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DEI CHIMICI DELL'EMILIA-ROMAGNA

# Risk Assessment of Laboratory Activities

## **Working Safety in the Laboratory**



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# Risk Analysis and Analytical Risk

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The data are the *end of pipe*  
of a process based on

security (data not numbers: accreditation and  
professional competence)

traceability, repeatability and comparison

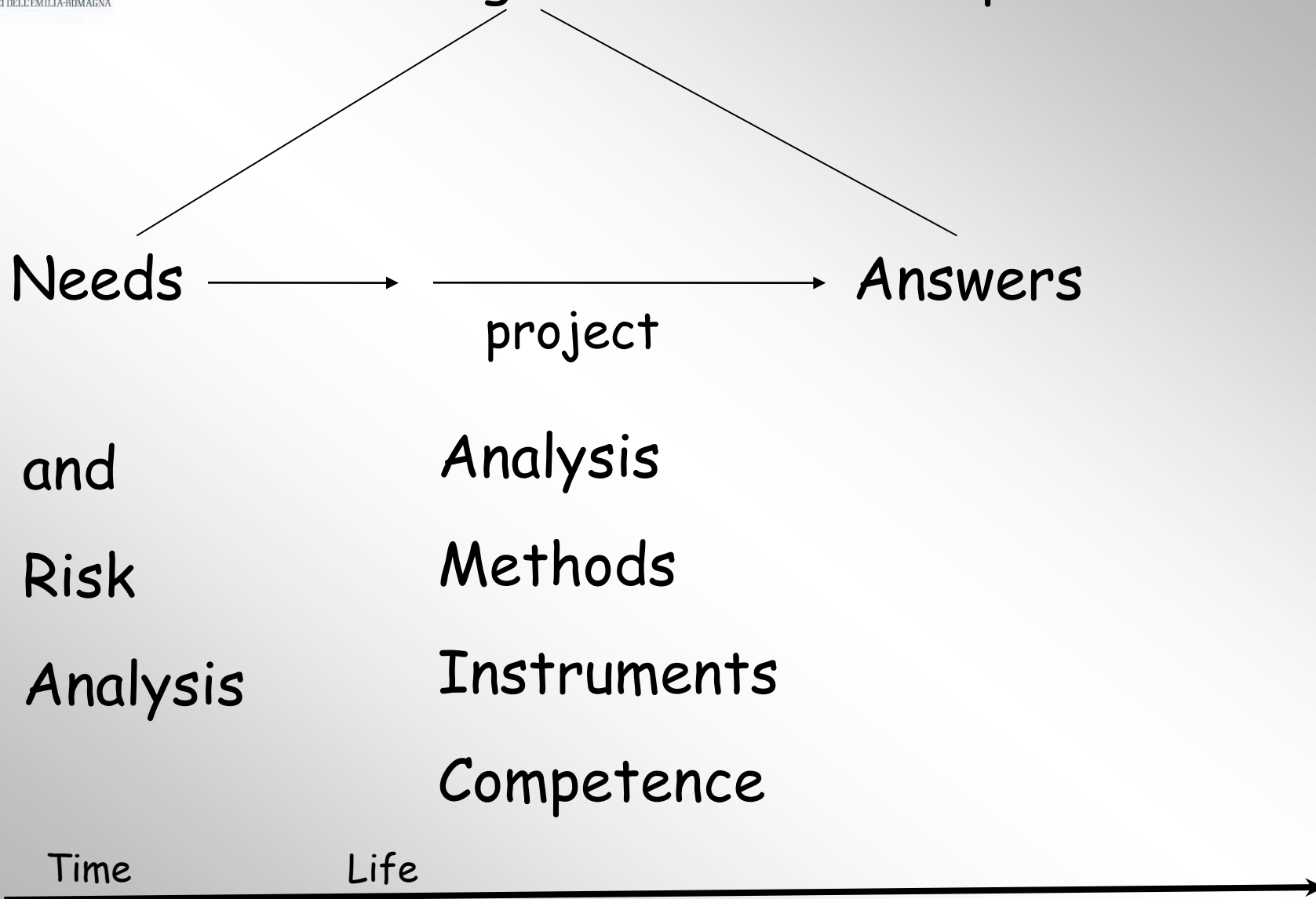
(ex Reg.to EC 765/08)



