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NANOSAFE 2016  
Grenoble, 8th October 2016

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# Implementation of a safe-by-design approach in the construction of three open pilot plants for manufacturing nano-enabled products targeted to the European aeronautics and automotive industries

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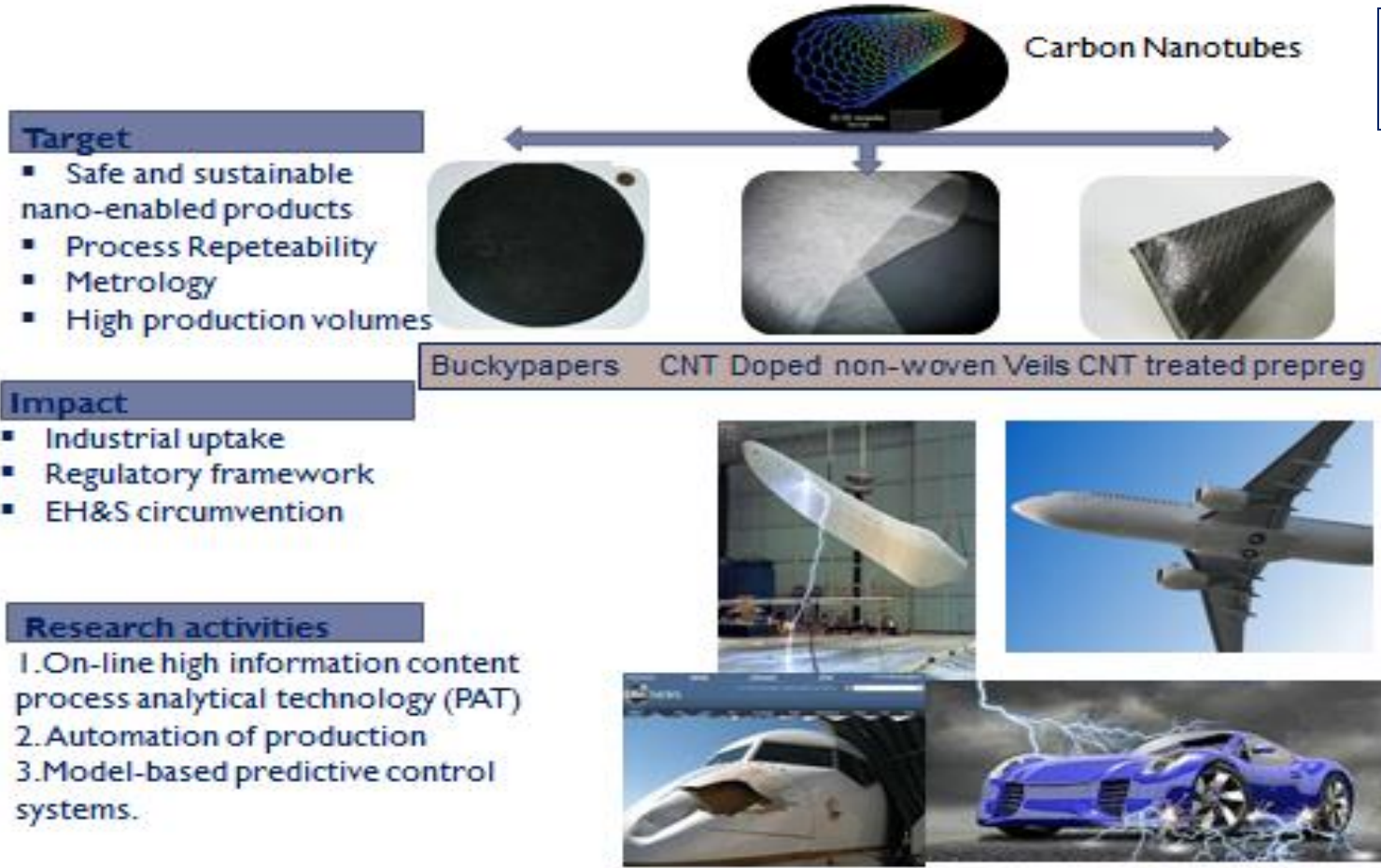
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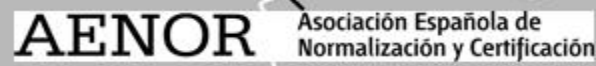
# Open access pilot plant for sustainable industrial scale nanocomposites manufacturing based on buckypapers, doped veils and prepregs (PLATFORM)



