

# Risk management: 10 years of experience in the organization of the proficiency testing AQUA (Istituto Zooprofilattico Sperimentale delle Venezie – IZSve)

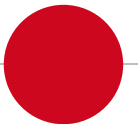
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*Istituto Zooprofilattico Sperimentale delle Venezie*

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**10<sup>th</sup> Eurachem PT Workshop**

Windsor, 25 -28 September 2023



## ● Istituto Zooprofilattico Sperimentale delle Venezie as PT provider

- Istituto Zooprofilattico Sperimentale delle Venezie (IZS<sup>Ve</sup>) is a **public veterinary institute** and it is part of II.ZZ.SS. network in Italy. Its current headquarters are located in Legnaro (Padua).
- The mission of the IZS<sup>Ve</sup> is to promote **public health** in the fields of **animal welfare** and **food safety**, also providing **scientific and technical support** to the central and regional authorities.
- IZS<sup>Ve</sup> is also the **provider of AQUA PT schemes**.



More than 600 employees



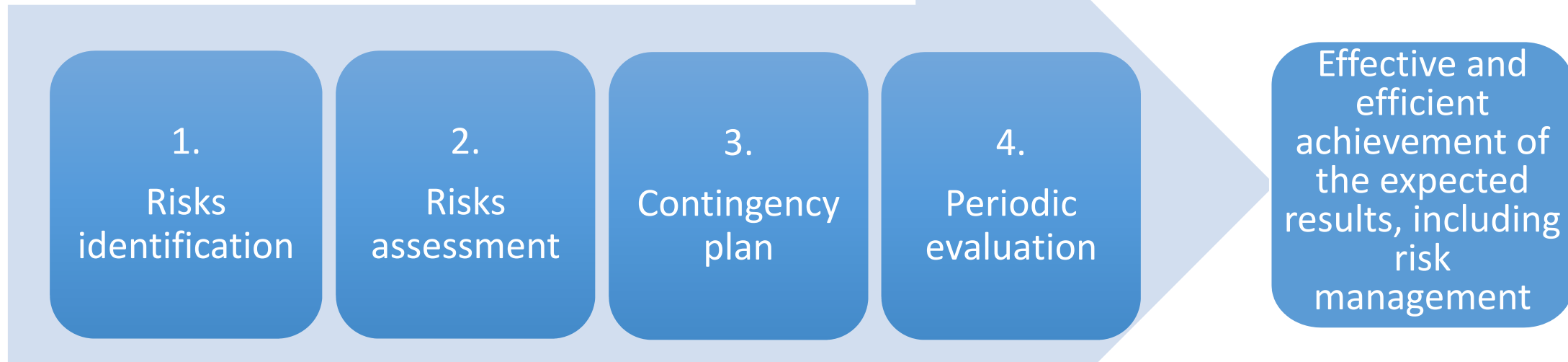


## **proficiency testing platform**

- **Food microbiology (MA)\***: microorganisms enumerations (quantitative methods) and microorganisms detection (qualitative methods)
- **Microbiology diagnostics (MD)**: microorganisms detection (qualitative methods) and identification
- **Serology for bovine and swine diagnostics (SI)**: qualitative methods
- **Molecular biology for bovine and swine diagnostics (BM)**: qualitative methods
- **Salmonella isolation, identification and typing (SA)\***: microorganisms detection (qualitative methods), identification and typing
- **Virology, serology and molecular biology for avian influenza and Newcastle disease diagnostics (IN)\***: qualitative methods (detection and characterization)
- **Bacteriology of aquatic organisms (IB)**: microorganisms detection (qualitative methods) and identification
- **Virology of aquatic organisms (IV)\***: quantitative and qualitative (titration and identification)
- **Parasitology of molluscs (PM)**: qualitative methods
- **Diagnosis of rabies (RV-D)\***: qualitative methods

## ● Implementation of IZSve's risk management (RM)

The project lasted 3 years and was developed in four stages:



**Risk:** the effect of uncertainty on objectives (ISO 31000:2018)

**Risk management:** coordinated activities to direct and control and organization with regard to risk <sup>4</sup>

## ● Step n. 1: Identify all possible risks

**Analysis of the organizational structure** based on the **process approach**, in order to **identify, map and manage the processes**, and their risks.

