



Implementation of the new version of ISO 17025 and outcomes of the evaluation by the accreditation body

**The example of ANSES Plant Health Laboratory,
unit in La Reunion Island (LSV-RAPT)**

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1 – The new ISO 17025 : Main changes

1-Main changes

- **Scope of the standard: laboratory activities**
 - **Testing, calibration, **sampling** associated with subsequent testing**
- **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 edition in the requirements for processes, procedures, documented information and organizational responsibilities;**
- **Emphasis on “**Impartiality**” vs. “Independence”**
- **Process orientation**
- **Information Technology: Risks, data integrity, confidentiality, validation of software, considering electronic documents**

2 – Focus on main new features & processing by LSV-RAPT

2.1-Transition management

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

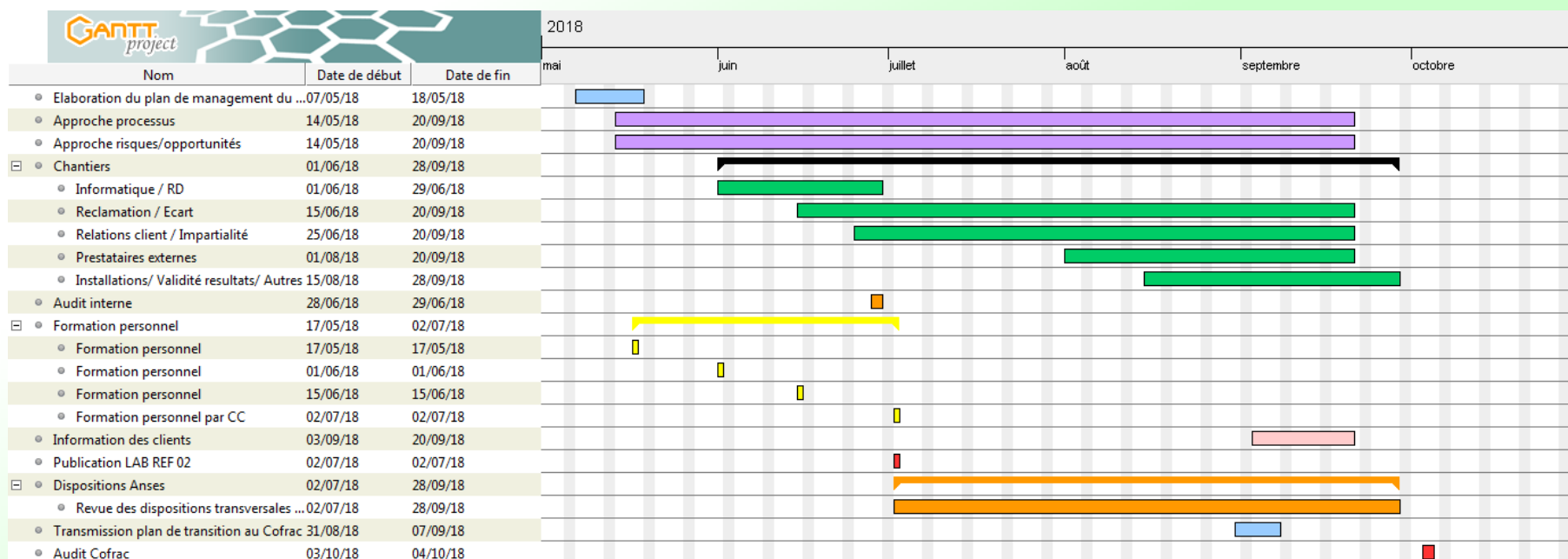
- ✓ Staff training
- ✓ Process approach
- ✓ Risk and opportunity management
- ✓ Information systems
- ✓ External providers
- ✓ Impartiality and confidentiality (risk approach)
- ✓ Management of nonconforming work
- ✓ Complaints
- ✓ Customer relation (General conditions of analyses / test reports)