The final objective of project PLATFORM is to put into service and operate, in the short-term (2020), **three NEW PLATFORM Pilot Plants ( PPPs)** for the **INDUSTRIAL PRODUCTION and COMMERCIALIZATION** of nano-enabled products (bucky papers, treated prepregs, and doped non-woven veils) (TRL6 2018, TRL9 2020 – Business Platform)



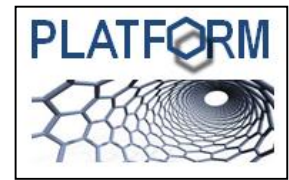
**TMBK PARTNERS**



# PLATFORM consortium

SbD





## Motivation and context

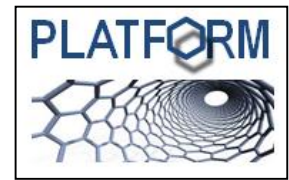
- The **future commercialization needs** as well as the **intended use of PPPs by third parties** force the design and construction of PPPs **in conformity with legal requirements (CE marking)**, before putting them into service and made available to workers.
- The **Machinery Directive 2006/42/EC (MD)** is the **European regulatory framework** for the design and construction of **new machinery - as future PPPs**.
- PPPs are not required to comply with the provisions of Directive 2006/42/EC until they are put into service (expected in 2020). **But in 2020, all requirements of the MD will be mandatory for PPPs.**

**The regulatory framework for the safe design and putting into service the PPPs: The Machinery Directive 2006/42/EC (MD)**



## Motivation and context

- In this **regulatory context**, project Platform is conducting the design of PPPs to comply with all the provisions of the MD to:
  - 1) **facilitate the CE marking** in 2020 (TRL9), as well as
  - 2) **avoid potential economic costs** associated with future re-adaptations or modifications needed to ensure compliance with MD, when PPPs are put into service.
- The major project **CHALLENGE** is to **integrate all nanosafety issues** in the well established SbD process of machinery according to MD.



## SbD principles of the Machinery Directive

**Principles of Safety Integration (SbD)** often referred to as the 3-step method (MD):

1. Eliminate or reduce risks as far as possible (**inherently safe machinery design** and construction),
2. Take the necessary **protective measures** in relation to **risks that cannot be eliminated**,
3. **Inform users of the residual risks** due to any shortcomings of the protective measures adopted, indicate whether any particular **training** is required and specify any need to provide **personal protective equipment**.

Prevention through Design (PtD), **Safe-by-Design (SbD)** or Safety Integration (SI) are similar concepts that refer to design out hazards or minimize risks early in the design process.

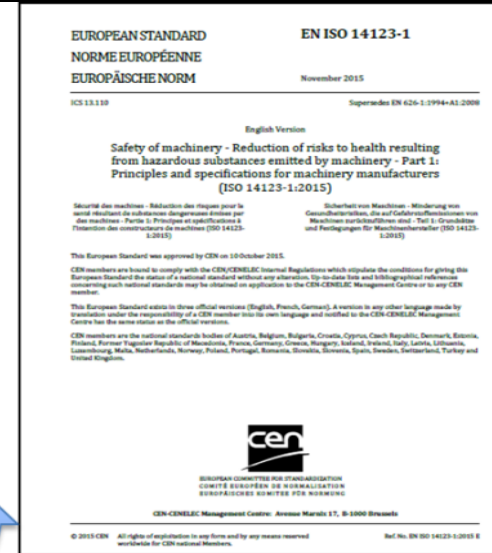


### 1.5.13. *Emissions of hazardous materials and substances*

Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.

Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation must be situated in such a way as to have the maximum effect.