Steps:

- a) Go over the **business process** to obtain a **clear understanding of overall internal context** and of company organization, along with its procedures and the risk arising as a result of the activities that are carried out. We identified **33 main processes**.

1. Customer services (e.g. Management of requests, paid services, customer satisfaction)
2. External communication (e.g. Website, service charter, public relations service)
3. Analytical process
4. Human resources (HR) (selection, training, qualification)
5. Equipment
6. Reagents, samples and reference materials
7. Research projects, validation of test methods
8. Logistics
9. Warehouse
10. Purchasing and supplier management
11. Informatic system (IT)
12. Financial
13. Waste management
14. Biobank
15. Strategy and planning
16. Selection, verification and validation of methods

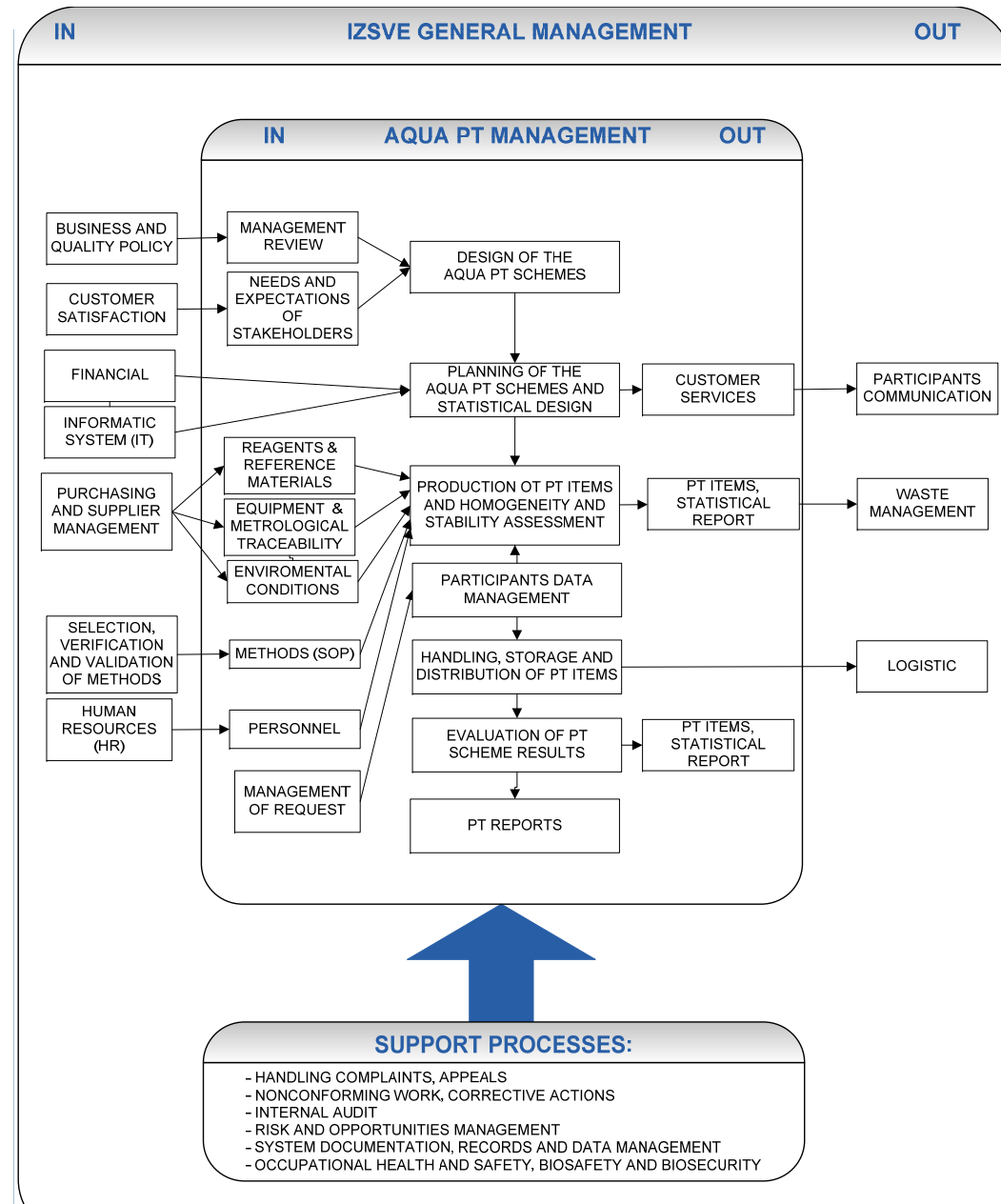
17. Occupational Health and Safety
18. Biosafety and biosecurity
19. Documents and data
20. Technical record management
21. Internal audit
22. Complaints, appeal, non-conformity, corrective actions and preventive actions
23. Management review
24. Training activities
26. Production process (e.g. Reagents, vaccines)
27. Medium production
28. Canine and feline blood bank
29. Genetic material deposit
30. Animal care
32. BSL3
32. Assessment of risks and opportunities
- 33. PLANNING, DEVELOPMENT AND EXECUTION OF AQUA PT SCHEMES**

