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Possible tools to perform the risk analysis and the risk and opportunities identification and management

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Risk definition (ISO terminology)

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- **Risk:** the effect of uncertainty on the objectives (ISO 31000:2018).
  - *i.e.* how likely is a deviation from what was planned?

- **Effect** is a deviation to what was expected
  - Positive and negative effects or both

Risk definition (ISO terminology)

- **Uncertainty** (embraces many concepts)
  - *i.e.* the source of risk
- At the strategic level
  - Associated with systemic issues (organization)
    - *e.g.* lack of competent staff during short periods with undefined impacts
    - Could be a consequence of a conflict of interest
- At the operational level
  - Variability in the parameters on which a decision is to be based
    - Intrinsic variability of the phenomena – cannot be reduced by further research
    - Accuracy of the methods
    - A bad batch of primers affecting the outcome of a test

Opportunity definition

*Eurolab Cook Book Doc No. 18

- **Opportunity:** an event with potential positive consequences for the organization*
  - At a strategic level
    - this could be expanding the scope of the laboratory activities
  - At an operational level
    - this could be investing in a new PCR machine to improve throughput.

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Risk identification two levels

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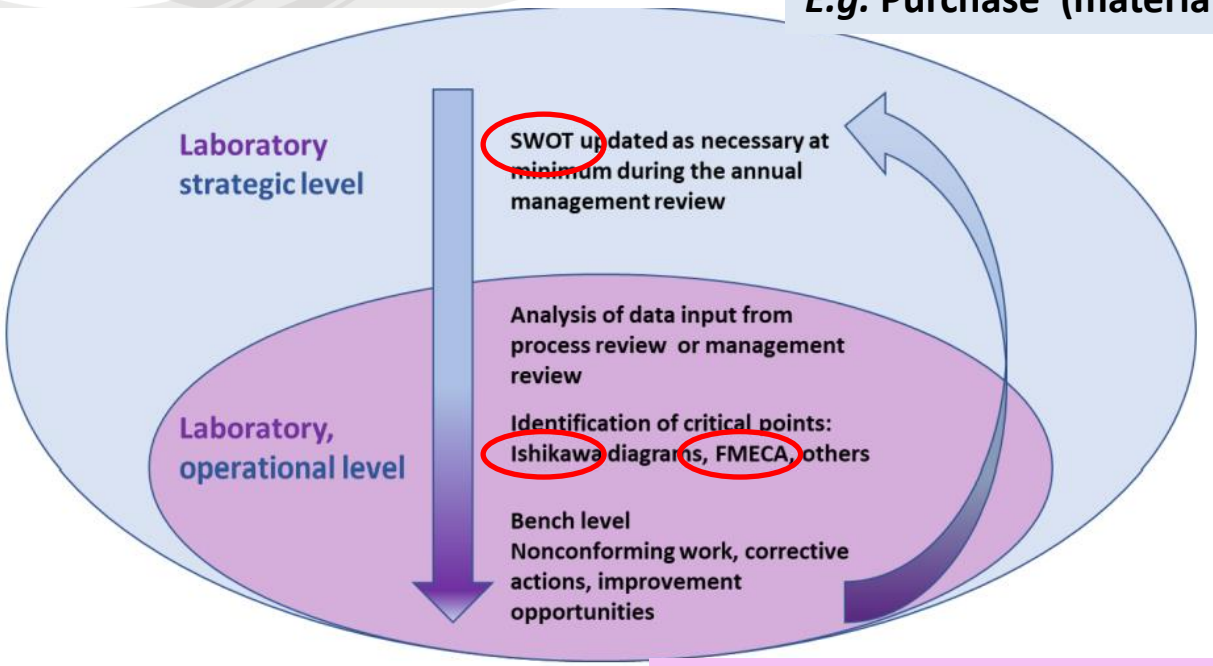
E.g. **staff management (recruitment and training)**