Elaboration of a transition plan also used for the transition tracking

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

2.1-Transition management

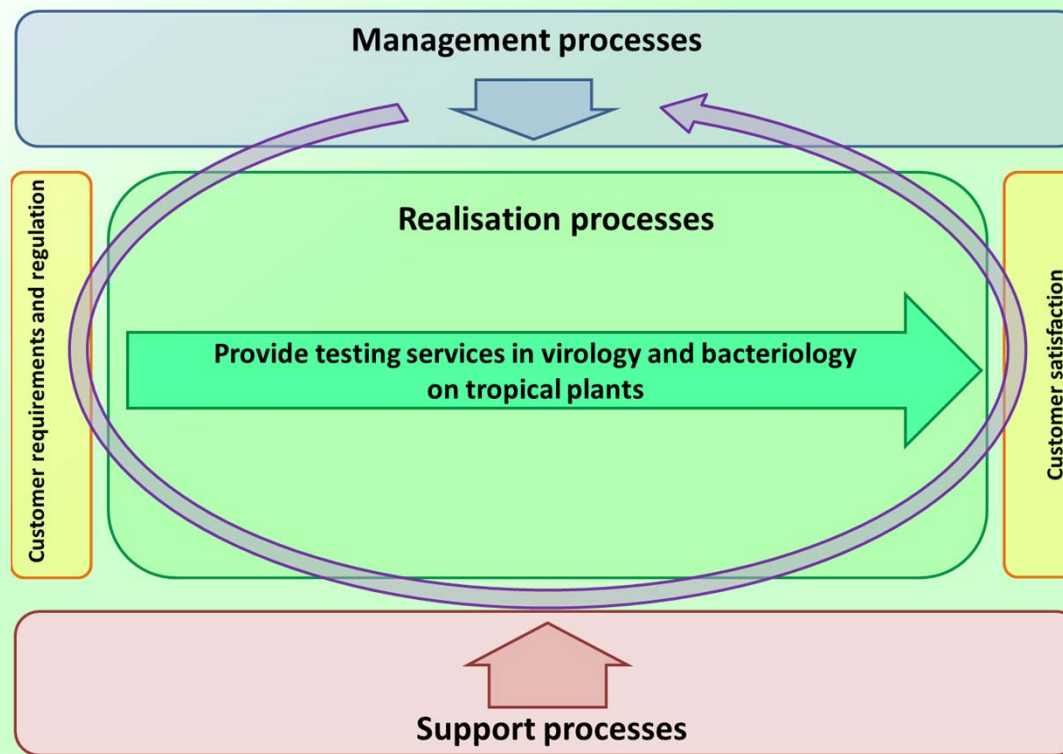
Use of a **GANTT chart** for the transition planning et scheduling :
May – October 2018