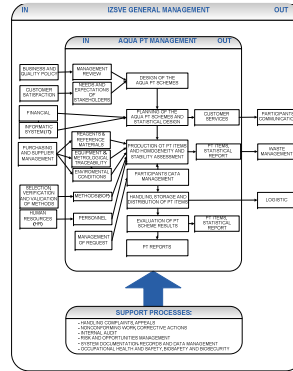
## ● Step n. 1: Identify all possible risks

Analysis of the organizational structure based on the **process approach**, in order to **identify, map and manage the processes**, and their risks.

Steps:

- a) Go over the **business process** to obtain a **clear understanding of overall internal context** and of company organization, along with its procedures and the risk arising as a result of the activities that are carried out. We identified **33 main processes**.
- b) Identify how each **process interacts** with the others, in order to be sure that there are **not gaps nor overlapping responsibilities**.



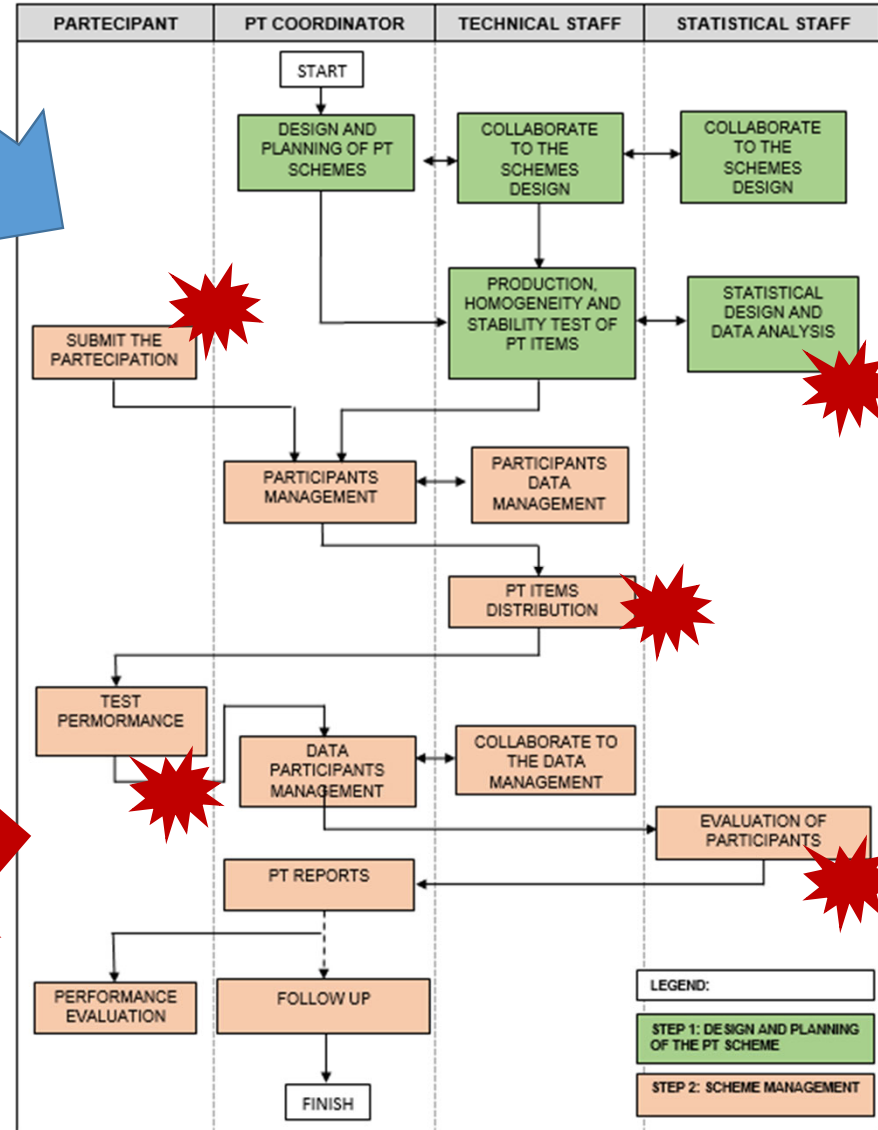


b) For each process, clearly identify every established **step** and define who is required to act and what, when, where and how activity has to be done.

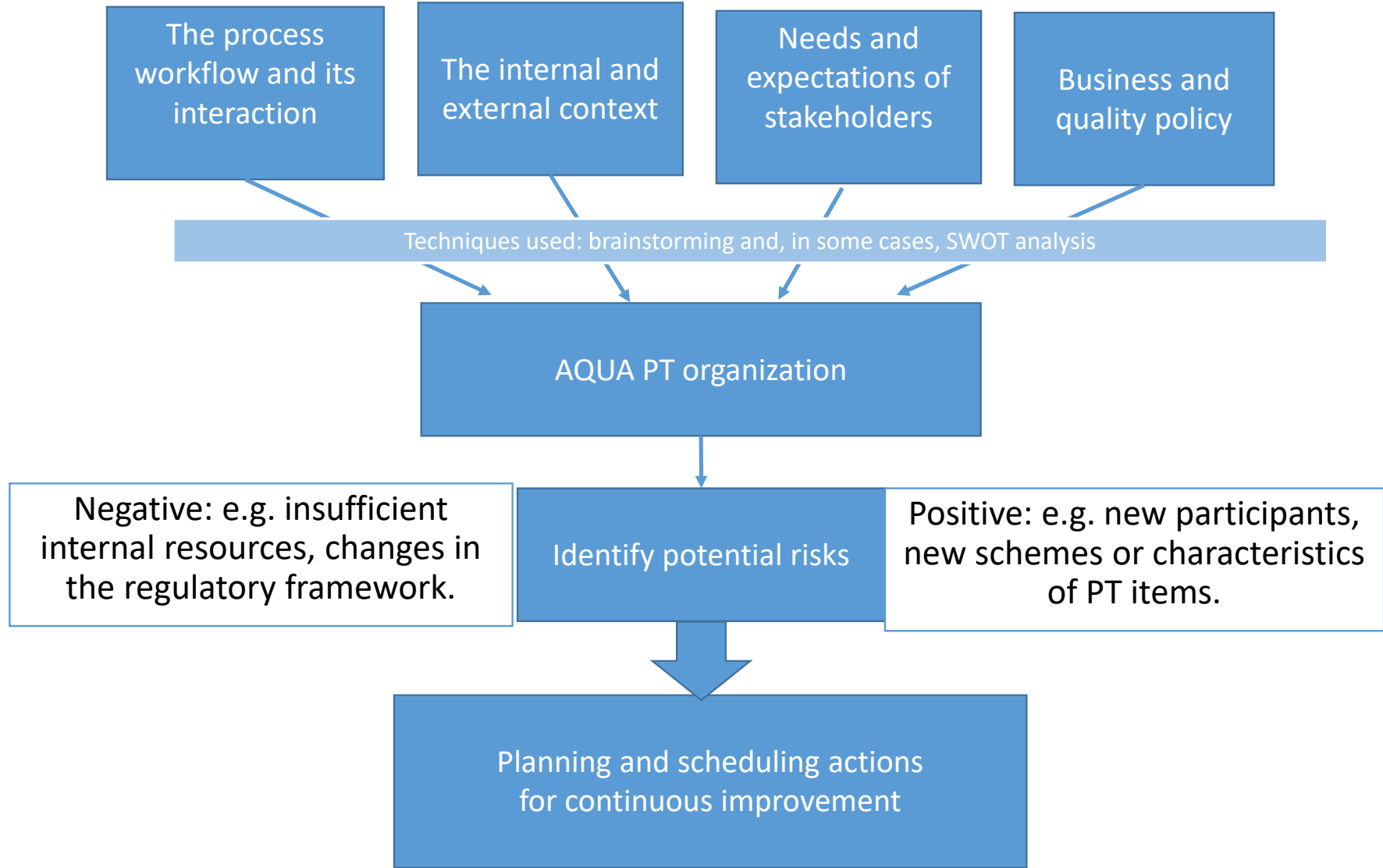
c) Draw the maps, with a visual representation of the task, process, or **cross-functional workflow**

