anses
French agency for food, environmental and occupational health & safety

Investigate, evaluate, protect

Implementation of ISO 17025 feedback from different QA systems in ANSES

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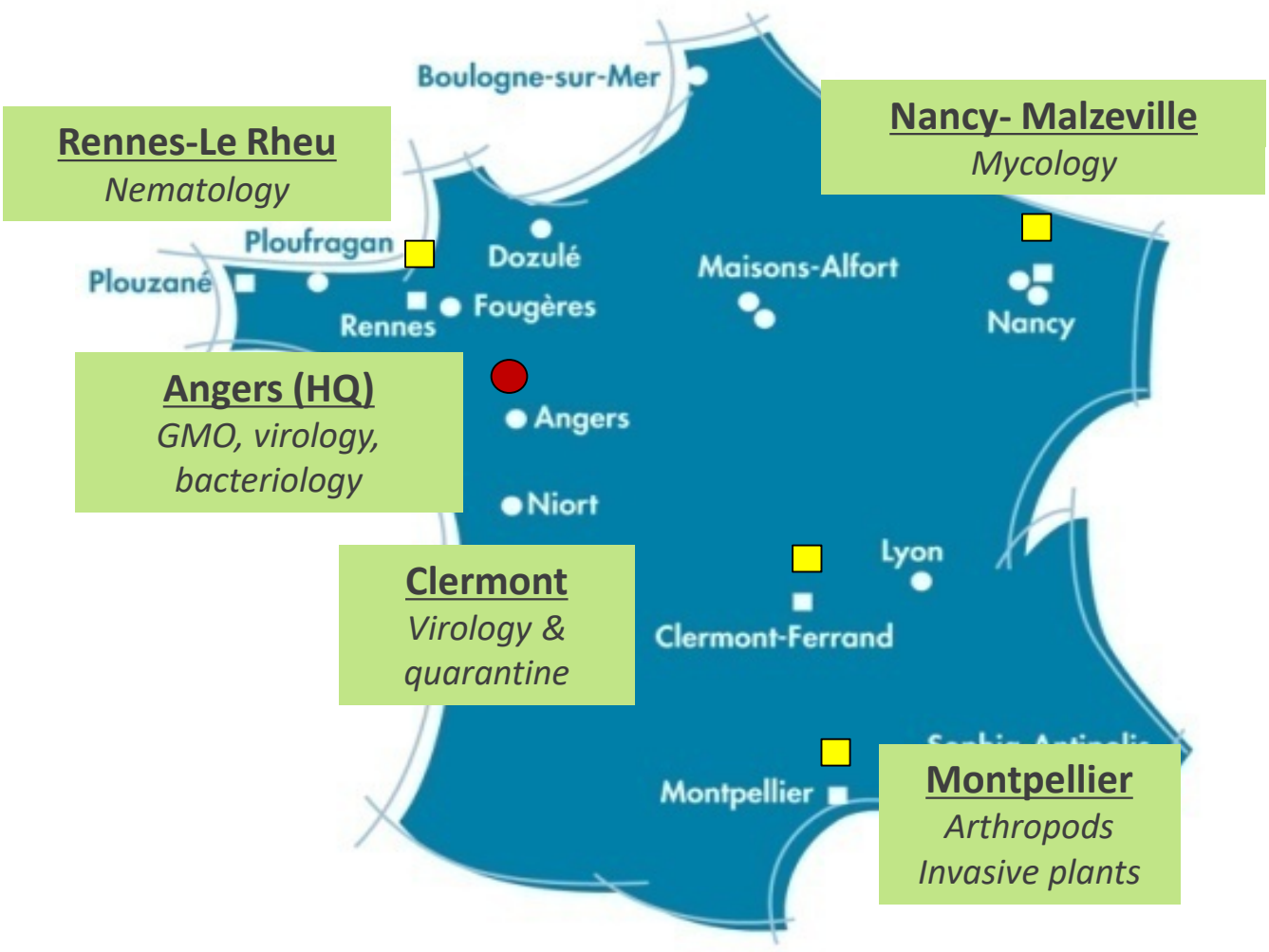
Workshop Heads of Laboratories, 2019-09-09/11