- The Directive sets out the **mandatory ESSENTIAL HEALTH AND SAFETY REQUIREMENTS (EHSRs)** for machinery while detailed **technical specifications** for fulfilling these requirements are given in **European harmonised standards**.
- **Machinery manufactured in conformity with a harmonised standard shall be presumed to comply with the EHSRs** covered by such a harmonised standard.
- Thus harmonised standards are **essential tools for applying the Machinery Directive**.
- **Harmonised standards: A, B and C-types**
- No harmonized standards for nanosafety



Link between EHSRs (mandatory) and harmonized standards (voluntary)

EUROPEAN STANDARD

**EN ISO 14123-1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2015

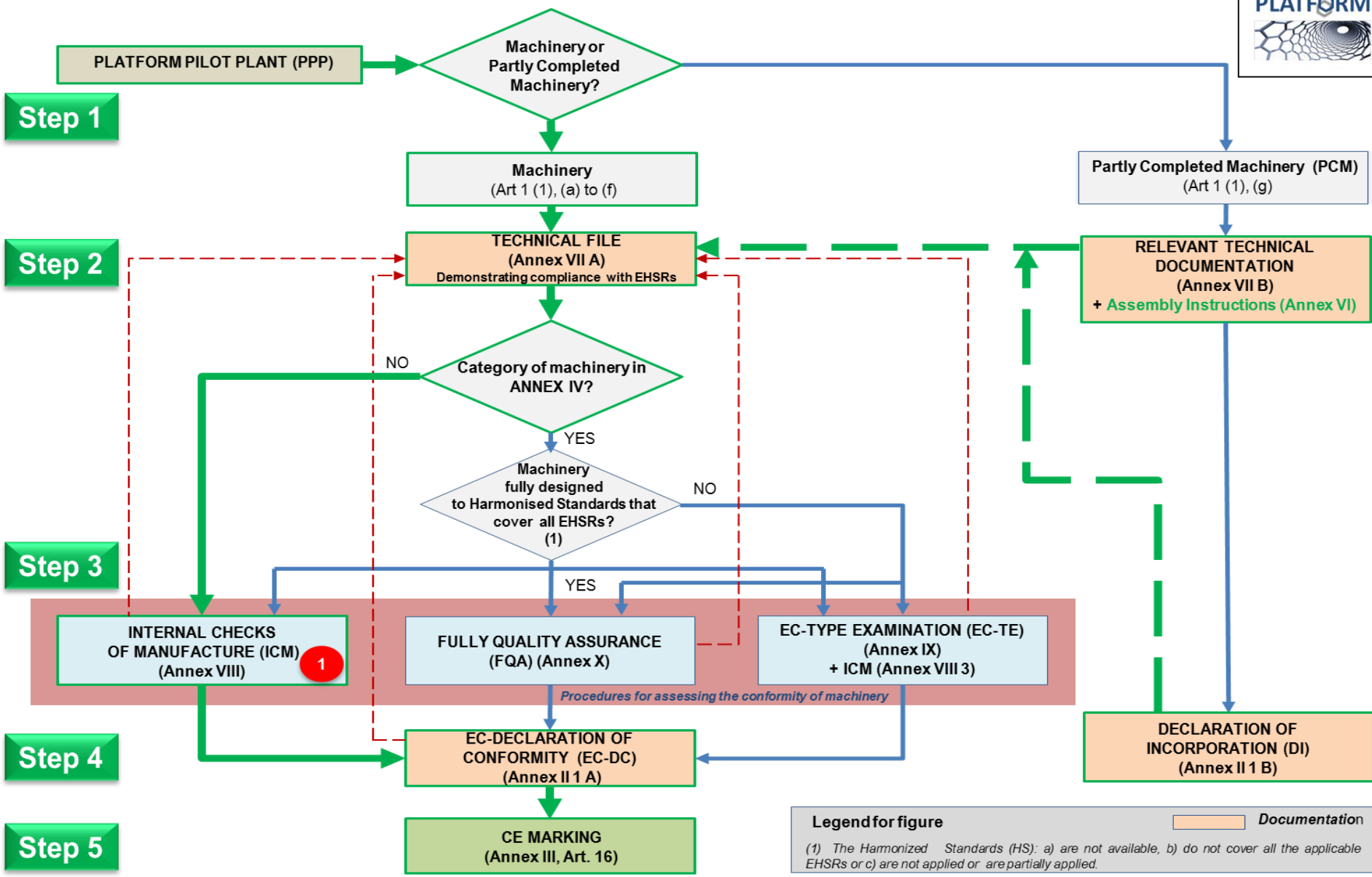
ICS 13.110

Supersedes EN 626-1:1994+A1:2008

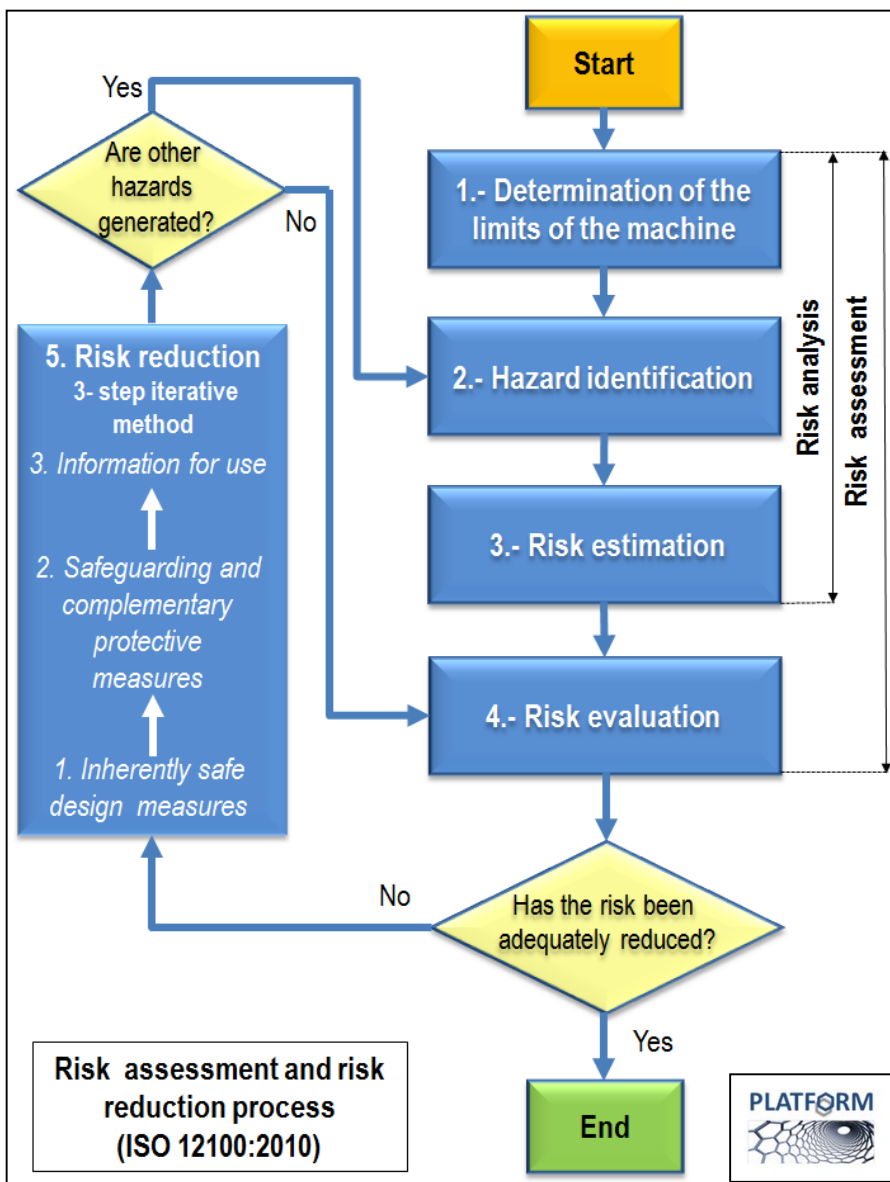
English Version

Safety of machinery - Reduction of risks to health resulting from hazardous substances emitted by machinery - Part 1: Principles and specifications for machinery manufacturers  
(ISO 14123-1:2015)