d) For each process, **identify the risks**.

Identify the risks

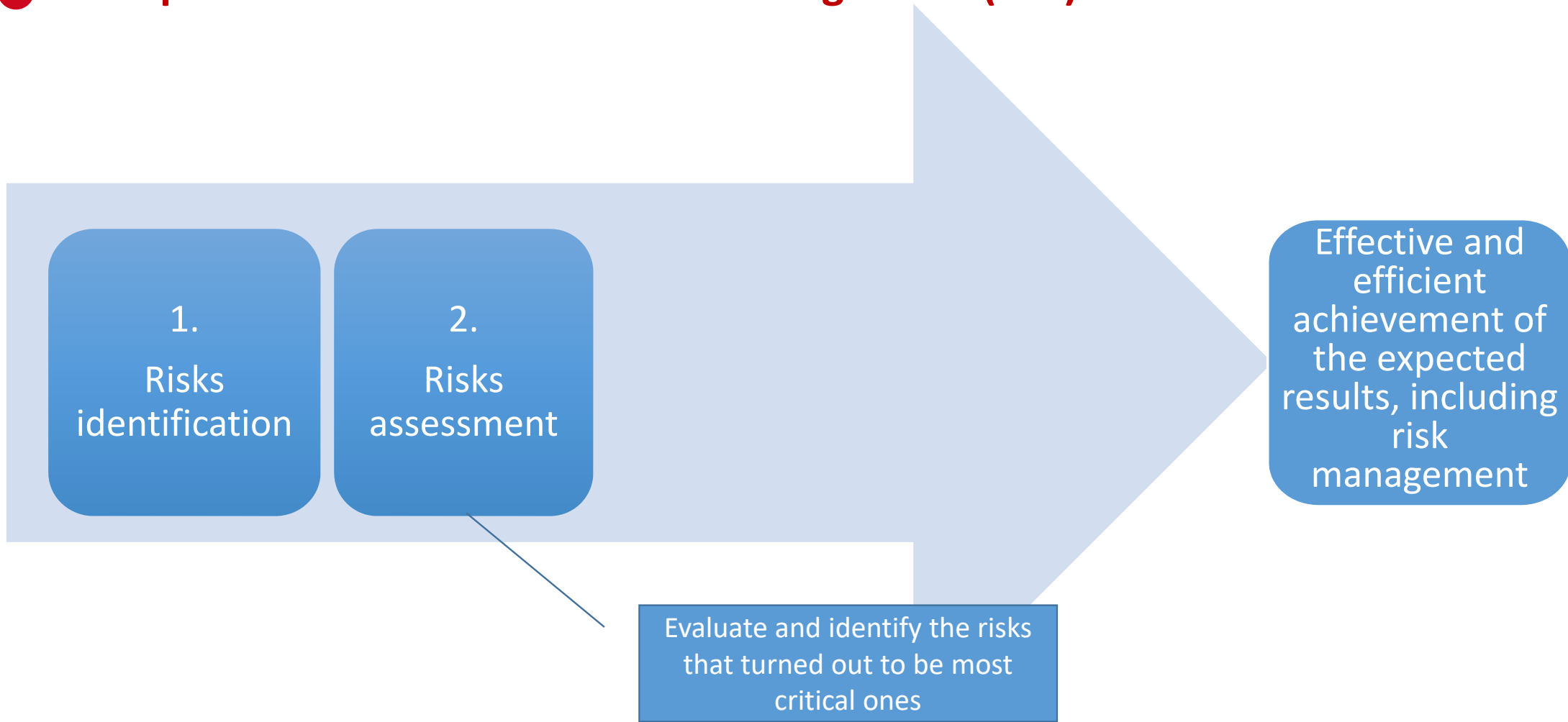


● Analyze:





# ● Implementation of IZSve's risk management (RM)



## Step n. 2: assess the risk

### Identify all possible risks, evaluate and prioritize them

Quantitative assessment technique:  
FMECA  
(Failure Mode, Effect and Criticality  
Analysis)

Identify the potential **Failure Mode (FM)**, their impact (**Effects**) on products, clients or services and the **causes** of the failure (Causes and Mechanisms). 22 FM were identified.

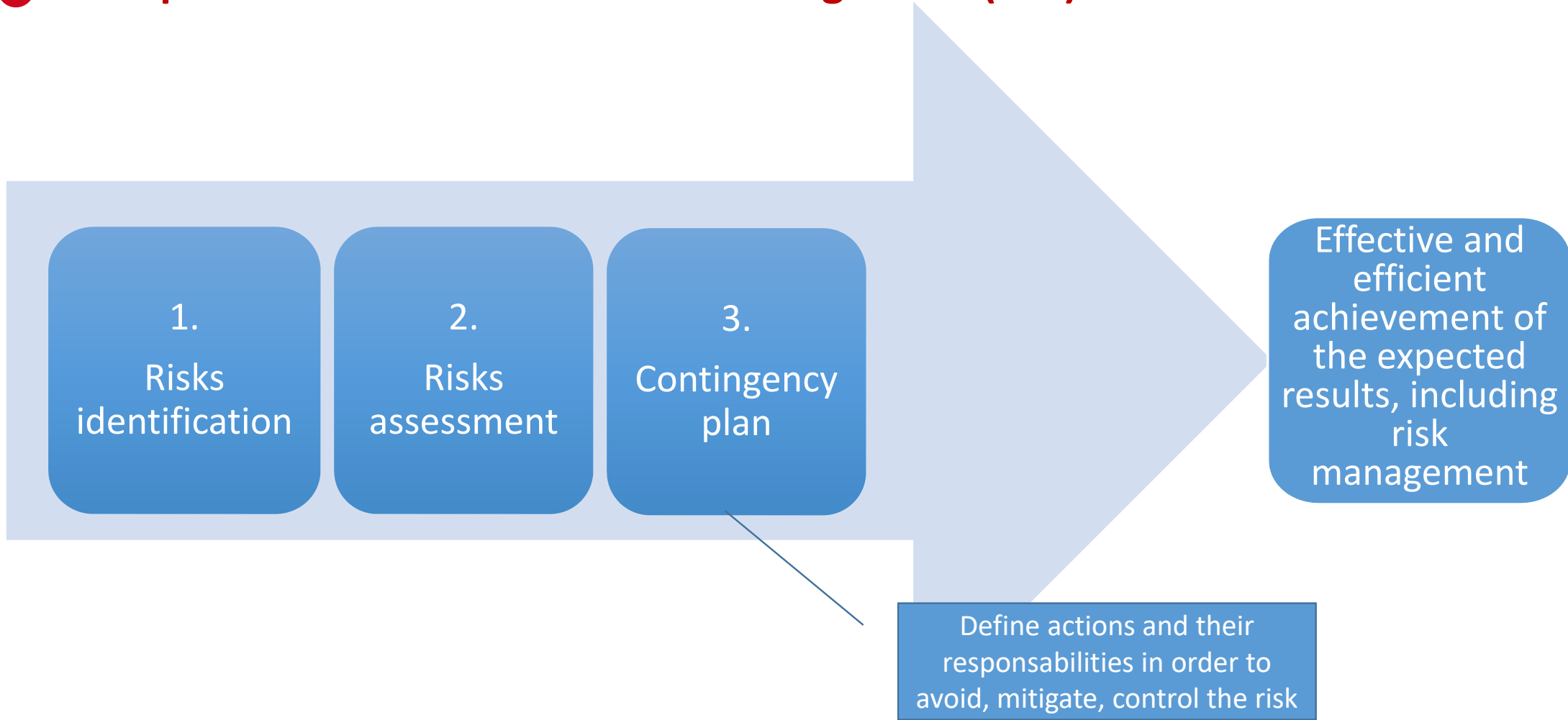
Process	Step	Failure Modes (Potential failures )	Effects	SEVERITY Rate 1-5 (5= most severe)	Failure cause or mechanisms	OCCURANCE Rate 1-5 (5= most frequent)	Current Process control Detection of failure	DETECTION Rate 1-5 (5= never detected)	RPN (1 = best; 125 worst)
Personnel	Assignment of staff roles	Lack of impartiality	Alteration of results or their advance communication	5	Personnel PT organizer, but also participants	2	No control	5	50
Logistic	Distribution of PT items	Incorrect PT items transport	Potential invalidity of the PT item	5	Delivery times not respected	3	Confirmation of delivery of the PT items	3	45
AQUA PT organization	Statistical design	Incorrect homogeneity and stability assessment of PT items	Cancellation of the PT	3	Guidelines for qualitative PT schemes assessment are limited	2	Comparison between experts; appeals	3	18
AQUA PT organization	Statistical design	Incorrect evaluation of performance	Appeals, lost of participants	3	Guidelines for qualitative PT schemes assessment are limited	2	Comparison between experts	3	18

