For ECMs maintaining wagons going to EU or third countries, application of EU legislation and OTIF rules

For:

1. **Other vehicles than freight wagons, under the scope of the Safety Directive**
2. **All vehicles outside the scope of the safety directive (Art 2.2), and consequently without the obligations of Art. 14a and the NVR Decision:**
   - **metros, trams and other light rail systems;**
   - **networks that are functionally separate from the rest of the railway system and intended only for the operation of local, urban or suburban passenger services, as well as railway undertakings operating solely on these networks;**
   - **privately owned railway infrastructure that exists solely for use by the infrastructure owner for its own freight operations.**

For these vehicles those provisions of Articles 4, 5(2) to 5(5) and Annex III of the ECM Regulation should also be regarded as best practises:

- **Art. 4: Maintenance system functions of the ECM**
- **Art. 5(2), 5(3), 5(4) and 5(5): Interchange of information between all involved parties**
- **Annex III: Requirements and assessment criteria for organisations**

VEHICLES UNDER THE SCOPE OF THE SAFETY DIRECTIVE		VEHICLES OUTSIDE THE SCOPE OF THE SAFETY DIRECTIVE
FREIGHT WAGONS (ECM Regulation is applied on a compulsory base) *Legal Base: ECM Regulation and Art 14(a) of Safety Directive*	OTHER VEHICLES (provisions of the Articles 4, 5(2) to 5(5) and the Annex III of ECM Regulation should apply as best practises to all vehicles under the scope of the safety directive) *Legal base: Art 33(5) of Interoperability Directive, NVR Decision and Art 14(a) of Safety Directive*	Art 2.2 of the Safety Directive (provisions of Articles 4, 5(2) to 5(5) and annex III of the ECM Regulation should also be regarded as best practises for the development and implementation of a maintenance system)
Freight wagons for high speed or conventional rail (not those only limited to the TEN but all wagons)		
Commercial transport of freight		

VEHICLES UNDER THE SCOPE OF THE SAFETY DIRECTIVE		VEHICLES OUTSIDE THE SCOPE OF THE SAFETY DIRECTIVE
FREIGHT WAGONS (ECM Regulation is applied on a compulsory base) *Legal Base: ECM Regulation and Art 14(a) of Safety Directive*	OTHER VEHICLES (provisions of the Articles 4, 5(2) to 5(5) and the Annex III of ECM Regulation should apply as best practises to all vehicles under the scope of the safety directive) *Legal b… NVR De…*	Art 2.2 of the Safety Directive (provisions of Articles 4, 5(2) to 5(5) and annex III of the ECM Regulation should also be regarded as best practises for the implementation system)
Freight wagons for high speed or conventional rail (not those only limited to the TEN but all wagons)		
Commercial transport of freight		

VEHICLES UNDER THE SCOPE OF THE SAFETY DIRECTIVE		VEHICLES OUTSIDE THE SCOPE OF THE SAFETY DIRECTIVE
FREIGHT WAGONS (ECM Regulation is applied on a compulsory base) *Legal Base: ECM Regulation and Art 14(a) of Safety Directive*	OTHER VEHICLES (provisions of the Articles 4, 5(2) to 5(5) and the Annex III of ECM Regulation should apply as best practises to all vehicles under the scope of the safety directive) *Legal base: Art 33(5) of Interoperability Directive, NVR Decision and Art 14(a) of Safety Directive*	Art 2.2 of the Safety Directive (provisions of Articles 4, 5(2) to 5(5) and annex III of the ECM Regulation should also be regarded as best practises for the development and implementation of a maintenance system)
Freight wagons for high speed or conventional rail (not those only limited to the TEN but all wagons)		
Commercial transport of freight		

VEHICLES UNDERTHE SCOPE OF THE SAFETY DIRECTIVE		VEHICLES OUTSIDE THE SCOPE OF THE SAFETY DIRECTIVE
FREIGHT WAGONS (ECM Regulation is applied on a compulsory base) *Legal Base: ECM Regulation*	OTHER VEHICLES (provisions of the Articles 4, 5(2) to 5(5) and the Annex III of ECM Regulation should apply as best practises to all vehicles) *Legal base: Art 33(5) of Interoperability Directive, NVR Decision and Art 14(a) of Safety Directive*	Art 2.2 of the Safety Directive (provisions of Articles 4, 5(2) to 5(5) and annex III of the ECM Regulation should also be regarded as best practises for the development and implementation of a maintenance system)
STILL UNDER DISCUSION WITH EIM		
Freight wagons operated by infrastructure managers or their contractors in the railway network under the Safety Directive. • **Non self-propelled OTMs** Example: ventilator wagon • Self-propelled OTMs operated **ONLY in non-self-propelled mode**	The sector could decide to extend the scope of the ECM certification on a voluntary base To: • **Other vehicles than freight wagons.** Self-propelled OTMs operated **in self-propelled mode** Example: ballast tampers • Vehicles **only operating in lines out of service**	All vehicles, operated by infrastructure managers or their contractors, in the railway network **NOT** under the Safety Directive.

Scope of ECM certification
ope (IV)

VEHICLES UNDERTHE SCOPE OF THE SAF		SIDE THE SAFETY
FREIGHT WAGONS (ECM Regulation is applied on a compulsory base) *Legal Base: ECM Regulation*	OT Artic Regu vehi *Lega* *NVR*	afety ns of Articles ex III of the also be ises for the ementation of a maintenance system)
STILL UNDER DISCUSION WITH EIM		
Freight wagons operated by infrastructure managers or their contractors in the railway network under the Safety Directive. • **Non self-propelled OTMs** Example: ventilator wagon • Self-propelled OTMs operated **ONLY in non-self-propelled mode**	The sector could decide to extend the scope of the ECM certification on a voluntary base To: • **Other vehicles than freight wagons.** Self-propelled OTMs operated **in self-propelled mode** Example: ballast tampers • Vehicles **only operating in lines out of service**	All vehicles, operated by infrastructure managers or their contractors, in the railway network **NOT** under the Safety Directive.

VEHICLES UNDERTHE SCOPE OF THE SAFETY DIRECTIVE		VEHICLES OUTSIDE THE SCOPE OF THE SAFETY DIRECTIVE
FREIGHT WAGONS (ECM Regulation is applied on a compulsory base) *Legal Base: ECM Regulation*	OTHER VEHICLES (provisions of the Articles 4, 5(2) to 5(5) and the Annex III of ECM Regulation should apply as best practises to all vehic *Legal* *NVR L*	Art 2.2 of the Safety Directive (provisions of Articles 4, 5(2) to 5(5) and annex III of the e r the ation
STILL UNI		
Freight wagons operated by infrastructure managers or their contractors in the railway network under the Safety Directive. • **Non self-propelled OTMs** Example: ventilator wagon • Self-propelled OTMs operated **ONLY in non-self-propelled mode**	The s ECM To: • **Ot** Se **m** Ex • Ve	eir work e.