E.g. **Purchase (materials and equipment)**



E.g. **before validation of verification of tests (ISO 17025, points 7.2.1.5 and 7.2.2);**

E.g. **calibration/verification (ISO 17025, points 6.4.7 and 6.5)**

Tool for the analysis at the strategic level

- Objective: to convert weaknesses into strengths and threats into opportunities
- Advantages:
  - Easy to understand
  - Applicable with different levels of detail
  - Can be linked directly to the objectives of the lab
  - It is attractive and easy to communicate
- Disadvantages:
  - it is tempting to undertake the SWOT using qualitative rather than quantitative data
  - The problems are more easily expressed as general than as specific
  - Easily biased due to personal perceptions and preferences

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Tool for the analysis at the operational level

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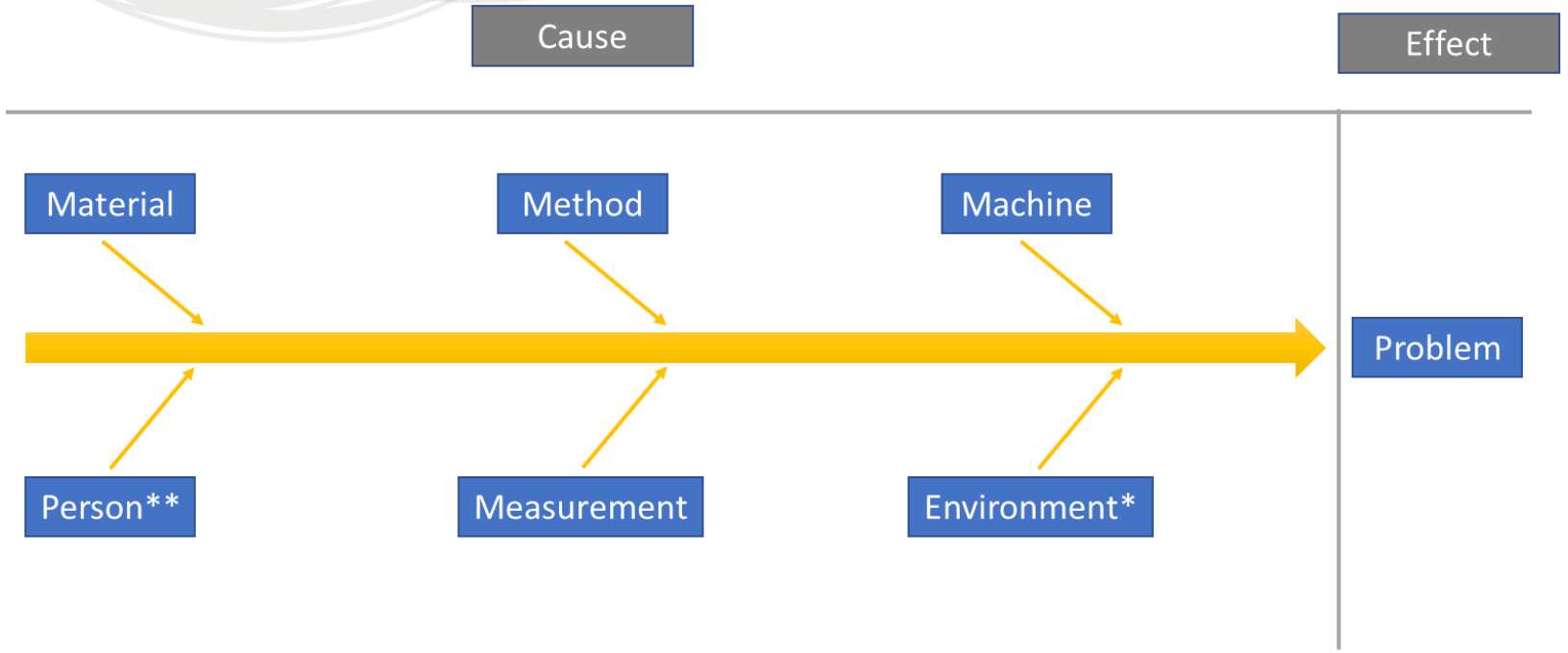
Ishikawa diagram* (aka fishbone diagram)