Plant Health: 1 laboratory with 6 sites

6 different and independent QA system



Rennes-Le Rheu
Nematology

Nancy- Malzeville
Mycology

Angers (HQ)
GMO, virology, bacteriology

Clermont
Virology & quarantine

Montpellier
Arthropods
Invasive plants

La Réunion
Tropical pathogens

Plan

1 - The new ISO 17025 – main changes

2 – Options for the management of changes

- 2.1 – Management of the transition
- 2.2 – Process approach
- 2.3 – Risk & opportunity management
- 2.4 – Control of data and information systems
- 2.5 – Complaints

Conclusions

1 – The new ISO 17025 : Main changes

1-Main changes identified by the laboratory

- **Scope of the standard: laboratory activities including sampling**
- **The risk-based thinking which enables some reduction in prescriptive requirements and their replacement by performance-based requirements;**
- **A greater flexibility than in the previous version in the requirements for processes, procedures, documented information and organizational responsibilities;**
- **Emphasis on "Impartiality" vs. "Independence"**
- **Process orientation but not restricted to it (*no obligation to develop processes*)**
- **Information Technology: Risks, data integrity, confidentiality, validation of softwares, considering electronic documents**
- **New requirements for complaints, reports and management review**

2 – Options for the management of changes

2.1-Management of the transition

Comparison of requirements between new & old version of ISO 17025: identification of major impacts in our system and major issues

- ✓ Exploratory internal audits
- ✓ Systematic analysis of the new requirements and the provisions in place

In the case of ANSES, benefit of the approach / developments in the 11 laboratories of the organisation.

2.1-Management of the transition

Comparison of requirements between new & old version of ISO 17025: identification of major impacts in the QA system and major issues

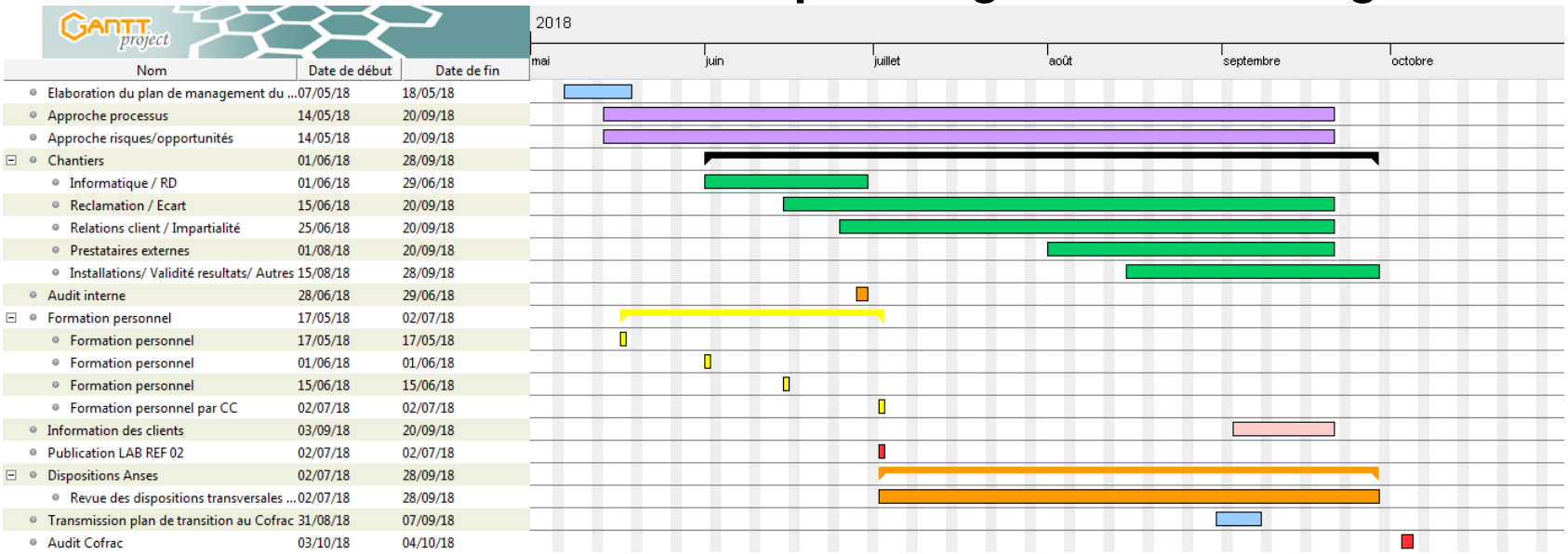
- ✓Staff training
- ✓Process approach (not obligatory)
- ✓Risk and opportunity management
- ✓Information systems
- ✓External providers and their control/evaluation (e.g IT services)
- ✓Impartiality and confidentiality (risk approach)
- ✓Management of nonconforming work
- ✓Complaints
- ✓Customer relation (General conditions of analyses / test reports)