Scope of ECM certification
4. Vehicle scope (IV)

VE…		VEHICLES OUTSIDE THE SCOPE OF THE SAFETY DIRECTIVE
FRE… appli… *Lega…*	…visions of the … Annex III of ECM …st practises to all … *…perability Directive, … Safety Directive*	Art 2.2 of the Safety Directive (provisions of Articles 4, 5(2) to 5(5) and annex III of the ECM Regulation should also be regarded as best practises for the development and implementation of a maintenance system)
	…ITH EIM	
Freight wagons operated by infrastructure managers or their contractors in the railway network under the Safety Directive. • **Non self-propelled OTMs** Example: ventilator wagon • Self-propelled OTMs operated **ONLY in non-self-propelled mode**	The sector could decide to extend the scope of the ECM certification on a voluntary base To: • **Other vehicles than freight wagons.** Self-propelled OTMs operated **in self-propelled mode** Example: ballast tampers • Vehicles **only operating in lines out of service**	All vehicles, operated by infrastructure managers or their contractors, in the railway network **NOT** under the Safety Directive.

VEHICLES UNDERTHE SCOPE OF THE SAFETY DIRECTIVE		VEHICLES OUTSIDE THE SCOPE OF THE SAFETY DIRECTIVE
FREIGHT WAGONS (ECM Regulation is applied on a compulsory base) *Legal Base: ECM Regulation*	OTHER VEHICLES (provisions of the Articles 4, 5(2) to 5(5) and the Annex III of ECM Regulation should apply as best practises to all vehicles under the scope of the safety directive) *Legal base: Art 33(5) of Interoperability Directive, NVR Decision and Art 14(a) of Safety Directive*	Art 2.2 of the Safety Directive (provisions of Articles 4, 5(2) to 5(5) and annex III of the ECM Regulation should also be regarded as best practises for the development and implementation of a maintenance system)
Flat wagons for intermodal transport of containers, swap bodies and trailers. **Not included in the category of dangerous goods wagons:** not specifically designed for the transport of dangerous goods and rarely used for that purpose.		

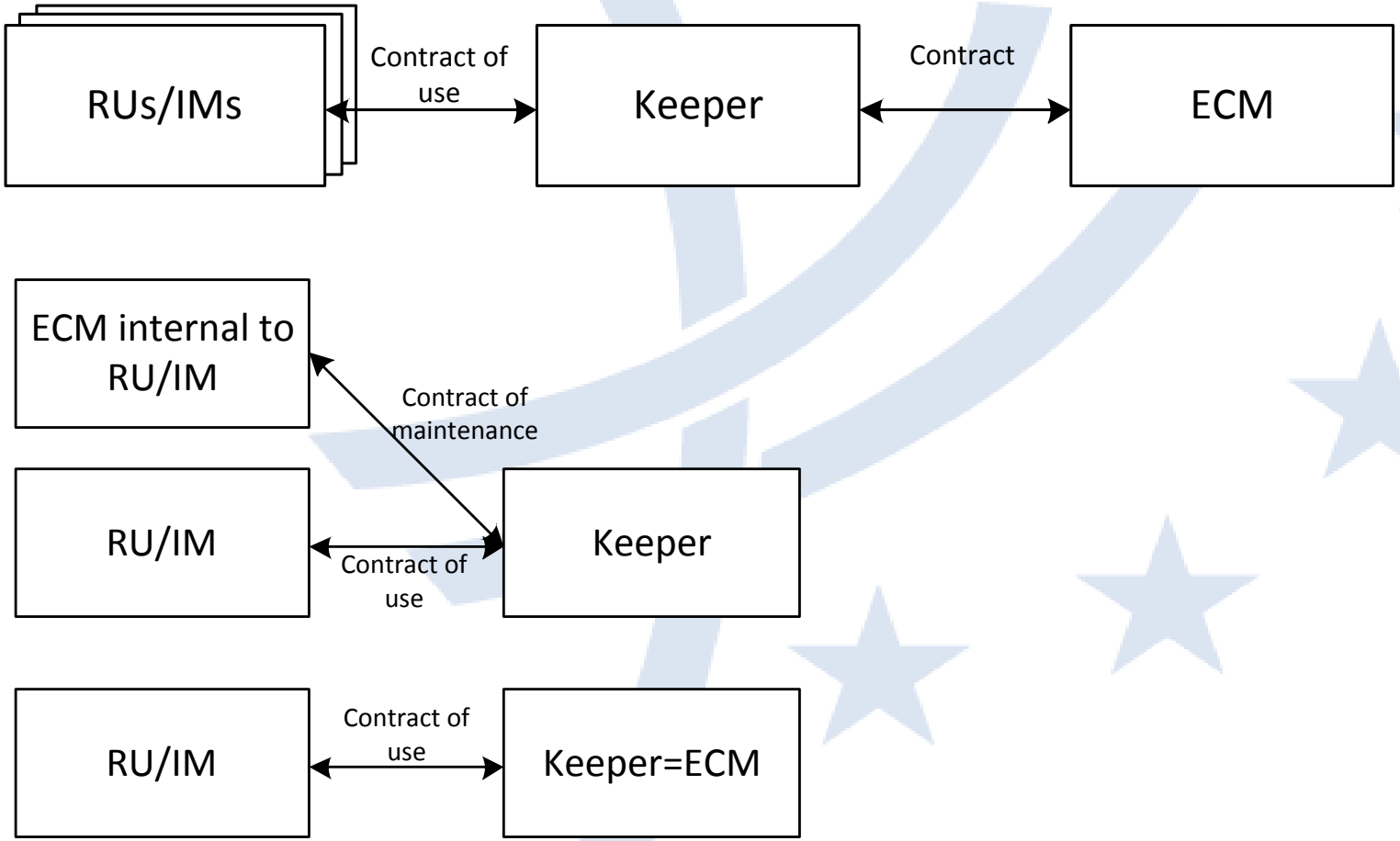
VEHICLES UNDERTHE SCOPE OF THE SAFETY DIRECTIVE		VEHICLES OUTSIDE THE SCOPE OF THE SAFETY DIRECTIVE
FREIGHT WAGONS (ECM Regulation is applied on a compulsory base) *Legal Base: ECM Regulation*	OTHER VEHICLES (provisions of the Articles 4, 5(2) to 5(5) and the Annex III of ECM Regulation should apply as best practises to all vehicles under the scope of the safety directive) *Le* *N*	Art 2.2 of the Safety Directive (provisions of Articles 4, 5(2) to 5(5) and annex III of the ECM Regulation should also be ed as best practises for the pment and implementation aintenance system)
Flat wagons for intermodal transport of containers, swap bodies and trailers. **Not included in the category of dangerous goods wagons:** not specifically designed for the transport of dangerous goods and rarely used for that purpose.		