Harmonized standards



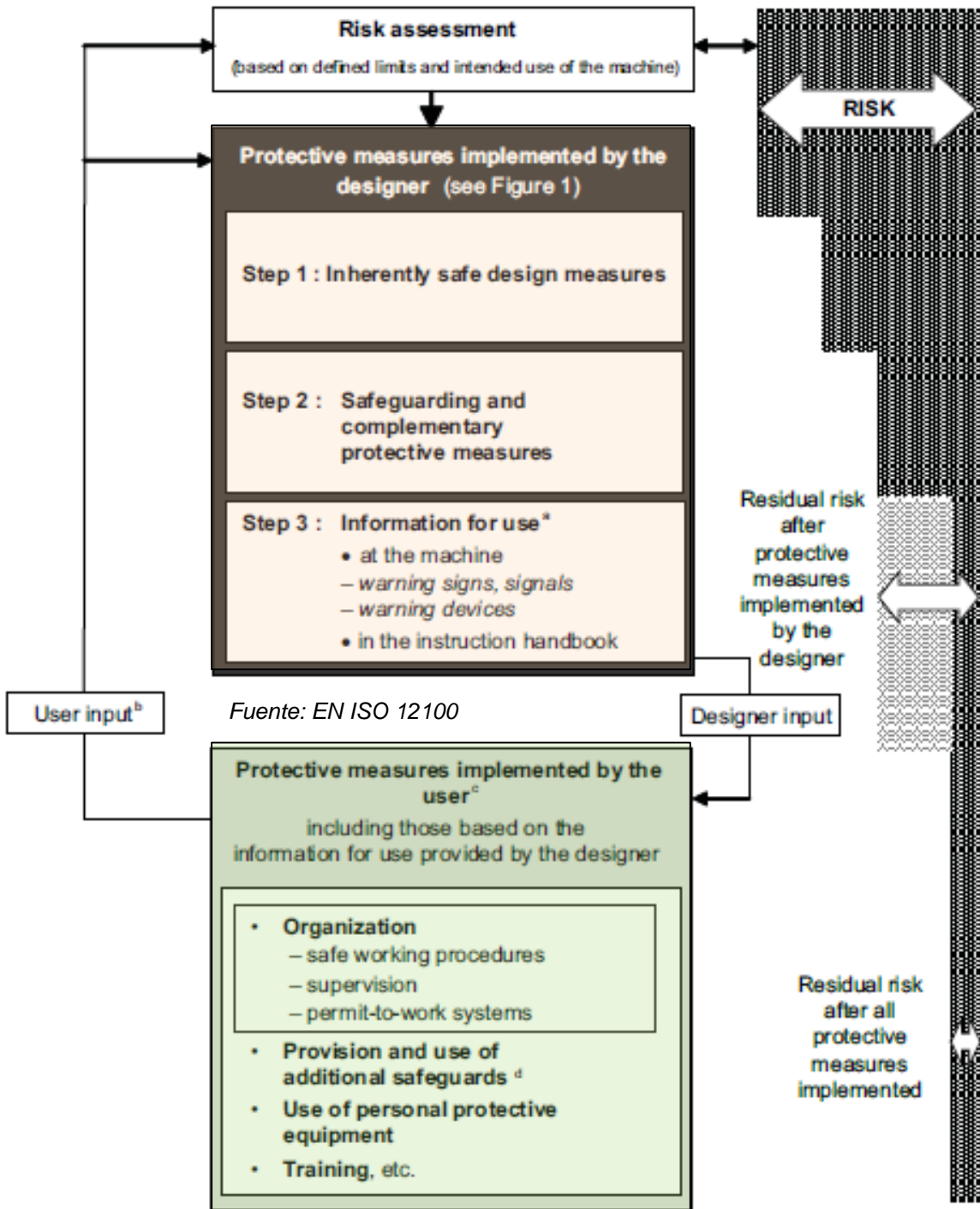
Five steps for the design, construction and putting into service the PPPs according to MD requirements (EHSRs)



Machine name	Life stage	Operating mode	Task	1. Hazard identification and determination of the limits				2. Risk estimation				3. Risk evaluation				4. Risk reduction				5. Information for use				Residual risk	Residual risk level														
				Hazard	Severity	Probability	Frequency	Severity	Probability	Frequency	Severity	Probability	Frequency	Severity	Probability	Frequency	Severity	Probability	Frequency	Severity	Probability	Frequency																	

The process has been guided by the harmonized standard EN ISO 12100 (and EN-ISO 14123-1,2), taking the relevant phases of life cycle, expected uses and operation modes of PPPs into account

Systematic and iterative approach for risk assessment and risk reduction followed to eliminate hazards as far practicable and to adequately reduce risks by the implementation of protective measures (EN - ISO 12100)





- **PLATFORM – SbD Tool (v1)** is a simple and friendly **Microsoft Excel** tool to guide the safe design and risk assessment of PPPs, in accordance with the EHSRs of the Directive 2006/42/EC.
- This tool can be applied to the **overall risk assessment** of PPPs or only for **risks related to the use and handling of ENMs and NEPs**.