Internal audit at mid-transition performed by a competent staff

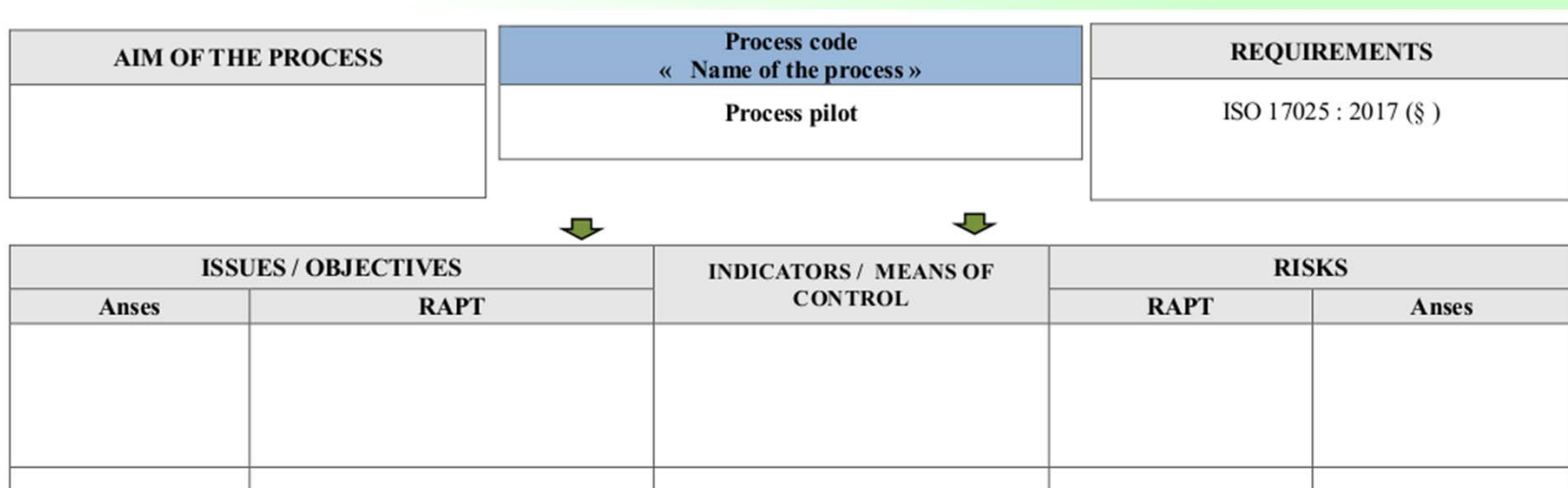
2.2-Process approach

- Process approach used to implement the risk and opportunity management
- Development of a process map



2.2-Process approach

- Creation of a **quality plan** “process approach & risk and opportunity management” and **process descriptive sheets** for each process
(used for risk management for impartiality and confidentiality)