*Mother Nature
** Man

Ishikawa, Kaoru (1968). Guide to Quality Control. Tokyo: Asian Productivity Organization

Benefits of Ishikawa

- Helps determine root causes and critical points
- Encourages group participation
- Visually simple
- Increases knowledge of the process by helping everyone to learn more about the factors at work and how they relate
- Identifies areas for collecting data

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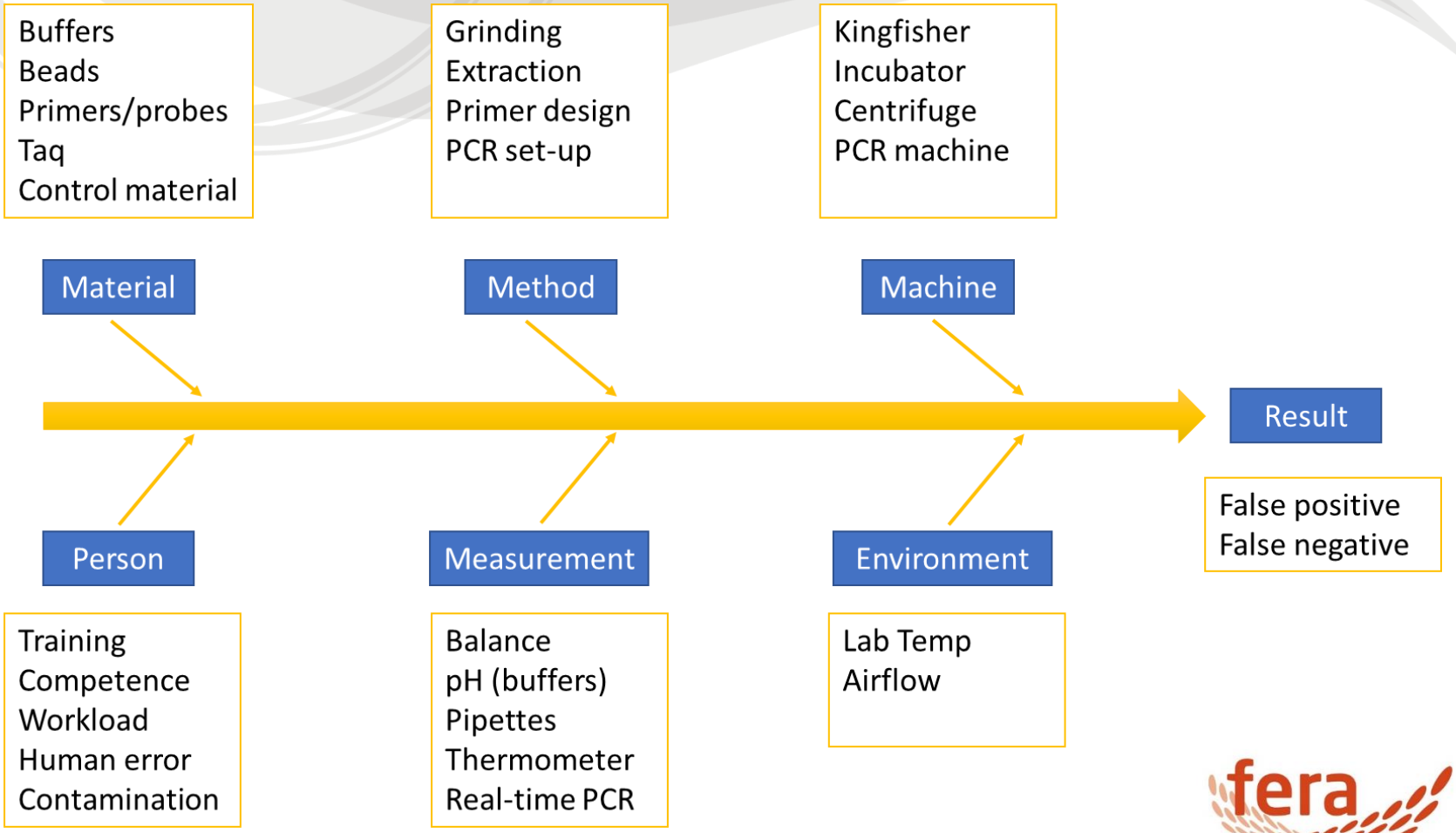
Using Ishikawa to identify sources of risk in PCR