2.1-Management of the transition

Development of a transition's action plan

Requirement status	§ V2017	ISO 17025 V2017 requirements	§ V2005	ISO 17025 V2005 requirements	Lab impacts	Lab actions	Delay	Priority	Effective implementation
	4.00	General requirements		-					
evolution	4.01	Impartiality		-	Incomplete provisions	Provisions should be consolidated with the risk-based thinking	09/20/2018	1	OK FP/001 on 08/31/2018 OK MM/001 on 09/20/2018
new	**7.09.6**	The outcomes (of complaints) to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question		-	Incomplete provisions	Create a specific procedure of the complaints management	09/07/2018	**1**	OK creation of PS/060 and FSE/102 on 04/09/2018

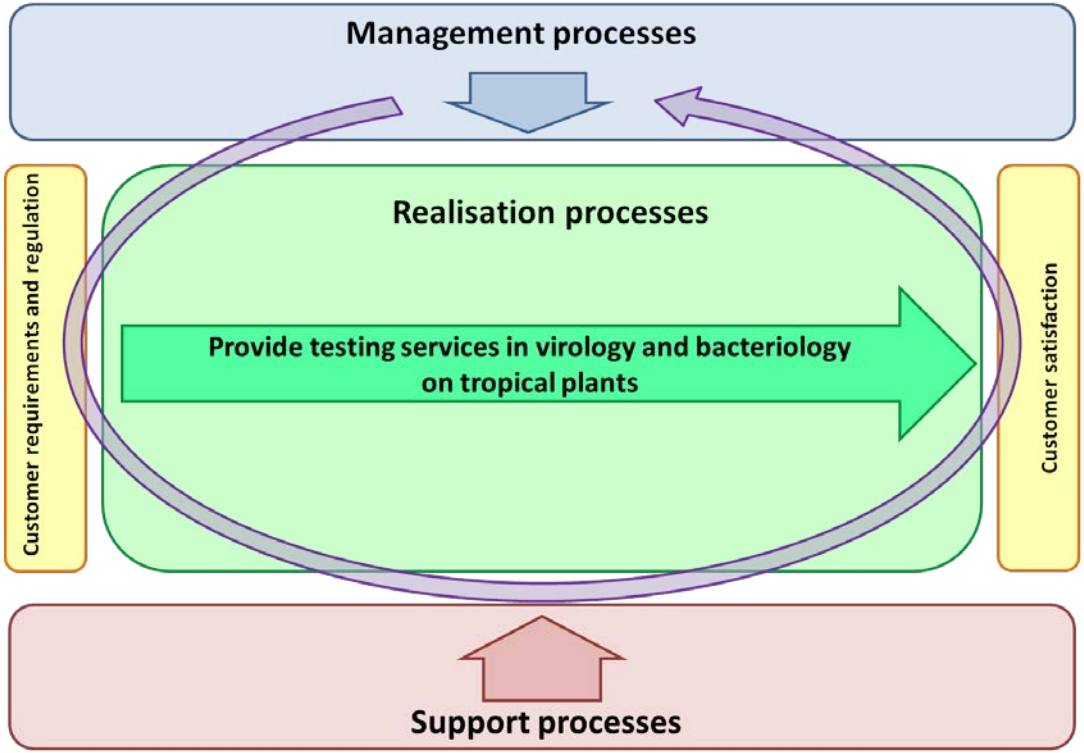
Use of a GANTT chart for the transition planning and scheduling



Internal audit at mid-transition performed by a competent staff

2.2-Process approach

- Not a formal requirement, different options possible
- Process approach used to implement the risk and opportunity management
- Development of a process map