Calculate the RPN for each FM:  
**RPN = SEV x OCC x DET**

Acceptance risk level:

>/=45	Critical	Take quick action
9-44	Major	Take action as soon as possible
</= 8	Minor	Action no needed

# ● Implementation of IZSve's risk management (RM)



## Step n. 3: Contingency plan

Define who, what, when, where, how implement the action.

Process	Step	Failure Modes (Potential failures )	Effects	SEVERITY Rate 1-5 (5= most severe)	Failure cause or mechanisms	OCCURANCE Rate 1-5 (5= most frequent)	Current Process control Detection of failure	DETECTION Rate 1-5 (5= never detected)	RPN (1 = best; 125 worst)
Personnel	Assignment of staff roles	Lack of impartiality	Alteration of results or their advance communication	5	Personnel PT organizer, but also participants	2	No control	5	50

**Avoid the risk:**  
Excluding the organizer as a participant

Process	Step	Failure Modes (Potential failures )	Effects	SEVERITY Rate 1-5 (5= most severe)	Failure cause or mechanisms	OCCURANCE Rate 1-5 (5= most frequent)	Current Process control Detection of failure	DETECTION Rate 1-5 (5= never detected)	RPN (1 = best; 125 worst)
Personnel	Assignment of staff roles	Lack of impartiality	Alteration of results or their advance communication	5	Personnel PT organizer, but also participants	1	Exclusion from the organizing laboratories as participants; declaration of no conflict of interest; limited access to the data	1	5



Process	Step	Failure Modes (Potential failures )	Effects	SEVERITY Rate 1-5 (5= most severe)	Failure cause or mechanisms	OCCURANCE Rate 1-5 (5= most frequent)	Current Process control Detection of failure	DETECTION Rate 1-5 (5= never detected)	RPN (1 = best; 125 worst)
Logisitic	Distrbution of PT items	Incorrect PT items transport	Potential invalidity of the PT item	5	Delivery times not respected	3	Confirmation of delivery of the PT items	3	45