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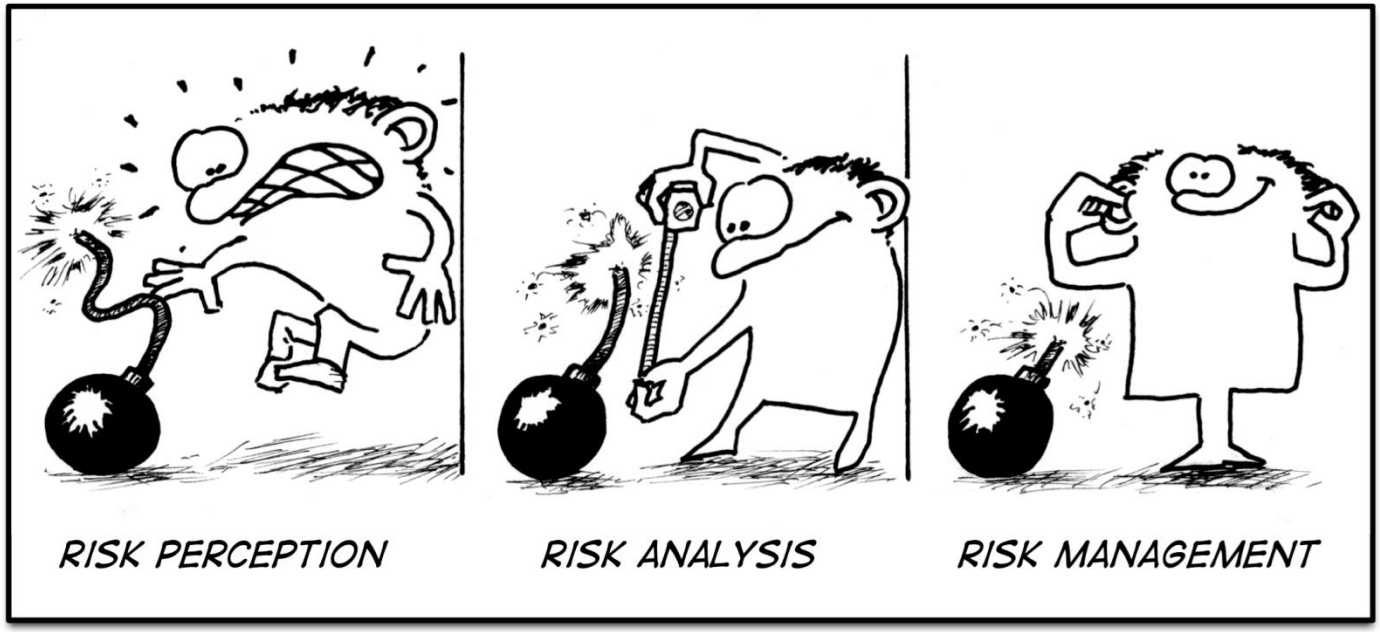
Tools at the strategic level
Process for risk management



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Process for risk management at the strategic level