**but it's not enough**

the analytical process must be managed like a  
**project management**  
with milestones in a life cycle, and  
before, during and after  
the **Risk Analysis** is an essential step

# Team Manager: Director or Specialist



Judgment  
&  
Accountability  
Cycle

P  
h  
a  
s  
e  
s

Preparatory (study & feasibility)  
Carrying out (operational)  
Final (Outcome  
Validation,  
Reliability  
Uncertainty)



It's usual to consider only  
industrial chemical processes  
or big plants / services  
as target  
for Risk Analysis and Technical Engineering Design

In Labs we can use:

the Gantt Diagram that illustrates a project schedule, with start and finish of no return elements and summary of a project.

e.g. the work breakdown structure of the project.

The chart also shows the dependency relationships between activities.





not only, but also

the PERT (Program Evaluation and Review Technique) and the CPM (Critical Path Method)

➤ PERT (Determination of costs / timing)

or

➤ CPM (Critical path and focal point)



The Risk Analysis and the Project Management today are instruments usually applied to big project (so called *complex activities*)

not to Analytical Processes

but why not?

# BECAUSE

Laboratory is a very complex situation with very complex processes

about large pattern matrices

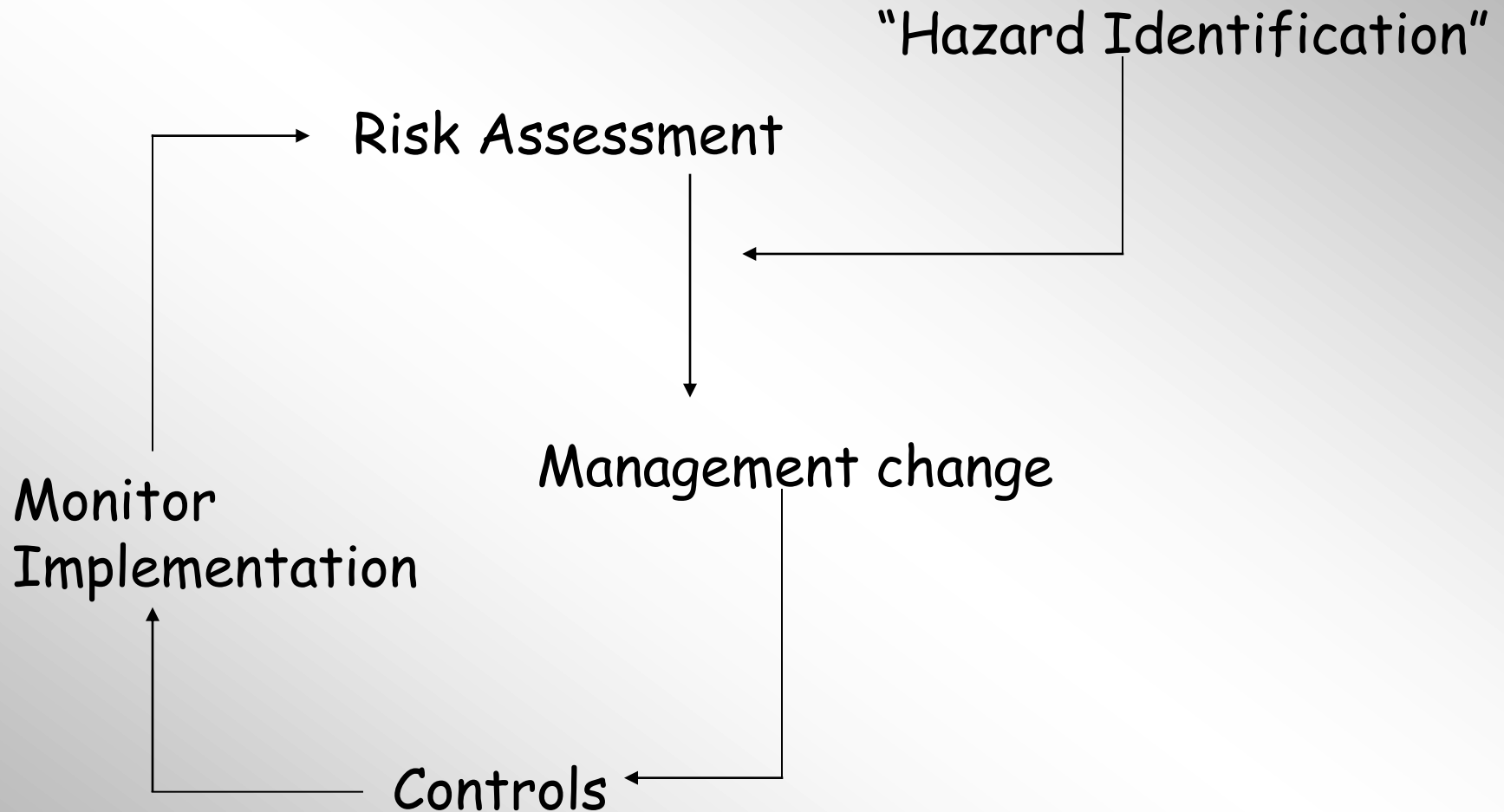
many parameters

and therefore we tune a lot of techniques and methods usually not tested (or managed) from the perspective of security.



# Risk Analysis and Risk Assessment

For each analytical process (or every method)  
it's necessary an "Hazard Identification" (ongoing  
data)





## In Labs

we may have nuclear isotopes

X,  $\gamma$  sources

chemical and biological Risk

substances, solutions, reagents

and also samples flammable, explosive,

cancerogenic/mutagenic and

teratogen agents

and we must consider the path and the mechanisms of human intake (inhalation, ingestion, contact)

Four focal points in the analytical project:

- the sample
- the analysis
- the workplace and
- the environmental conditions

but the Lab Organization often cut the process into two different phases (sampling and analysis)