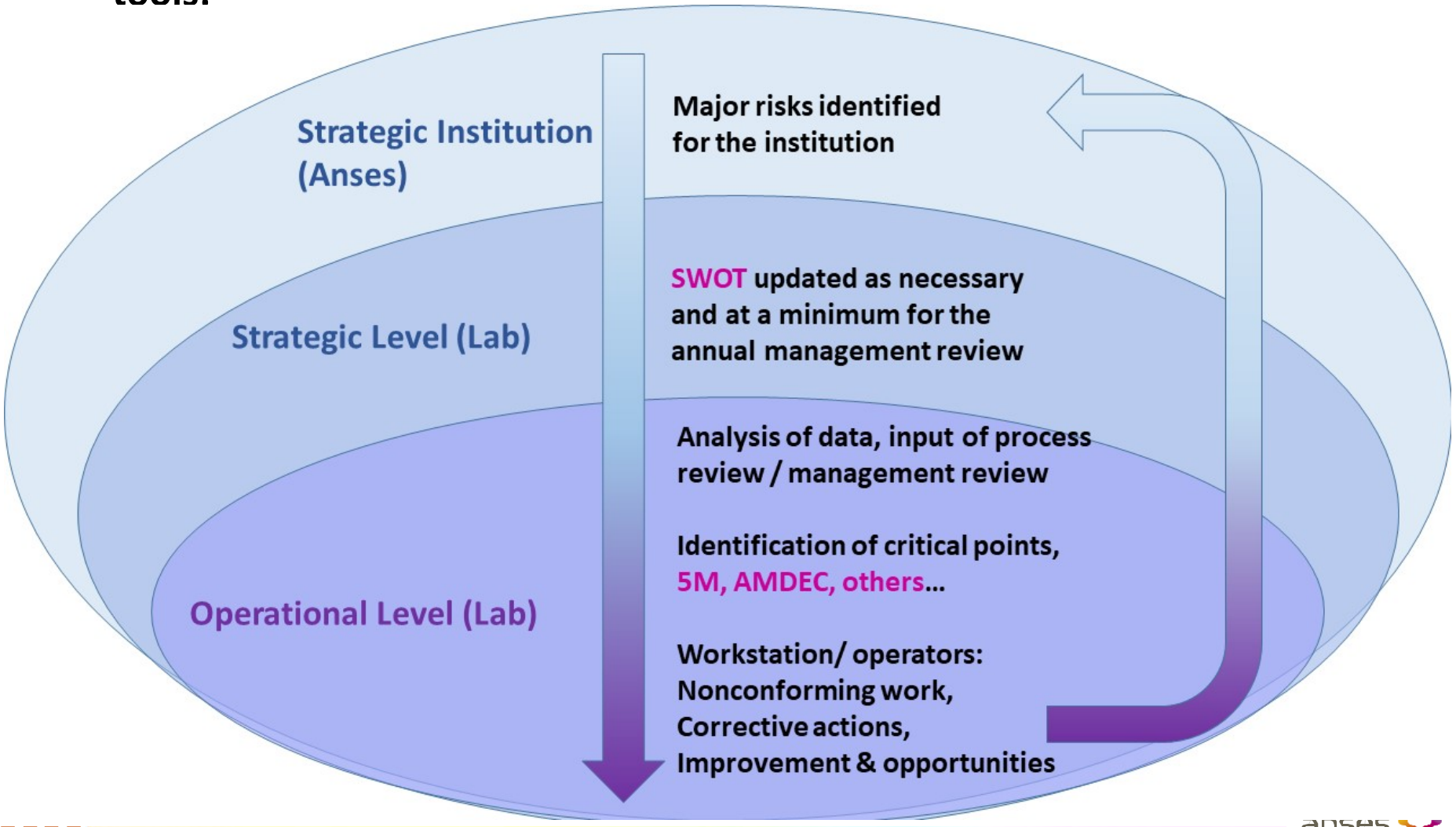


2.2-Process approach

- Not a formal requirement, different options possible
- Process approach used to implement the risk and opportunity management
- Development of a process map
- Development of a dedicated documentation :
  - quality plan “process approach & risk and opportunity management”
  - and process description forms for each process

2.3-Risk & Opportunity management

- **Risk & opportunities are appreciated at different levels, with dedicated tools:**