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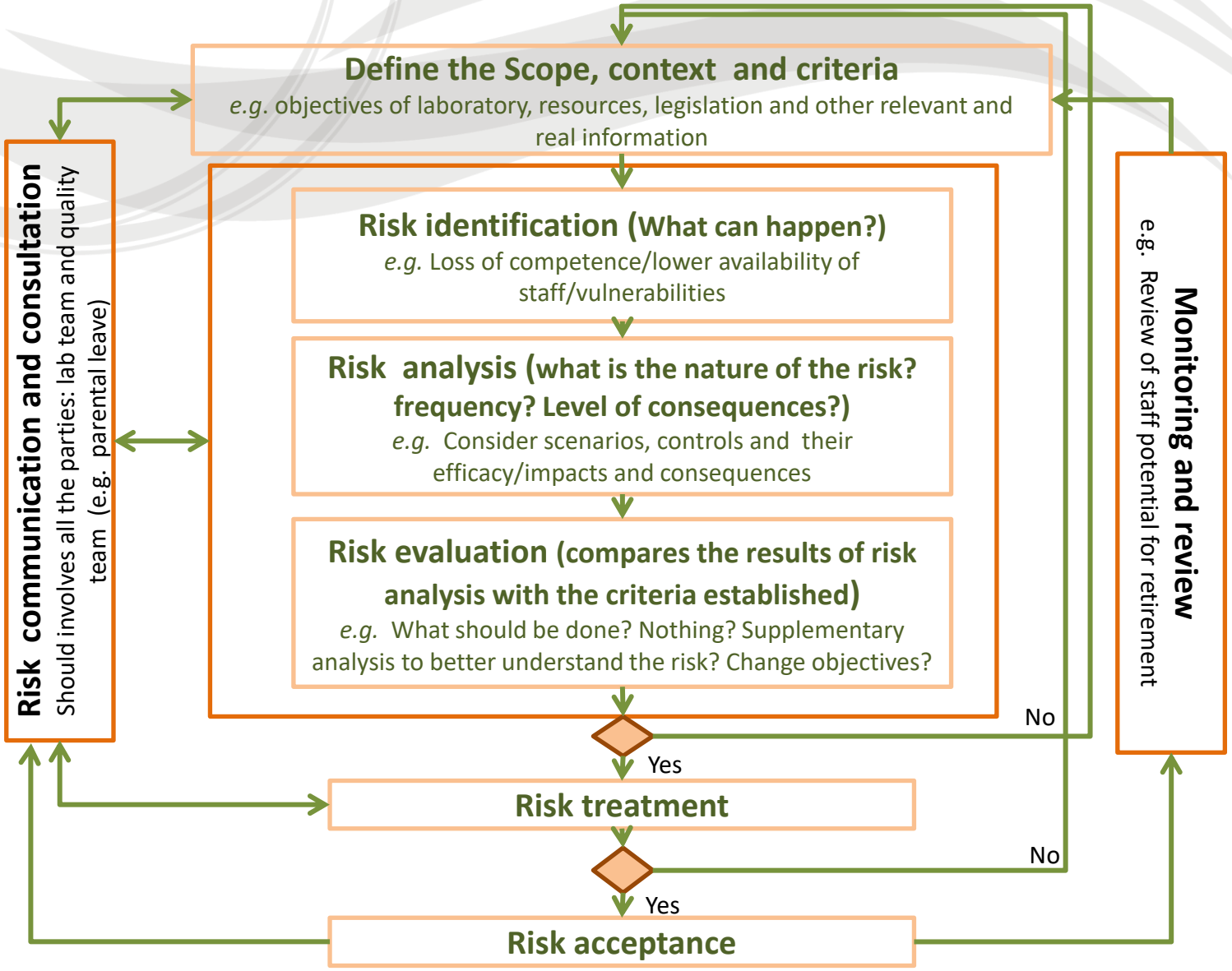

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Remember … your assessor will not check whether every aspect relating to risks and opportunities has been taken into consideration. The key is to ensure that the laboratory has implemented actions to manage them adequately.

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Thank you for your attention.
Any questions?

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