European Railway Agency

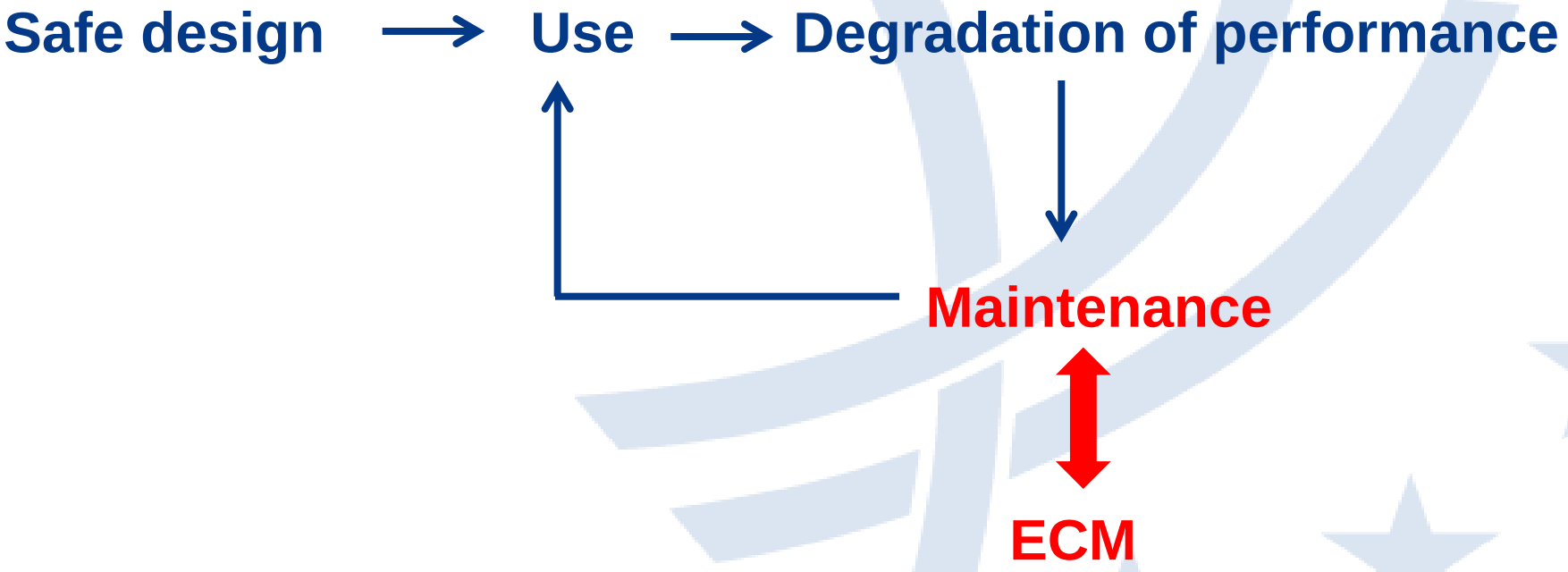
Allocation of responsibilities

1. Business models
2. ECM
3. RU
4. Keeper
5. Current situation
6. Exchange of information

Remark: the following slides address the main responsibilities and therefore should not be considered as exhaustive.


RUs/IMs
Contract of use
Keeper
Contract
ECM
ECM internal to RU/IM
Contract of maintenance
RU/IM
Keeper
Contract of use
RU/IM
Contract of use
Keeper=ECM

Maintenance is under the responsibility of ECM



Safety Directive 2004/49, Article 14a(3), 2nd part

"To this end, the entity in charge of maintenance shall ensure that vehicles are maintained in accordance with:

a) the maintenance file of each vehicle;

b) the requirements in force including maintenance rules and TSI provisions.

The entity in charge of maintenance shall carry out the maintenance itself or make use of contracted maintenance workshops."

- **ECM must set up and keep updated the maintenance file (maintenance development)**
- **ECM must ensure that the maintenance file is effectively applied (fleet management and delivery)**
- **ECM must coordinate all those activities and supervise its subcontractors**

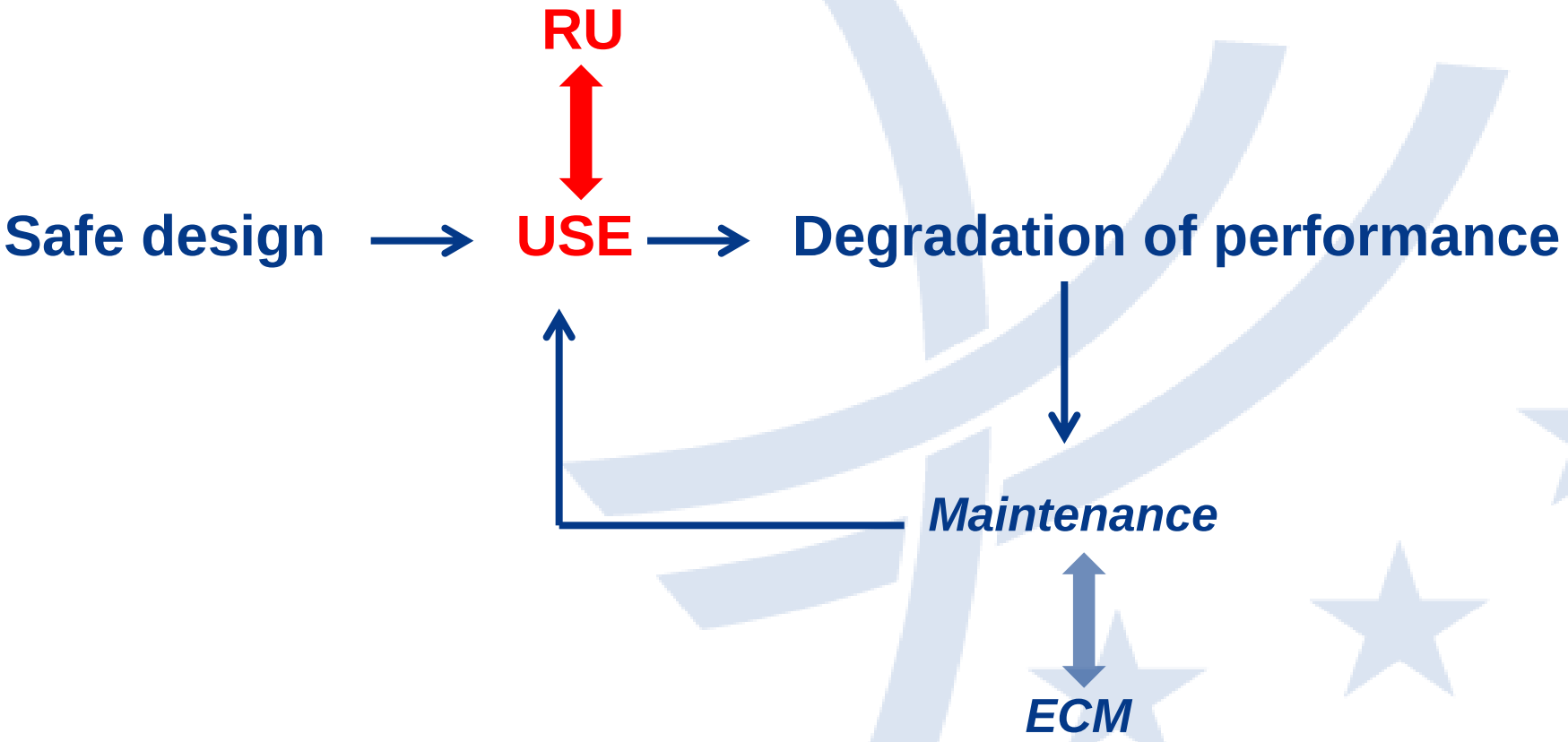
Exchange of information - Article 5(2) of Commission Regulation 445/2011

The ECM has to address return to operation issues to RUs and keepers.