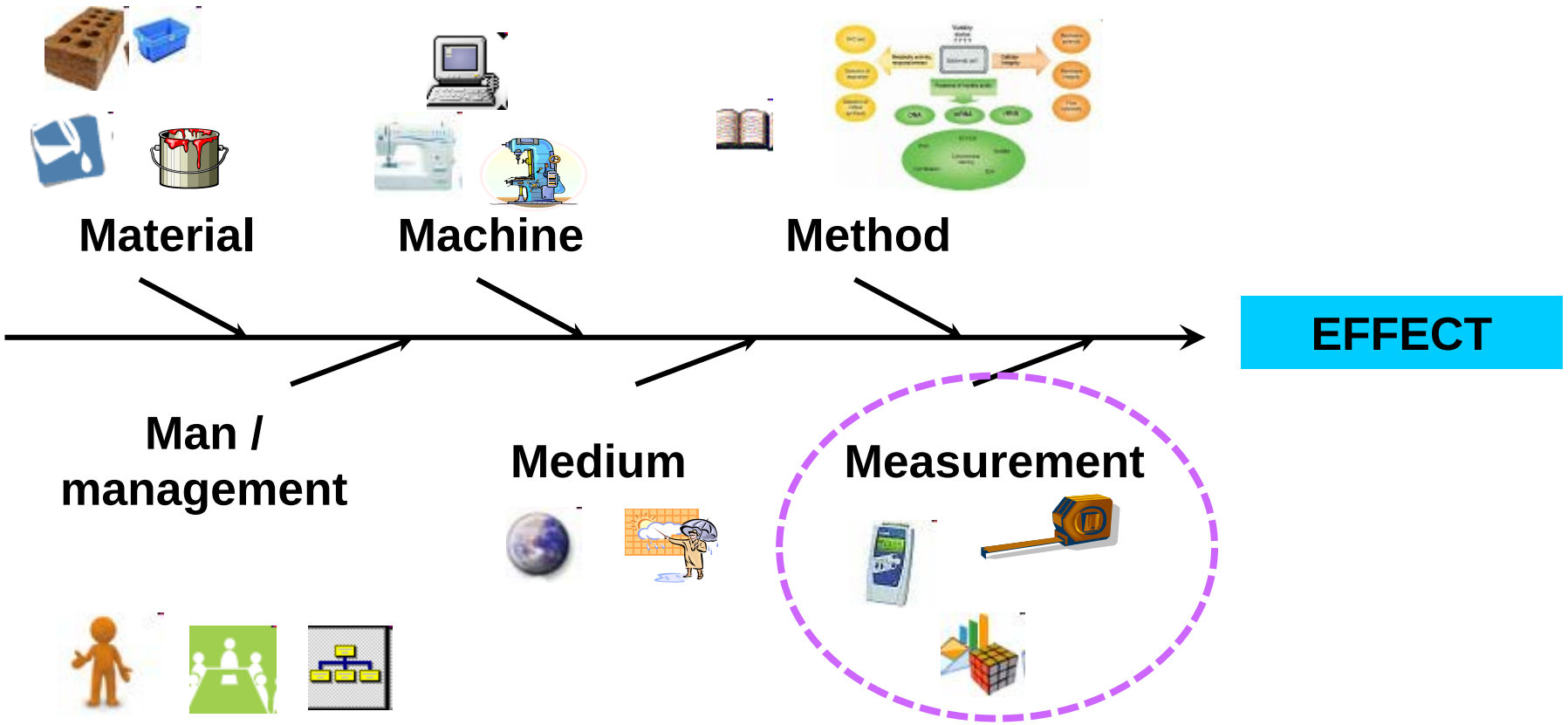
2.3-Risk & Opportunity management

Tools used : SWOT analysis

=> Allows to identify topics for actions which can be implemented to control risks/threats and to promote strengths and opportunities

