

**NanoSafety  
Cluster**



Research Infrastructure  
**QualityNano**

NanoValid



**nanoSTAIR**

**Scaffold**

**iNTeg-Risk**



**NanoFASE**

# A STEP-BY-STEP GUIDANCE FOR AN EFFECTIVE INTEGRATION OF STANDARDIZATION IN NANOSAFETY R&D PROJECTS – FROM THE PROPOSAL TO THE DELIVERABLES AND BEYOND

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**NanoSafe, Grenoble, 08.11.2016**



# Introduction

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**Transfer from research**  
**Commitment of researchers**



Remain difficult  
Are possible  
Can be impulsed



- A) Motivation
- B) Barriers
- C) Embedding standardization in the R&D project:

**Step by step guidance**

# A) Motivations for researchers

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## Share your knowledge / research

- Improve the system: consistent research worldwide
- Make your work useful
- Moral / contractual obligation (public funding!)
- Get your work recognized

## Have a say in coming standards

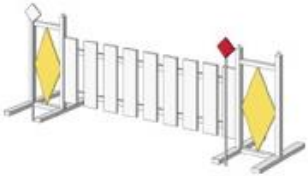
- Adequate in your view
- Compatible with your protocols
  - ➔ Continuity in your practices and data

## Improve your work

- Gain full discussion on your protocol(s)
- Networking effect



## B) Barriers to researchers

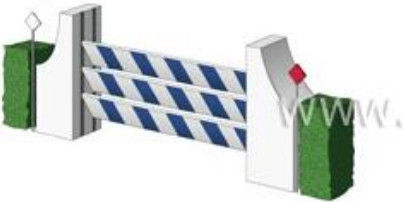


Lack of awareness  
Ignorance of each other's activities

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Process : - complicated  
- **not flexible and fast enough**  
- low own impact on standard



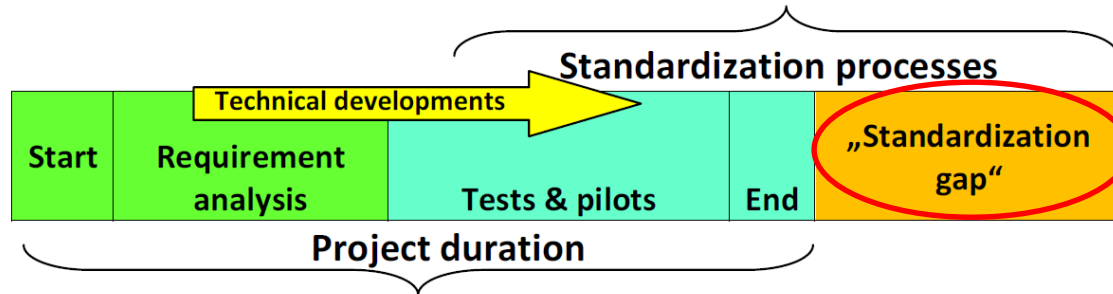
No resources (MM) in project / organisation  
**No funding after project!**  
No funding out of project!



**Low recognition** (no author list) # ISI

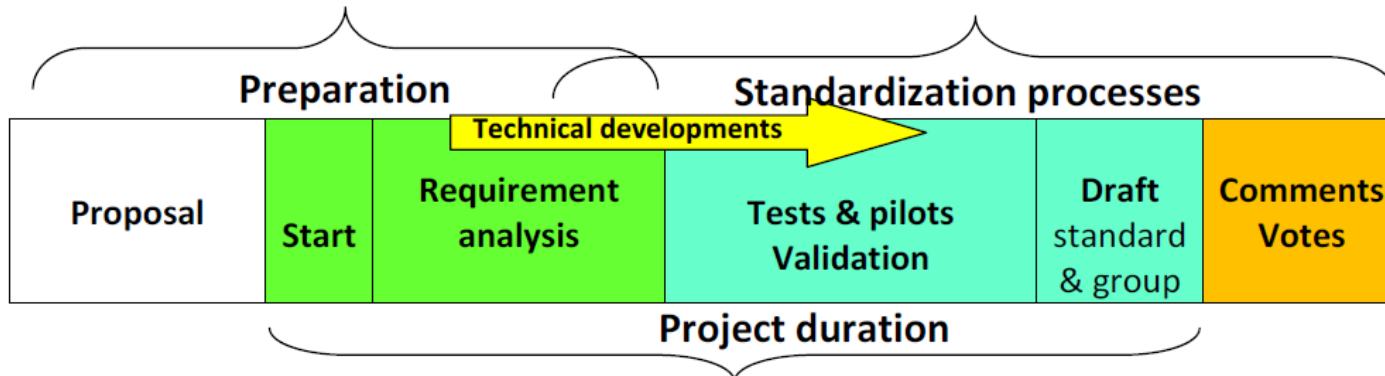
# C) Embedding standardization in the R&D project