Certification - Commission Regulation 445/2011

For freight wagons:

- ***The ECM must be certified against the Commission Regulation 445/2011.***
- ***The ECM must inform its partners, RUs, IMS and keepers, about all changes (amendment, renewal, suspension, revocation)***


RU
Safe design
USE
Degradation of performance
Maintenance
ECM

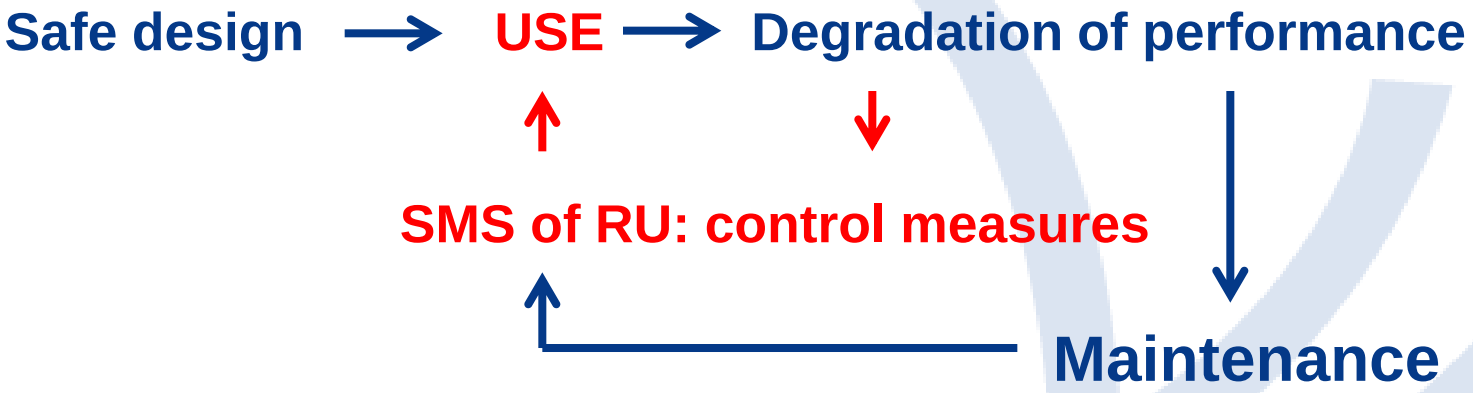
Safety Directive 2004/49, Article 4(3)

"The RU shall be made responsible for safe operation and associated control of risks"

Safety Directive 2004/49, Article 9

"Through its SMS, the RU shall control all risks associated with its activities including supply of maintenance and use of contractors"

- ECM certification provides assurance to RU that ECM is competent to address the risks associated to supply of maintenance
- Article 5(1) of Commission Regulation 445/2011 imposes to RU to ensure that the ECM is registered in the NVR and appropriately certified



Between maintenance interventions,

risks of degradation of performance

Certification is not a full guarantee that no error will happen

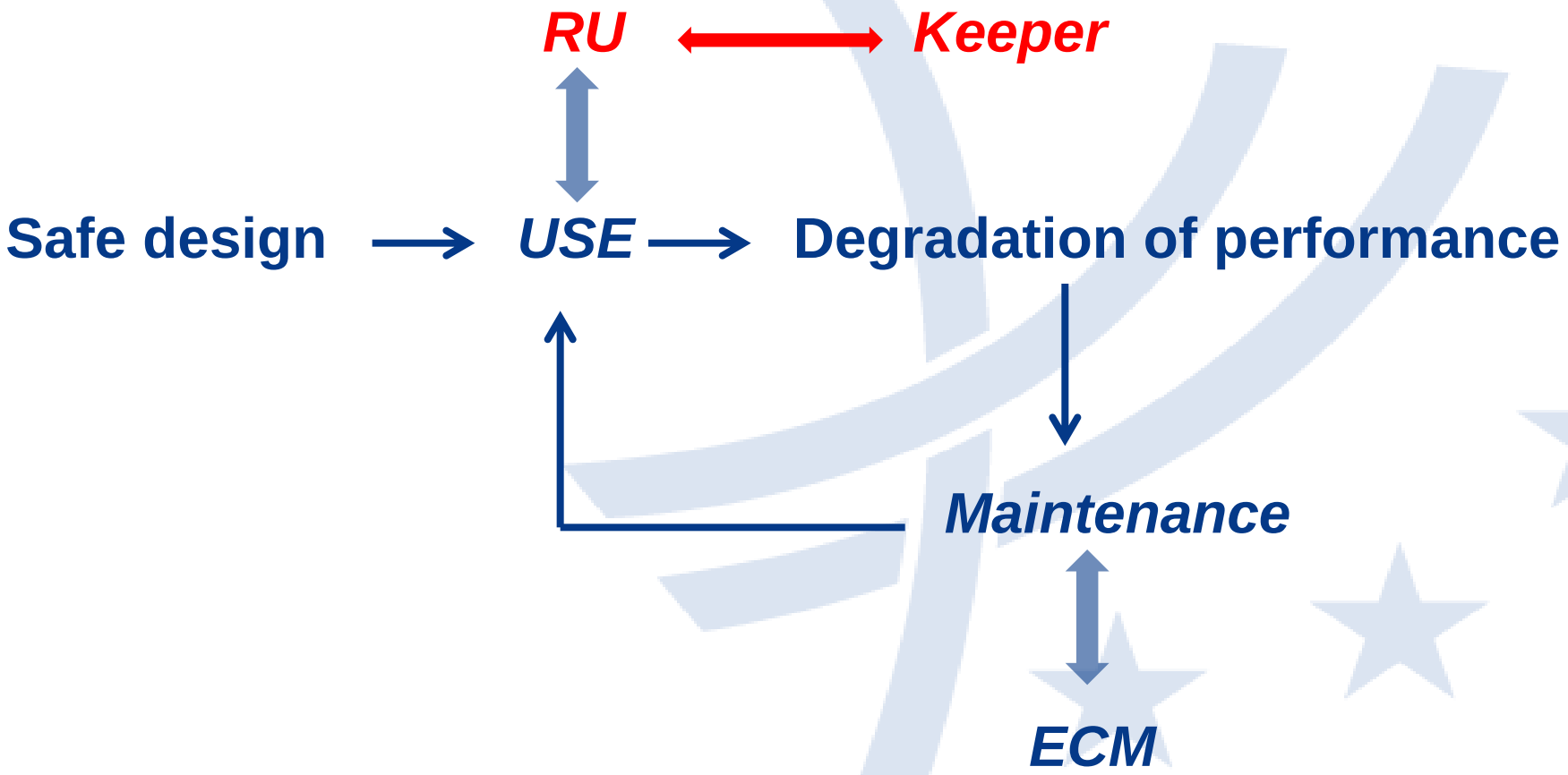
→ RU must address those risks

↓

SMS of RU: control measures such as pre-departure and en route inspections, restriction in operations