2.3-Risk & Opportunity management

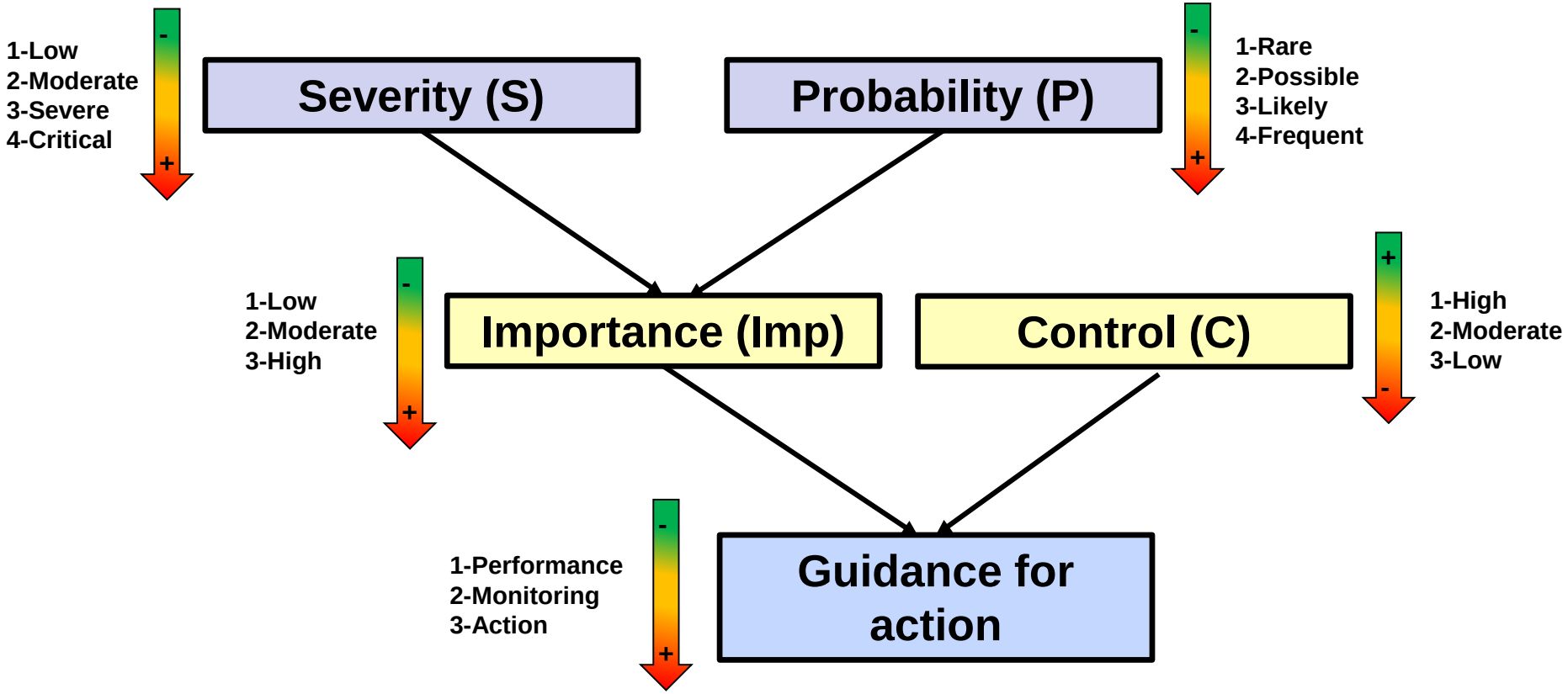
Tools used: systematic analysis / 5M (to 8M) or Ishikawa diagram



=> Allows to identify critical points in each analytical protocol, and to decide actions to secure the operations and results

2.3-Risk & Opportunity management

Tools used : simplified FMEA (Failure Mode and Effect Analysis)



=> Allows to prioritise the risks
to implement a rational strategy of actions

2.3-Risk & Opportunity management

Tools used : simplified FMEA (Failure Mode and Effect Analysis)

Example adapted from Nematology unit – biomolecular analysis

Step of the analysis	Identified risk	Contribution to uncertainty of analysis	Probability	Severity	Control
			A	G	M
Extraction d'ADN	Risk of contamination	when adding beads	Rare	Severe	High
		during crushing step with individual pestle	Rare	Severe	High
		during the distribution of reagents /buffers	Rare	Severe	High
		when opening tubes at the different steps	Rare	Severe	High
		while transfering solutions / extraction from tubes to plates	Rare	Severe	High

2.3-Risk & Opportunity management

Tools used : simplified FMEA (Failure Mode and Effect Analysis)

Example adapted from Nematology unit – biomolecular analysis

Contribution to uncertainty of analysis	Control	Description of controls in place	Guidance of action	
	M		AxGxM	
when adding beads	High	beads added tube by tube without touching the tubes	4	Monitoring
during crushing step with individual pestle	High	Use of individual and non reusable pestle	4	Monitoring
during the distribution of reagents /buffers	High	Distribution of reagent with no contact with tubes' walls; change of pipette tips between tubes	4	Monitoring
when opening tubes at the different steps	High	centriguation prior to opening tubes careful opening of tubes appropriate rack to avoid contact between tubes change of gloves if necessary	4	Monitoring
while transfering solutions / extraction from tubes to plates	High	centriguation prior to opening tubes careful opening of tubes appropriate rack to avoid contact between tubes change of gloves if necessary	4	Monitoring