### 1.3. RISK ASSESSMENT AND RISK REDUCTION

MACHINE ZONE:	Drying tunnel
LIFE STEP:	Use
OPERATING MODE:	Normal

Create a new worksheet for each Life Step and/or Operating Mode (Click on the tab, Move or copy, Create a copy)

2. HAZARD IDENTIFICATION AND 3. RISK ESTIMATION (ISO/TR 14121-2:2012)						4. RISK EVALUATION AND RISK REDUCTION (ISO/TR 14121-2:2012)														
Ref	Task	Hazard	Hazardous situation	Hazardous event	Risk (before)			Measures /solutions for Risk reduction			Risk (after)			Standards	Verification					
					S	P	R	Description	Type	SF	S	P	R		V	M	FT	DV	C	
A1-O-A1-01	Drying the buckypaper	Respiratory disease due to inhalation of and aerosol of toxic substances	Operator is driving the machine (Drying)	Emission of a substance that can be hazardous			0	Installing an exhaust system with HEPA filter						0	EN ISO 14123-1:2015					
A1-O-A1-02								Slight negative pressure												
A1-O-A1-03																				

Excel spreadsheet to document the stages of **hazard identification, risk estimation, risk evaluation and risk reduction** of the risk assessment & risk reduction process, including the verification of the measures / solutions required for adequate risk reduction.



1.4. CONTROL SYSTEM (SIL and PL REQUIRED)	
MACHINE ZONE:	
LIFE STEP:	
OPERATING MODE:	

Create a new worksheet for each Life Step and/or Operating Mode (Click on the tab, Move or copy, Create a copy)

2B. SAFETY FUNCTIONS										3. RISK REDUCTION				
Ref.	Description	Risk classification									Measures /solutions for Risk reduction			
		Safety Integrity Level						Performance Level			Description	Verification		
		EN 62061-5						EN ISO 13849-1						
		Se	Fr	Pr	Av	C	SIL	S	F	A			PL	
A1-O-A1-01														
A1-O-A1-02														
A1-O-A1-03														

Excel spreadsheet to evaluate and document the **Safety Integrity Levels (SIL)** and **Performance Levels (PL)** required by the control systems of PPPs related to safety functions.





## Verification

**Strategy 1: Measuring PPPs airborne emissions and the performance of the control systems integrated in these machines,** in general, according to EN 1093-1.

On-line measurement using CPC-OPC + *Laser Induced Incandescence LII-EC (AT)* will be explored .

**Strategy 2: Measuring PPPs immissions.** If strategy 1 is technically unfeasible, indirect technique, by measuring the occupational exposure of the workers and comparing such measurements with suitable criteria.

Occupational exposure to all types of CNT can be quantified using NIOSH Method 5040 (Personal sampling + offsite analysis, including TEM). NIOSH REL of  $1 \mu\text{g}/\text{m}^3$  8-hr TWA (NANOCYL  $2,5 \mu\text{g}/\text{m}^3$ ).

## To summarize

- 1. PPPs design:** SbD following MD principles for safety integration and integrating all relevant nanosafety aspects to achieve final safe designs in conformity with relevant EHSRs (**Technical File**).
- 2. PPPs construction:** according to the SbD produced in step 1 and in a controlled dedicated room.
- 3. PPPs - SbD verification by:** 1) Visual inspection, 2) Measurement, 3) Functional testing, 4) Design validation or 5) Calculation.
- 4. PPPs putting into service and CE marking:** after fulfilling all the obligations relating to the conformity with the MD.

# Thank you very much for your attention!



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*Project PLATFORM have received funding from the European Union's Horizon 2020 research and innovation programme, under grant agreement No 646307. This presentation reflects only the author's views and the Commission is not responsible for any use that may be made of the information contained therein.*

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