Exchange of information - Article 5(4) of Commission Regulation 445/2011

RU must provide to ECM information on operations performed (e.g. mileage, results of inspections)


RU
Keeper
Safe design
USE
Degradation of performance
Maintenance
ECM

Safety Directive 2004/49, Article 3(s)

'keeper' means "*the person or entity that, being the owner of a vehicle or having the right to use it, exploits the vehicle as a means of transport and is registered as such in the National Vehicle Register (NVR) provided for in Article 33 of Interoperability Directive 2008/57/EC.*"

Role the keeper is to provide vehicles to RU:

- *renting or leasing of empty wagons.*
- *provision of loaded wagons for transport though commercial transport contract.*

According to NVR legal rules, the keeper is the registration holder in the sense of article 33 of Interoperability Directive 2008/57 (if not otherwise mentioned)

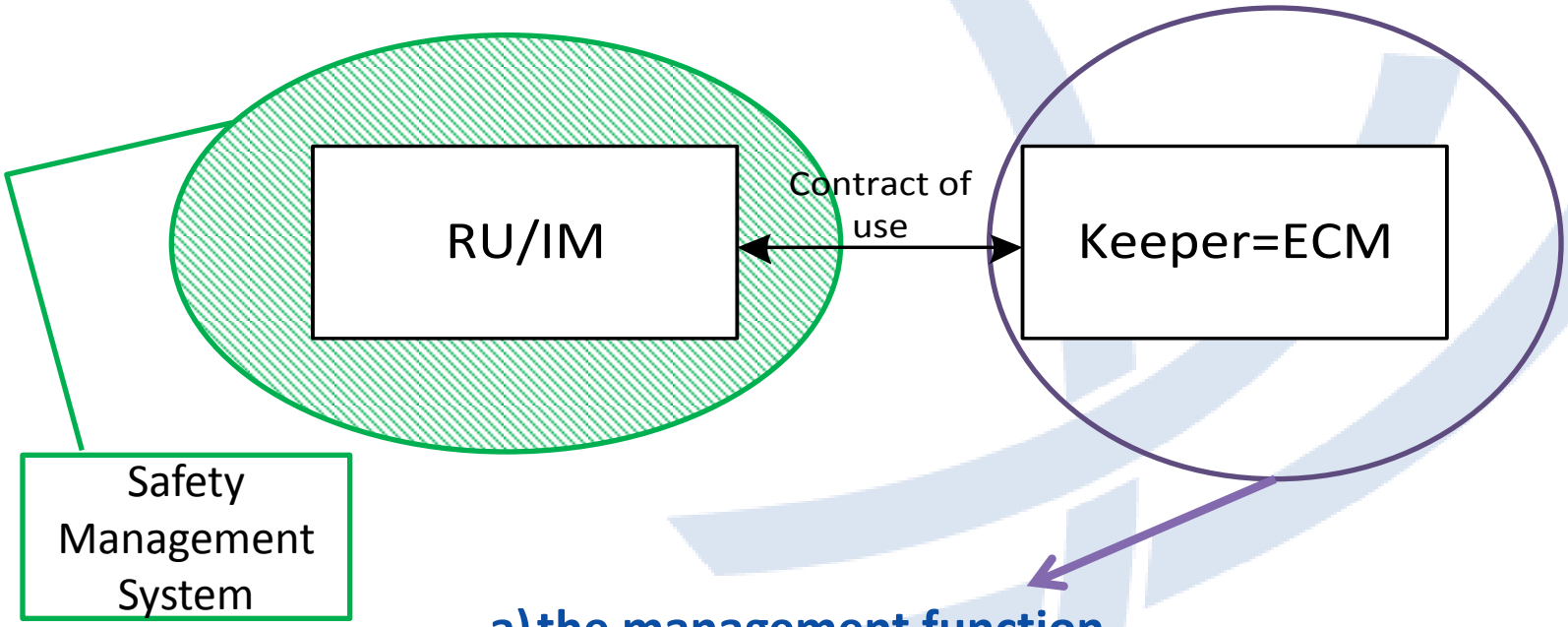
The keeper has contracts with ECM and RU

The keeper is responsible for all its allocated contractual tasks

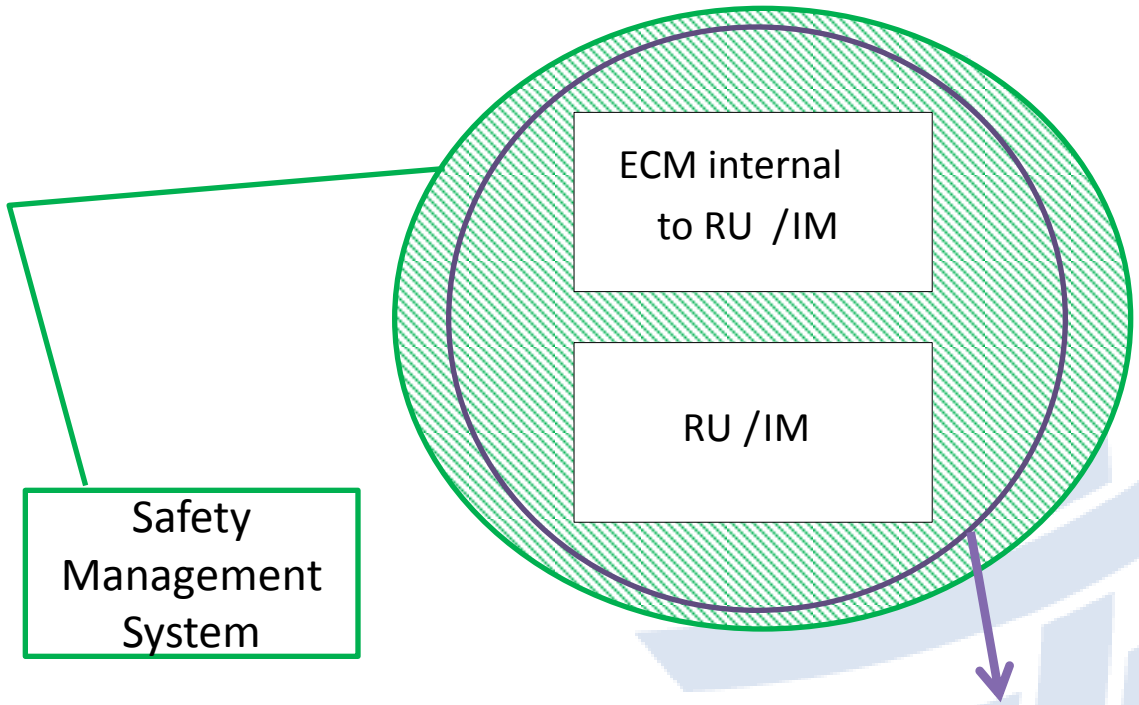
Contractual tasks may be related to exchange of information between RU and ECM (keeper = intermediate)