## Now



Adapted from  
Jean-Marc  
Aublant , LNE,  
chairman TC352

## After



Ex: **CWA**  
**Integ-Risk:**  
At end + 1 year

# Proposal

## Step 1: Evaluate your potential

**f(Interest x Technical readiness x Organizational readiness)**

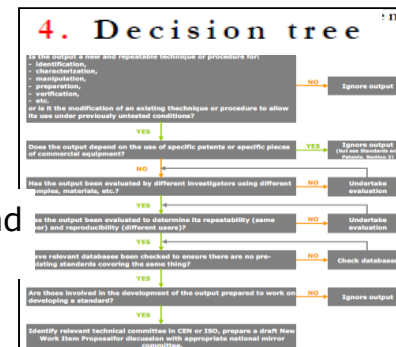
SOP directly <b>related to a standard</b> already existing or under preparation? <i>(Yes/No, name of the standard, type of relation***)</i>	Most relevant Committee / WG	Lead?	Interest for ... <i>(0 to 10, 10 = highest)</i>		Approx. date (actual or planned) of		Participation after project? <i>(yes/No)</i>
			research	industry	submission of proposal	start of drafting group	

Technical readiness, harmonization/validation work done					
Protocol shared with other labs? (how many?)	Interlab- training done? (how many labs?)	Round-Robin done? ** (how many?)	Interlaboratory comparison study** done?	Degree of validation/ harmonization done (%)	Degree of drafting already done (%)

Organizational readiness (for launching a drafting group)		
Number of experts ready to participate	From how many EU countries?*	How many from industry?*



Hatto, 2010. Standards and Standardization handbook



# Proposal

## Step 2: Set your objectives

**f(Interest x Technical readiness x Organizational readiness)**

→ 3 categories of methods, goals, works (here for CEN, ISO)

Methods	Pre-normative Work	Normative Work	Outcome
<b>New</b>	(Development) (Pre-validation) Evaluation for NWIP		<ul style="list-style-type: none"><li>• <b>Clear SOP</b> for vote of pre-work item</li><li>• Post-project standardization <b>plan</b></li></ul>
<b>Pre-existing</b>	Harmonization Validation (ILC, RR...) Clustering initiatives		<ul style="list-style-type: none"><li>• NWIP <b>“Working draft” submitted</b></li><li>• <b>Support ensured</b> for positive vote</li><li>• <b>Drafting group</b> ready</li></ul>
<b>Mature</b>	(Use & fine-tune)	Drafting and amending	<ul style="list-style-type: none"><li>• <b>Standard (almost) finished</b></li></ul>

NWIP: New Work Item Proposal = candidate for standardization

ILC: InterLaboratory Comparison

RR: Round Robin

# Proposal

## Step 3: Plan pre-standardization as full R&D activity

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1. Clear, controllable **deliverables** (see objectives)

2. Technical **experts/scientists** responsible

3. **Budgets**

- Man months
- Sub-contracting

# voluntary basis (see



4. **Scientific Publications**

5. **In the technical WPs**

# **WP dissemination**: organizational support: strategy, workshops, secretary, logistics, contacts to standardization bodies ... → **Standardization experts in the field**:

- Expert of ILC and RRs
- National Standardization Body, e.g. DIN's Support to researchers\*
- Dedicated structure, e.g. nanoSTAIR [www.nanostair.eu-vri.eu](http://www.nanostair.eu-vri.eu)

\*Support from a national standardization body (DIN). Christine Fuß, DIN. Workshop "Standardization in a Research Cluster". Brussels, 27.03.2017. [www.nanostair.eu-vri.eu](http://www.nanostair.eu-vri.eu)



## Step 4: Consolidate the action plan

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### Standardization Strategy Seminar (SSS)

- What is standardization, how it works?
- Standardization in the field of nanotechnologies
- **Check: Project's SOPs vs. Standards** (existing or under work)
- **Selection** and **orientation** of NWIPs
- **Action plan**: what is missing, what to do, who, when!  
→ **SSS at the beginning of the project**