## Four Risk phases:

**Sampling** (competent staff, methods, techniques, environmental conditions)



**Transportation** (proper shipping and conditions)

**Preparation**

**Analysis** (queries, staff, methods, instrument, workplaces)



Accreditation (ISO/IEC 17025:2005 - now revision in progress)

is

essential as concern comparison, repeability, reproducibility, competence

but is not enough

it's only a part of Analytical value - we get the full value with a Risk Analysis, Evaluation and Assessment related to work in safety, to live in safety and to achieve an actual analytical outcome.



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Quality Management System must be implemented and integrated with Safety Management System (and Environmental also).

# A spot about

Safety & Health Management

System: OHSAS 18001/18002

based on

Hazard Identification, Risk Assessment and  
Determining Controls,

step one: design stage

step two: on the process

The Organization must control the situation by  
monitoring and Change Management

# What's new!

ISO 9001:2015; ISO 14001:2015, BS OHSAS  
18001:2007 (and ISO/WD 45001)

Approach

Risk Based Thinking

then

Risk Management

by now

Risk Analysis



# Risk Analysis is

a preliminar transversal activity.

Output is not only the customer satisfaction

but is the Life Cycle Assessment also.



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# The Lesson of Major Industrial Accidents and Nuclear Plant

Seveso

Chernobyl

## Lesson Learnt

Each event/process is not  
related to only one Risk

**Risk** is a probability based on a frequency and a magnitude.

It's weighed: is the change of probability that a person will be harmed or experience an adverse health effect if exposed to Hazard.

It may also apply to situations with property or equipment loss, or harmful effects on the environmental.



**Hazard** is any source of potential damage, harm or adverse health effects on something or someone.

It's not weighed: it's a qualitative condition, activity, material or situation.





We must stop to think about  
Analytical Process or Lab  
as only Hazards (biological, chemical, physical and so on)

We must think  
Lab as preliminary weighed  
Risk Assessment

# The Instruments of Risk Analysis

Failure

Mode (and)