The keeper is also responsible to the RU to provide vehicles in conformity with the legislation:

- ***Vehicles with a valid authorisation of placing in service***
- ***Freight wagons with ECM duly certified***



a) the management function
b) the maintenance development function
c) the fleet maintenance management function
d) the maintenance delivery function

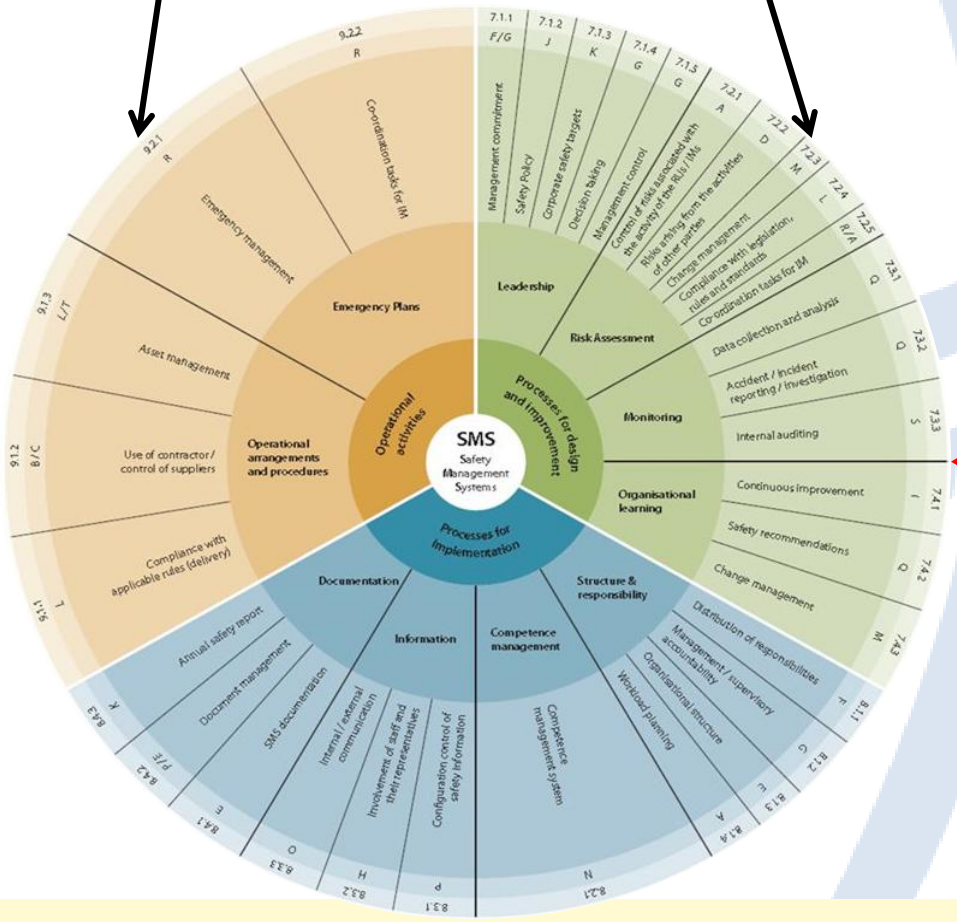


a) the management function
b) the maintenance development function
c) the fleet maintenance management function
d) the maintenance delivery function

Caution ! Don’t mix the different criteria

Art. 9 and Annex III of Railway Safety Directive

Annex II of CSM Conformity Assessment

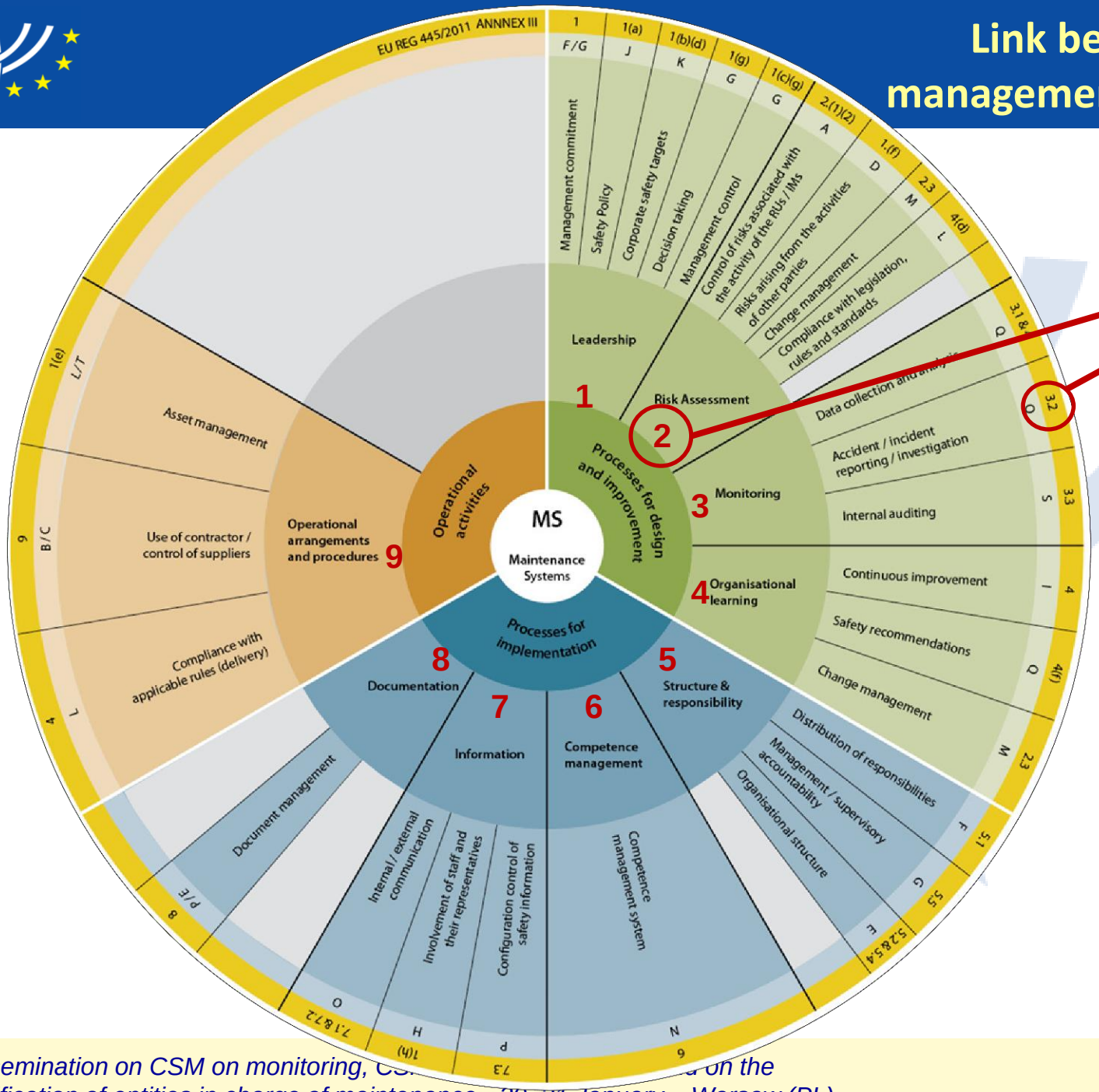


SMS Elements

ECM Maintenance System

- Maintenance Management (Annex III.1 of ECM Regulation)
- Fleet Maintenance Management
- Maintenance Development
- Maintenance Delivery

Link between maintenance management function and SMS



Reference to sections and paragraphs in Annex III of ECM Regulation

Management function's requirements can be seen as a subset of the RU's or IM's SMS, but…caution! Don't mix the different criteria!