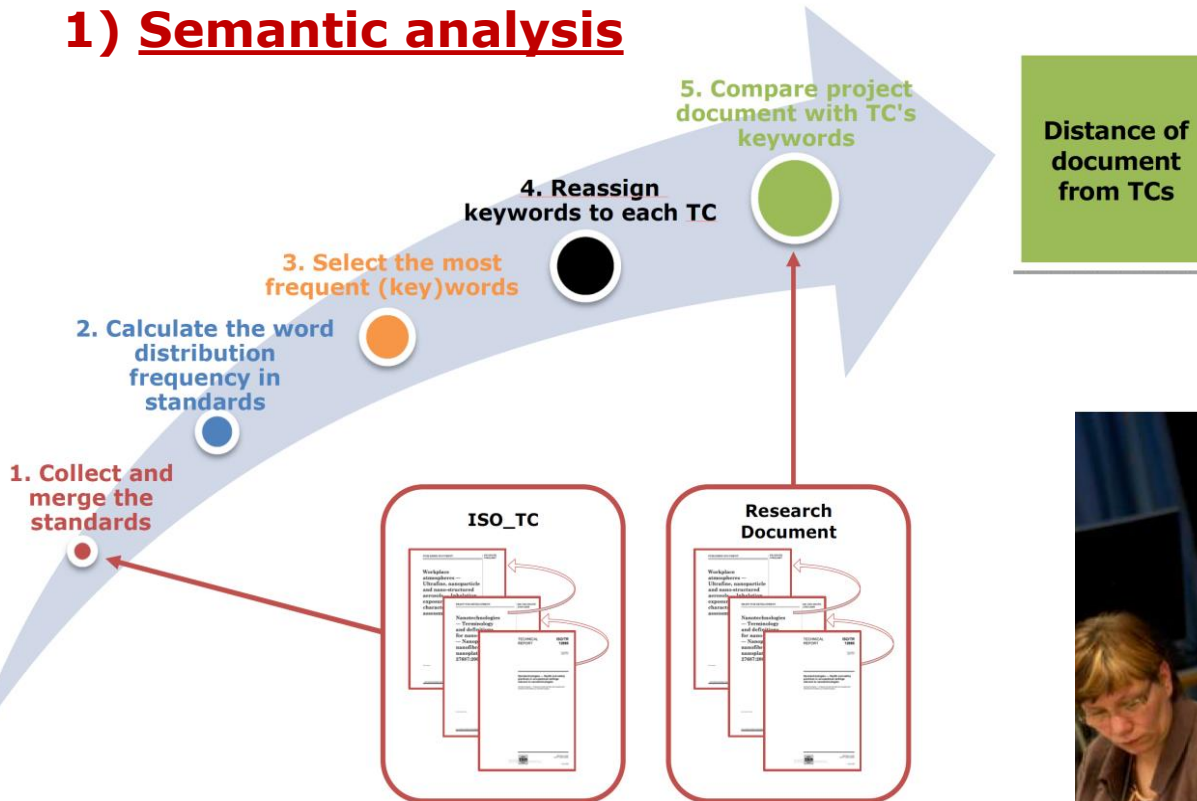
SOP = Standard Operation Procedure

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# Step 4 c<sup>ed</sup>: Consolidate ...: the **nanoSTAIR** check

## 1) Semantic analysis



## 2) Expert review



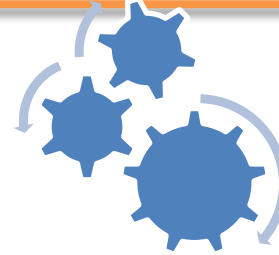
## 3) Gathering experts



## Project

# Step 5a: **Technical Pre-normative Work**

- **Harmonization** of protocols
- **Inter-Lab training**
- **Inter Laboratory Comparison (ILC) or Round Robin (RR)**  
Also with **external labs** → **subcontracting**



→ **Working draft** - also with **external experts**

+ **Publish** : scientific publication, white paper

# Project

## Step 5b: Organizational Pre-normative Work

Ex: Hydrochemical reactivity at CEN 352 (~ ISO)

July 2013 First **working draft** (DIN + proposer)  
Form N „**New Work Item Proposal**“ →