2.4-Control of data and information systems

- ✓ **Description of the information systems: Computer mapping / List of softwares & firmwares used / monitoring of the versions (software / firmware)**
- ✓ **Control of information systems: validation of computer tools / traceability of verification in case of software upgrades**
- ✓ **Data securing: Confidentiality / protection against intrusion / computer backup / test of data recovery**

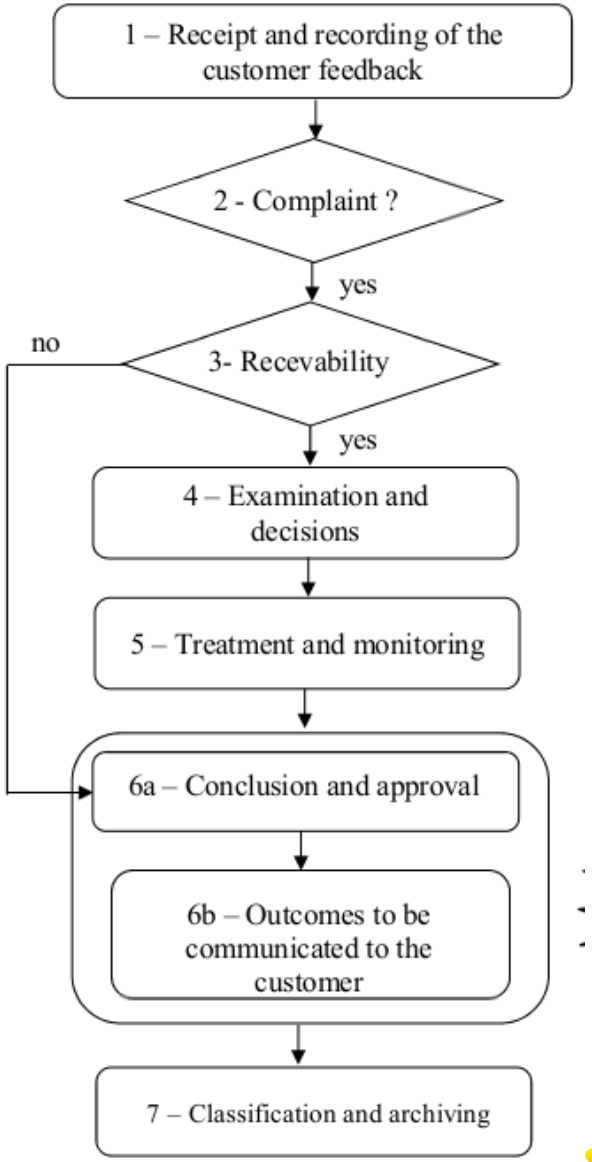
2.5-Complaints

✓ **The new ISO 17025 requires :**

-a description of the complaints handling process to be available to any interested party upon request

-the outcomes to be communicated to the complainant to be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question

=> Creation of a specific procedure + a recording for the management of complaints

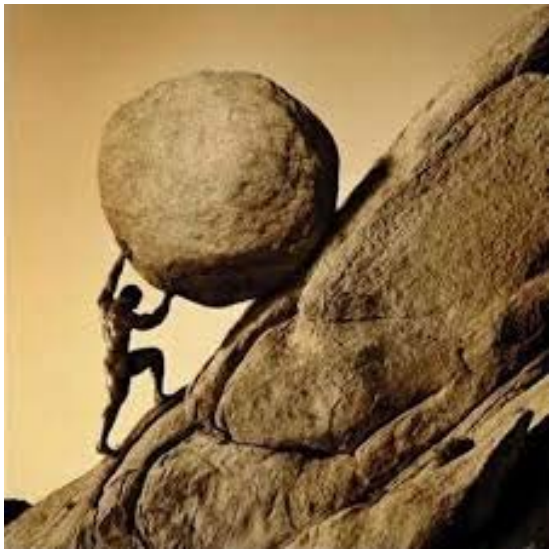


Conclusions

- **Examples of implementation of ISO 17025: 2017 in several QA systems**

- **No non compliance identified for 3 QA systems evaluated so far**

Thank you for your attention



From Sisyphe…

…to Deming