The exchange of information is critical.

It is an important requirement taken in account in the ECM Regulation for the 3 parts: RUs, keepers and ECMs.

- **TSI Telematic Application for Freight (TAF TSI), in order to harmonise all the information systems related to the transport of freight wagons.**

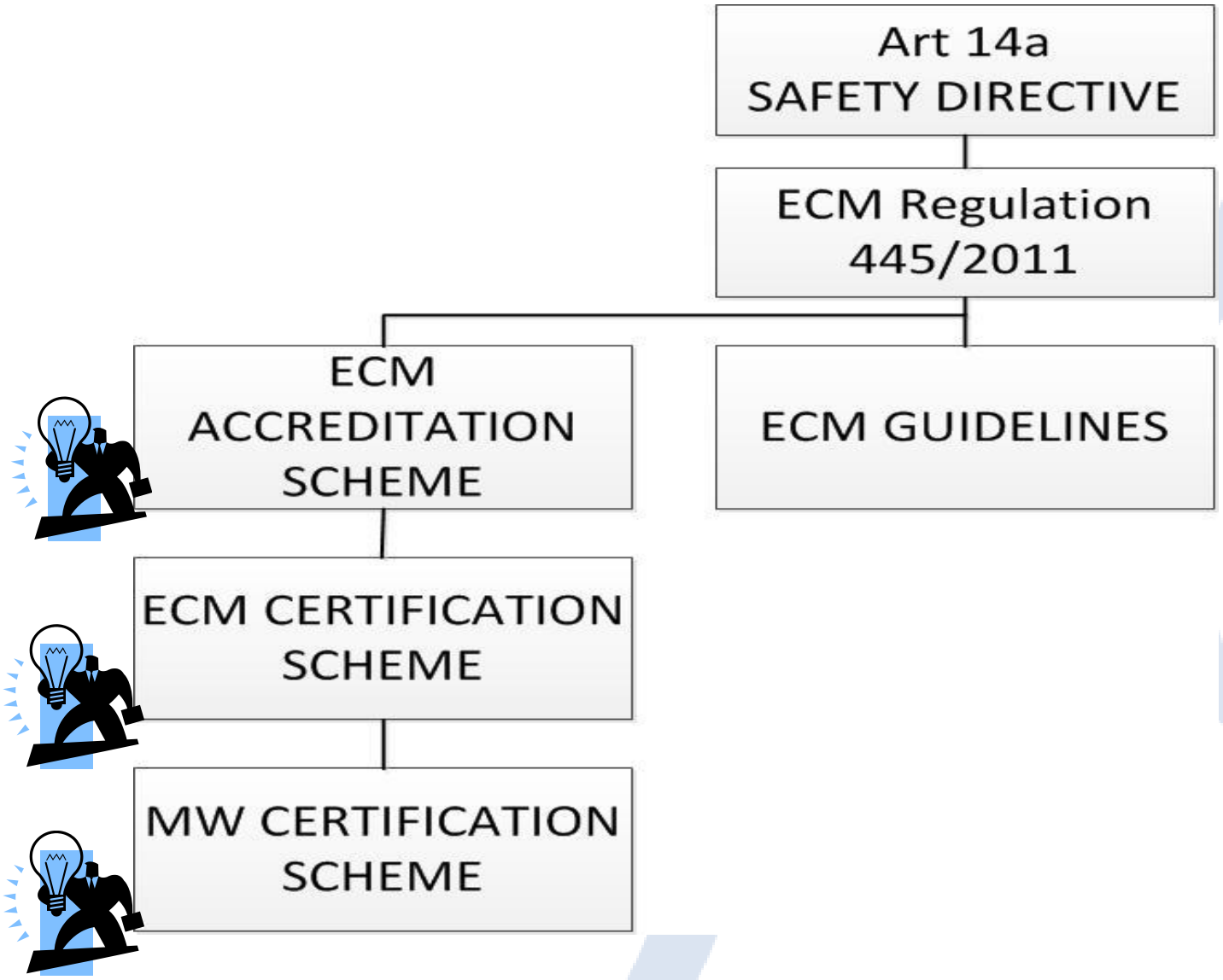
- **Private initiative : eg UIP, is developing a Rolling Stock reference Database (RSRD²) in order to respond to the TAF TSI requirements (Telematic Application Freight)**

ECM certificates will be uploaded from June 2012 in the database ERADIS to disseminate the information to the sector.

European Railway Agency

ECM certification scheme

1. Context
2. State of play
3. Mandatory and voluntary certification
4. Certification process
5. Certification requirements
6. Relevant standards for certification
7. Why accreditation or recognition?
8. Type of certification bodies in EU


Art 14a
SAFETY DIRECTIVE
ECM Regulation
445/2011
ECM
ACCREDITATION
SCHEME
ECM GUIDELINES
ECM CERTIFICATION
SCHEME
MW CERTIFICATION
SCHEME

European co-operation for Accreditation

ISO 17011
Regulation 765/2008/EC

European cooperation accreditation

Supervises, monitors (cross auditing)

Accreditation scheme EN 45011

National Accreditation Body

Recognition by Member State

Designation by Member State

Certification scheme Chap.9 and Chap.7 17021

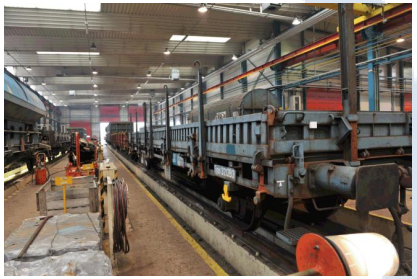
Certification body

Cooperation of Certification bodies (ERA)

NSA as Certification body

ECM Certificate

+



Entity in charge of maintenance

- **Maintenance development**
- **Fleet maintenance management**
- **Maintenance delivery**

Article 2.1 : the system of certification shall apply to any ECM for freight wagons

Maintenance workshop

- **Maintenance delivery function**

Article 2.2 : Maintenance workshop may apply the system of certification on a voluntary basis

Initial application review	Document review	On-site audits	On-site inspections	Surveillance activities