**Mitigate the risk:**  
Thermal abuse validations for transporting freeze-dried test samples

**Transfer the risk:**  
subcontractor contract clauses

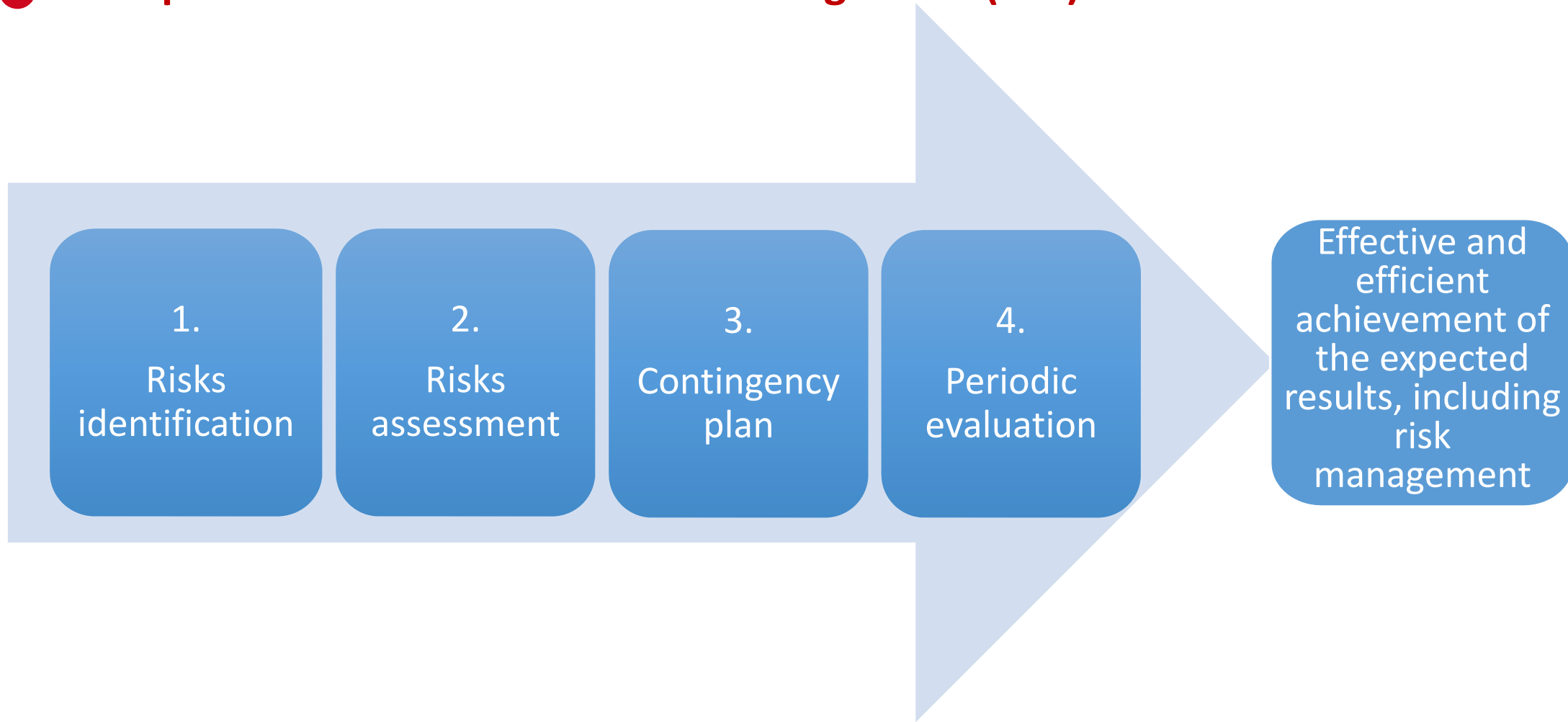
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Logisitic	Distrbution of PT items	Incorrect PT items transport	Potential invalidity of the PT item	3	Delivery times not respected	1	Confirmation of delivery of the PT items; thermal abuse during the PT items delivery, specific clauses in subcontractor contract	3	9



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AQUA PT organization	Qualitative PT: Statistical design	Incorrect evaluation of participant performance	Appeals, lost of participants	3	Guidelines for qualitative PT schemes assessment are limited	2	Comparison among experts; complaints	3	18

**Accept and control the risk:**  
waiting for a guidelines for qualitative statistical analysis.

## ● Implementation of IZSVe's risk management (RM)



## ● Step n. 4: Periodical evaluation

Monitoring & reviewing risks is a **continuous process**.

**Evaluations were conducted through:**

- a) Analysis of the KPIs,
- b) Complaints and appeals,
- c) Management reviews,
- d) Internal audit,
- e) Nonconforming work.

When necessary the risks **were reassessed** and based on the results or new information, actions were implemented or corrected where necessary.



**In conclusion:**

RM and FMECA have become an **integral part** of our organizational culture, which **supports proactive management**.



# Thank you for your attention



## ● Bibliography & credits

- ISO/IEC 17000:2004 - Conformity assessment - Vocabulary and general principles
- ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17043:2023 - Conformity assessment — General requirements for the competence of proficiency testing providers
- ISO 3100:2018 - Risk management — Guidelines
- ISO 9001:2015 - Quality management systems — Requirements