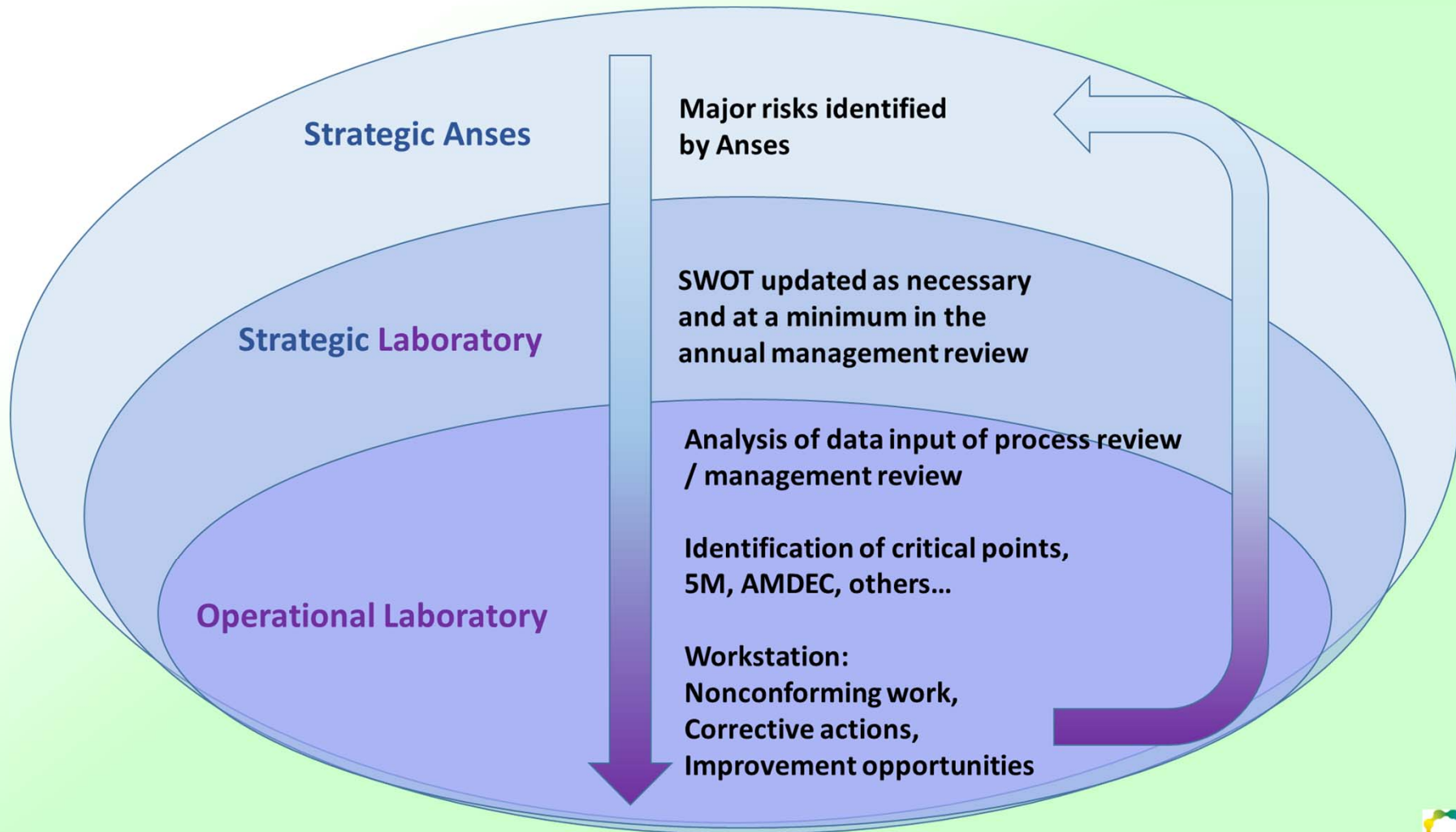


ANNEX 1 : Impartiality : Identification, analysis, evaluation and control of risks In the framework of ISO 17025 activities

Sources of risks	Identification of risks and possible damages	Analysis and evaluation		Risk treatment		Guidance/ Action to be taken (and review periodicity) ¹
		Grav. x Prob. = Criticality	Criticality level	Means of controls	Control levels	
Conflict of interest	Customer pression Share of activities : possible collusion Partnership with private company	G=5 P=1 C=5	2	Anses deontology code Public status of Anses Public declaration of interests (PDI) Etc.	1	1 Review in case of change of status of Anses PDI updated in real time

2.3-Risk & Opportunity management

- Risk & opportunities are appreciated at different levels:



2.3-Risk & Opportunity management

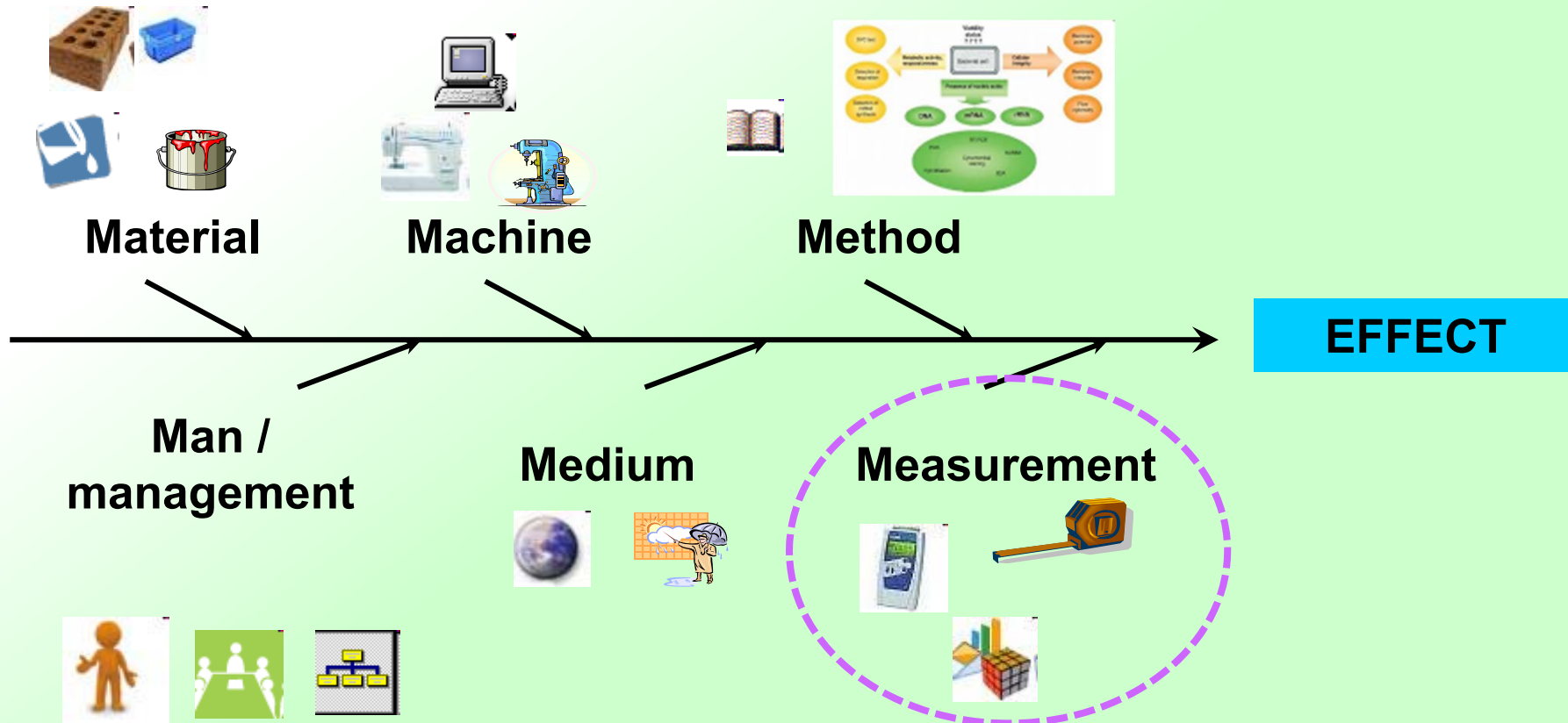
Tools used : SWOT analysis



=> Allows to identify actions which can be implemented at a strategic level to control risks/threats and to valorize strengths and opportunities