• Review of the application collected to ensure that:
  • Information is sufficient
  • Certification activities can be prepared
	• Assessment of maintenance documentation
	• Evaluate presence of necessary processes (requirements)
		• Evaluate implementation of maintenance system	• Evaluate appropriatness of competences in place
			• Coherence between activities (sampling)
			• Activities affecting safety
				• Regular monitoring of representative areas and functions covered by the scope of the maintenance system

starting of certification process

4 months

DECISION
Granting of ECM Certificate

5. Certification requirements (I)

Initital application review	Document review	On-site audits	On-site inspections	Surveillance activities

• Review of the application to ensure that:
  • Information is sufficient
  • Certification activities can be prepared
	• Collect necessary information on scope of maintenance system
	• Evaluate presence of necessary processes (requirements)
		• Evaluate implementation of maintenance system	• Evaluate appropriatness of competences in place
			• Check sample of activities
				• Regular monitoring of representative areas and functions covered by the scope of the maintenance system

	(EU) 445/2011	(EU) 445/2011	(EU) 445/2011	(EU) 445/2011
	• Article 7 and Annex III of the ECM regulation	• Article 7 and Annex III of the ECM regulation	• Article 7 and Annex III of the ECM regulation	• Article 7 and Annex III of the ECM regulation

Maintenance development

- Conformity with interoperability rules II.2
- Establishment of maintenance file II.4
- Update of maintenance file II.5

Fleet maintenance management

- Issue of maintenance orders and removal from service III.2,3,4
- Issue of return to operation III.6

Maintenance delivery

- Issue of working instructions from maintenance orders IV.1
- Issue of release to service IV.6

return

6. Relevant standards

Initital application review	Document review	On-site audits	On-site inspections	Surveillance activities

• Review of the application to ensure that:
  • Information is sufficient
  • Certification activities can be prepared
	• Collect necessary information on scope of maintenance system
	• Evaluate presence of necessary processes (requirements)
		• Evaluate implementation of maintenance system	• Evaluate appropriatness of competences in place
			• Check sample of activities
				• Regular monitoring of representative areas and functions covered by the scope of the maintenance system

ISO 17021:2011 Chapter 7 Personnel -**Resource requirements – Competence – Outsourcing – Management**

ISO 17021:2011	ISO 17021:2011	ISO 17021:2011	EN 45011:1998 ISO (17065:2012)	ISO 17021:2011
• 9.2.2 (review of application)	• 9.2.3.1 (stage 1 audit)	• 9.2.3.2 (stage 2 audit)	• Chapter 8 part 8.1.2 b	• 9.3 (surveillance)

Requirement of mutual recognition necessitates sufficient trust in the work performed by ECM certification bodies

ACCREDITATION IS THE WAY PRIVILEGED BY THE EUROPEAN

LEGISLATION TO ACHIEVE THIS TRUST

BUT

- ***Regulation 765/2008 Article 5(2): when a MS decides not to use accreditation it shall demonstrate, to the Commission and the other MS, the equivalence of the national recognition scheme with the ECM accreditation***

- ***The ECM accreditation scheme is the reference document for the demonstration***

ECM certification scheme
Type of certification bodies in EU

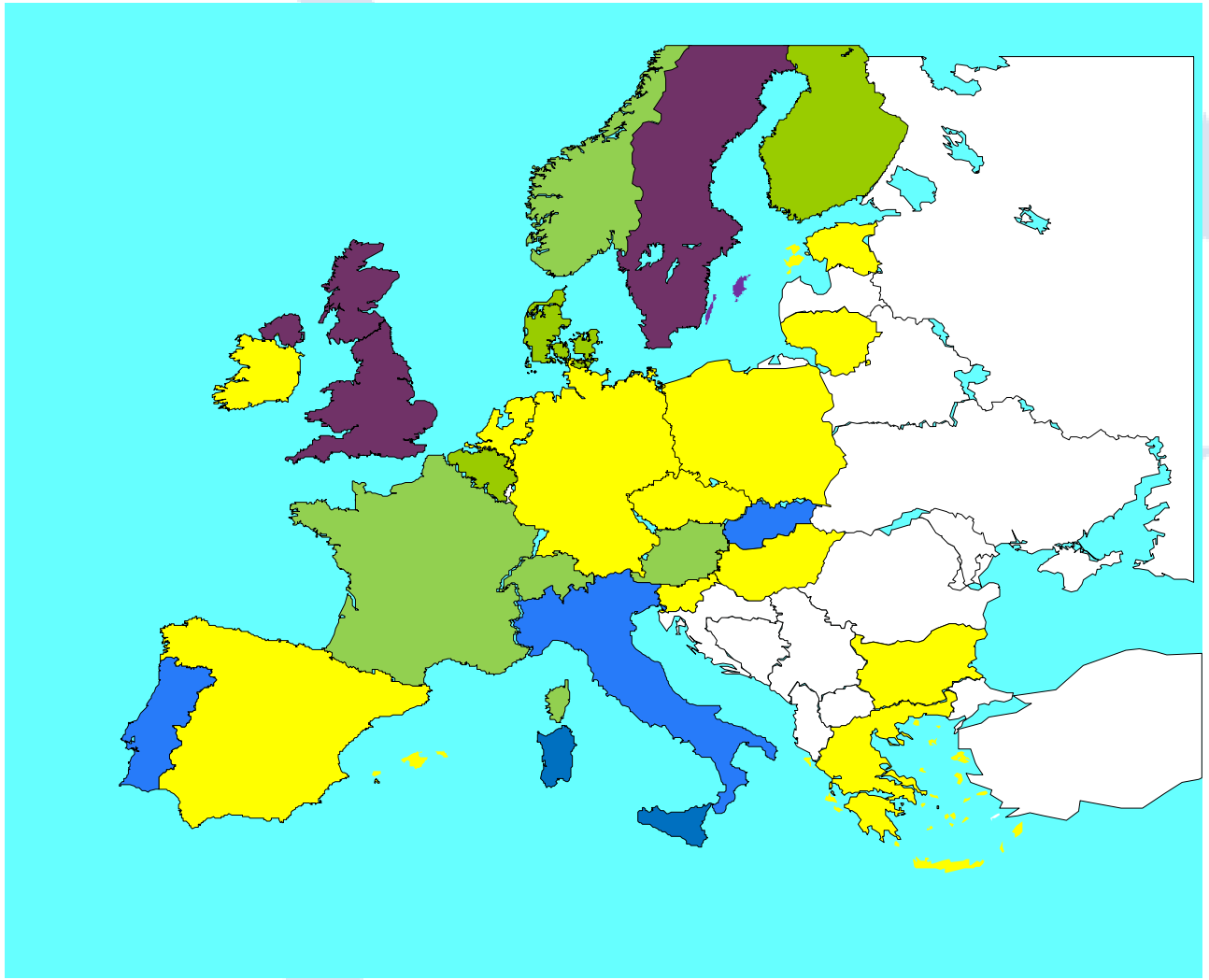
No answer

NSA

accreditation

Member state

NSA + accreditation



European Railway Agency

Summary of the first day and preparation of the second day