Effect

Analysis

F  
M  
E  
A



Analytical  
Report



Design

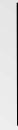
Failure

Mode

Effect

Analysis

Analytical  
Process



Process

Failure

Mode

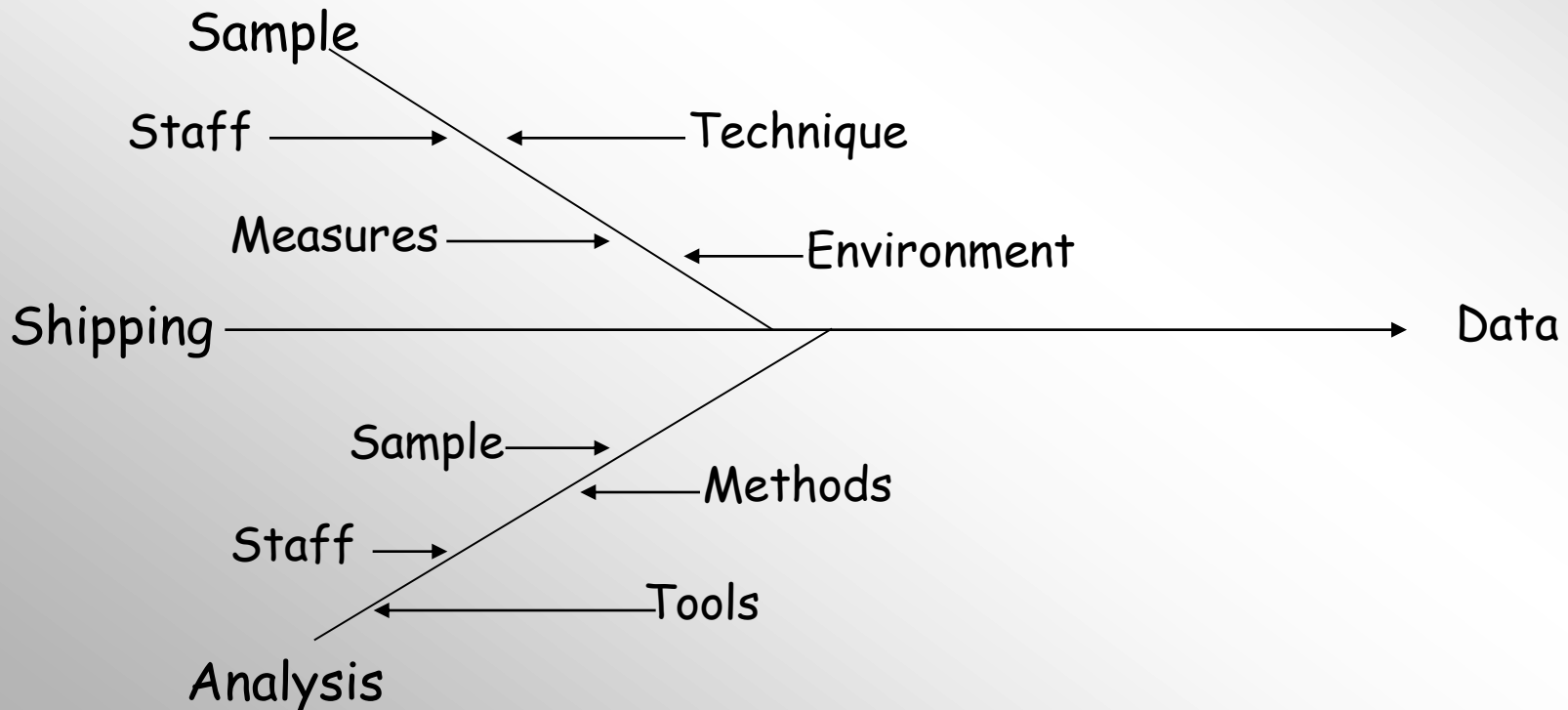
Effect

Analysis

In the first step

we can identify all sources of failure by

the *fishbone Diagram* (Ishikawa: cause-effect)  
applied to Lab





## FMEA Indicators

**Severity** (failure - effects)  
(1 - 10)

**Occurrence** (frequency)  
(1 - 10)

**Detection** (ability to find failure in project)  
(1 - 10)

**Severity . Occurrence . Detection = RPN**  
(Risk Priority Number)

Not only FMEA

but also

Hazop (Hazard & Operability Studies)

CCA (Cause Consequence Analysis)

ETA (Event Tree Analysis)

FTA (Fault Tree Analysis)

PRA (Preliminary Risk Analysis)



Analytical Process:  
not only data but  
safety,  
competence and  
integration of skills



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Grazie per l'attenzione

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