2.3-Risk & Opportunity management

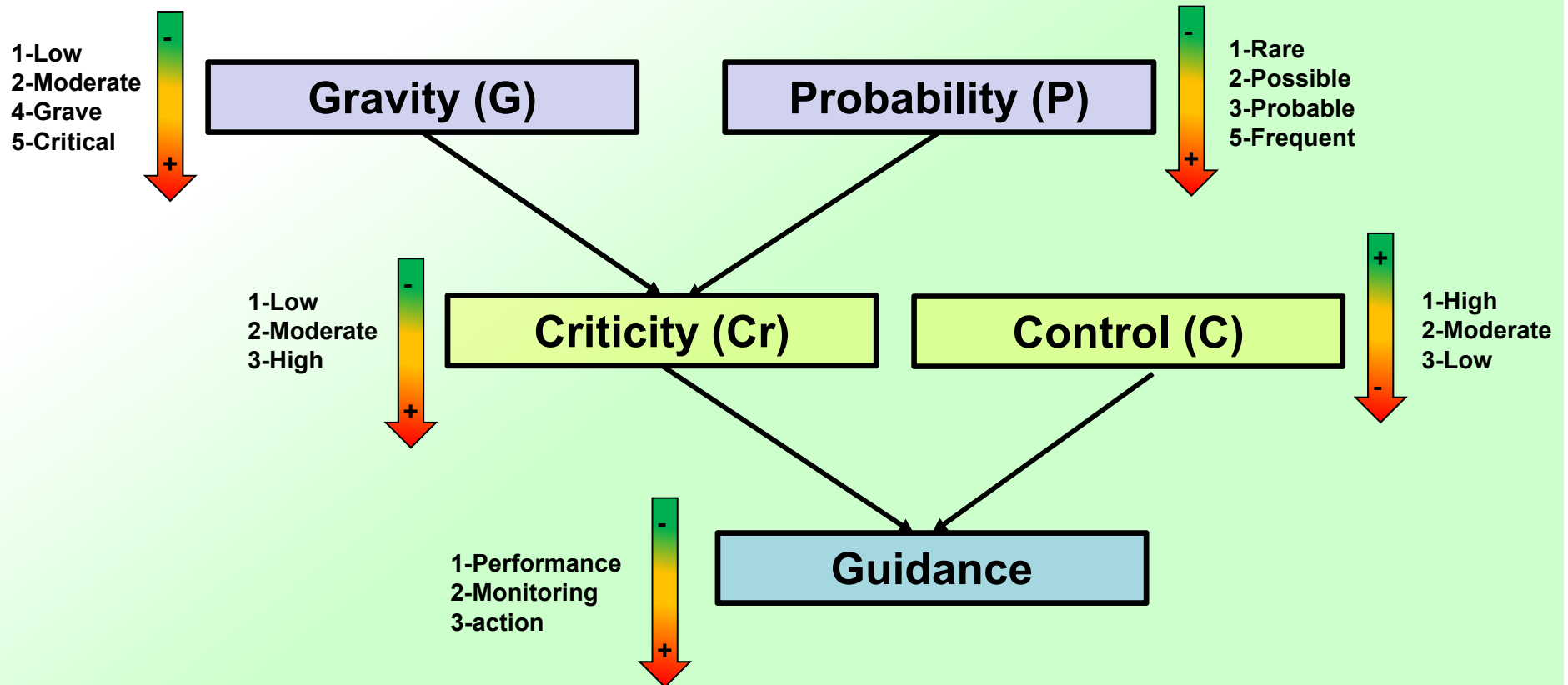
Tools used : 5M (to 8M) or Ishikawa diagram



=> Allows to identify critical points in analytical protocols, and to decide actions to securise the protocols

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 action**

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 release upgrade**
- ✓ **Data securisation : Confidentiality / protection against intrusion / computer backup / test of data recovery**

2.5-Externally provided products and services

- Combines 4.5 Subcontracting and 4.6 Purchasing services and supplies from 2005 version
- In all cases, it is necessary to have requirements and controls
- Computer direction of Anses included as “external provider”