Oct. 2013 Presentation to CEN/TC 352 Strategy Group

Form N		
Proposal for a preliminary new work item		
Title: Nanotechnologies — Determination of hydrochemical reactivity of nano-objects for toxicity studies		
Proposer: DIN (for nanoSTAIR)		
Information to be supplied by the proposer of the PWI		
A1 Subject		
A1.1 Scope: Specification of a test method to determine the hydrochemical reactivity of nano-objects		
A1.2 Keywords (Descriptors) characterising the scope (Multiple listed are possible and/or necessary)		
Product <input type="checkbox"/>	Requirements <input type="checkbox"/>	EN <input type="checkbox"/>
System <input type="checkbox"/>	Characteristic <input type="checkbox"/>	CEN/TS <input checked="" type="checkbox"/>
Service <input type="checkbox"/>	Guidance <input type="checkbox"/>	CEN/TR <input type="checkbox"/>
Interface <input type="checkbox"/>	Test method <input checked="" type="checkbox"/>	Other (e.g. CEN Guide) <input type="checkbox"/>
	Terminology etc. <input type="checkbox"/>	
A2 Market relevance		

End 2013 - Ballot on the topic (NSBs)  
Aug. 2014 → **Yes** → Pre-Work Item

Call for expert: **nanoSTAIR**

- 9 experts volunteered
- 6 countries > 5 requested

Oct. 2014 -  
Begin 2015 Ballot (NSBs) for creation of a **Project Group**

2018 (?) **TS or EN**

OECD: Convincing through MS, ECHA...

## Step 6: Conclude & Organize the follow up

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### Update **Standardization Strategy Seminar (SSS)**

#### → Strategy and action plan for after the project

Incl.:

- **Commitment** of persons /intitutes:
  - As participants
  - As leaders
- **Funding** if still necessary:
  - COST action? (travel & logistics)
  - CEN Mandate?
  - Empire? (metrology)
  - Pre-standardization in EU calls !
  - EU calls on pre-standardization ?

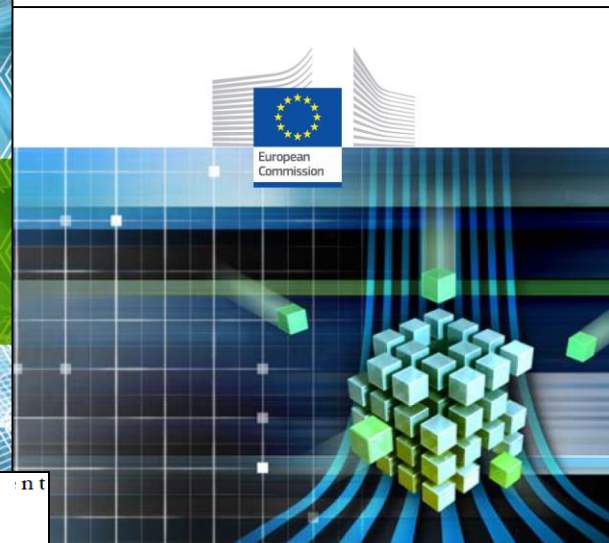
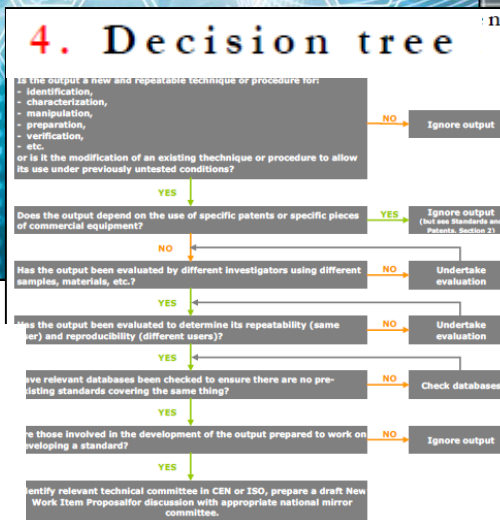
# PS: Support documents



LINKING RESEARCH AND STANDARDIZATION



*Integrating standards in your research project:  
a pocket guide for project proposers*



Standards and Standardisation

A practical **guide** for researchers

Research and Innovation

**What is standardization?**

**The way towards standardization**

Luc van den Berghe, CEN. Workshop

“Standardization in a Research Cluster”.

Brussels, 27.03.2017. [www.nanostair.eu-vri.eu](http://www.nanostair.eu-vri.eu)

# Acknowledgement

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