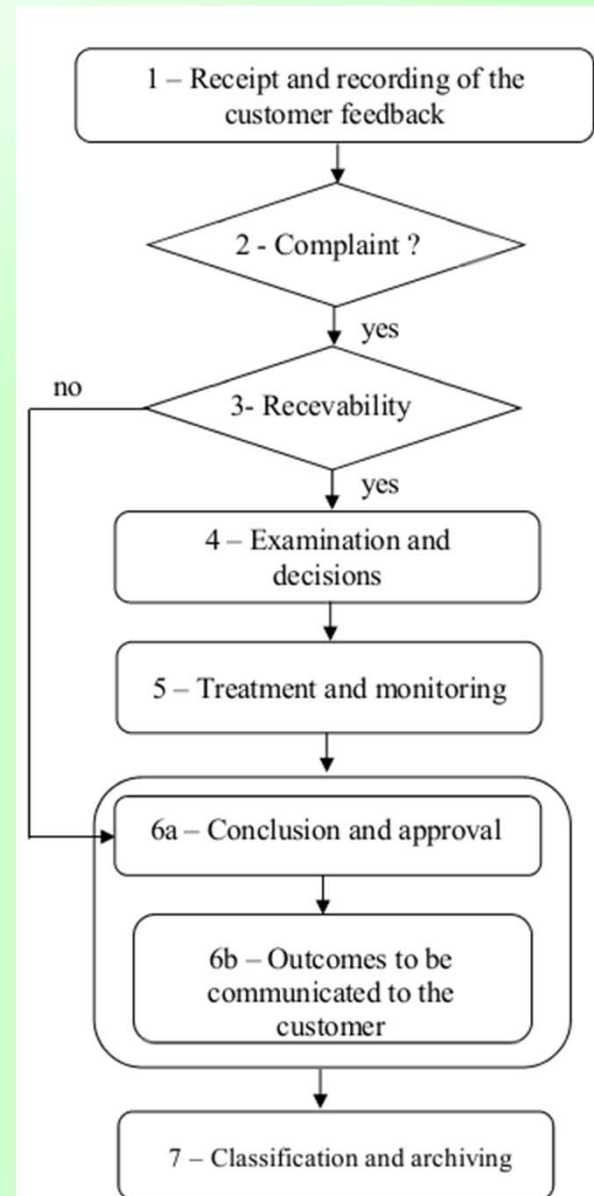
2.6-Complaints

✓ 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**



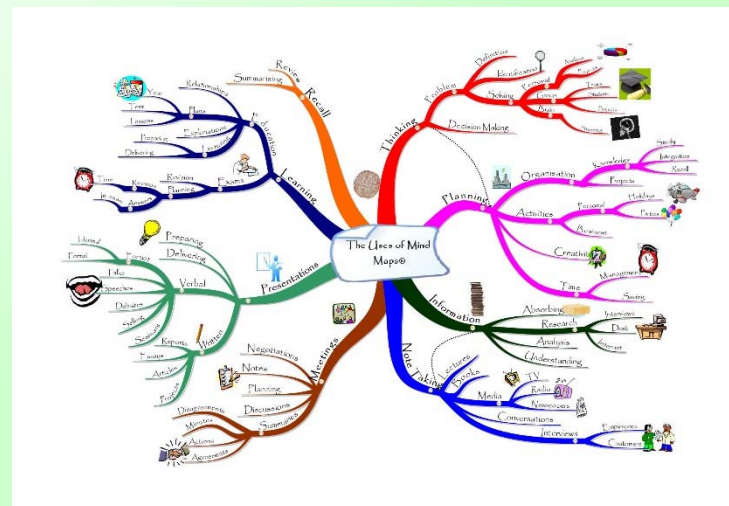
3 – Outcomes of the evaluation by the accreditation body

3.1-Conduct of the evaluation

Beginning of the evaluation by the two thematics « impartiality » and « confidentiality » ~ 2h

On the mode of « mind map »

⇒ personnel, infrastructure, external providers, information systems, shared activities, general conditions of analyses...



Other provisions were considered on a more conventional mode: linear and sequential

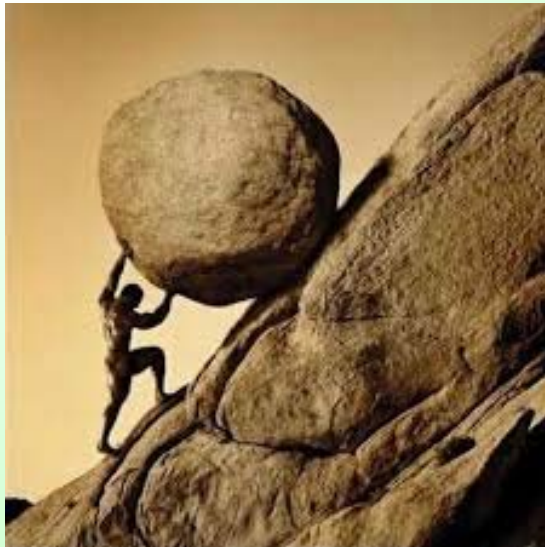
⇒ **A key issue : Actions to address risks and opportunities: Process approach, process review, quality reunions, Management reviews**

At the technical level : no real impact – however we had already included the risk approach in our analytical protocol

3.2-Results of the evaluation

- **No nonconformities** were identified
- **3 points to watch** (for next evaluation), mainly due to the youthfulness of the new provisions

Thank you for your attention



From Sisyphus...



...to Deming