Culture in laboratory :

A change after accreditation

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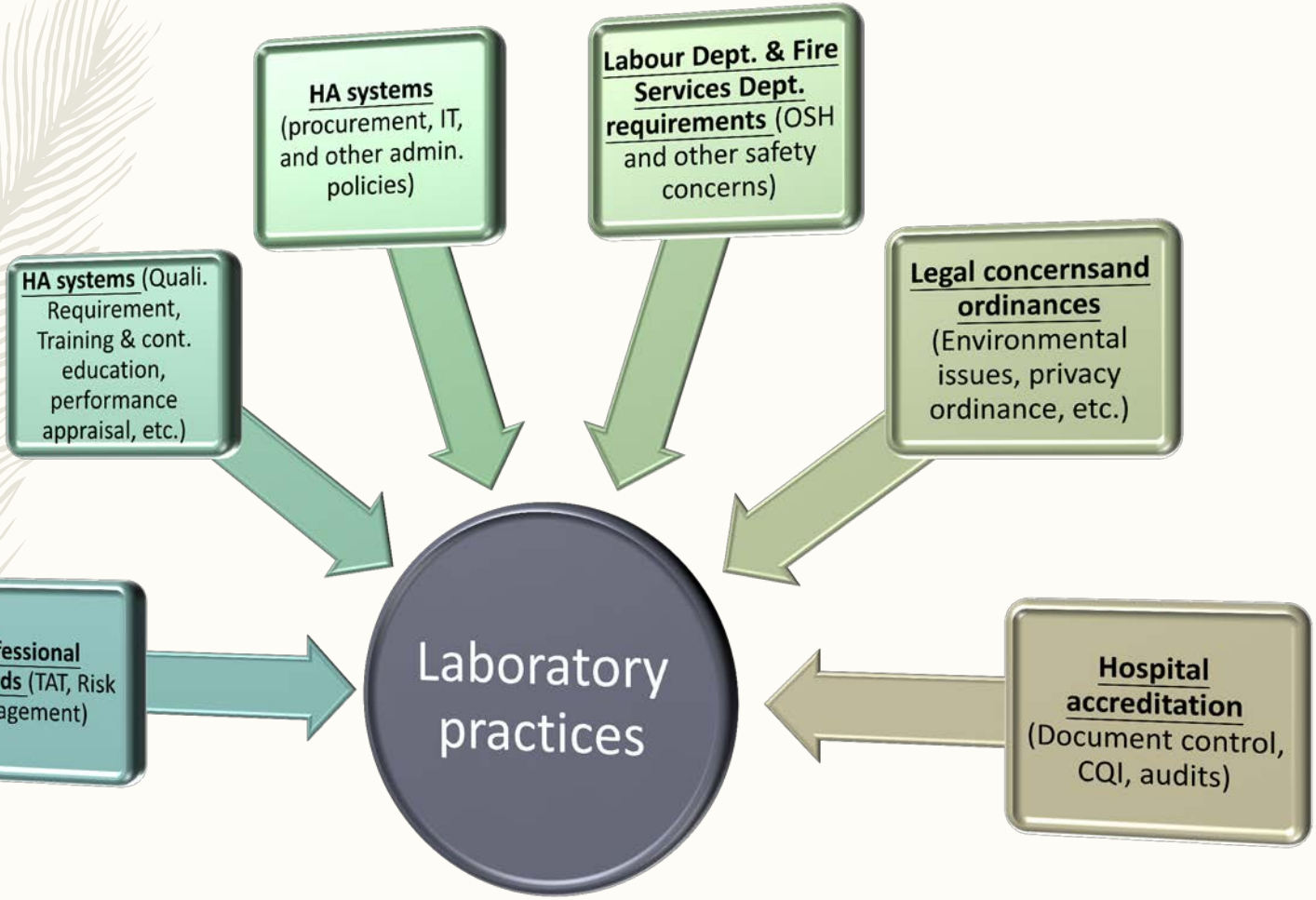
How was the lab before seeking accreditation ?

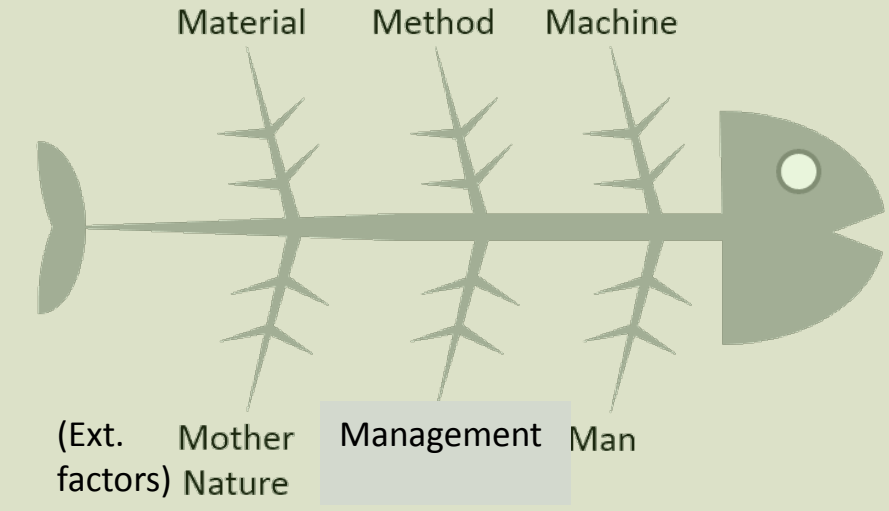


How was the lab before seeking accreditation ?

Not bad,
but greatly depends on a highly competent leader to put all the things together

What improvement does ISO 15189 bring ?

- A **structured quality management system** as a standard to assure the performance of the medical testing
- Aspects which will affect QUALITY will be included into the quality management system to monitor



What more are in ISO 15189

(the quality management standard for medical testing laboratories) ?

➢ Management Requirements

- **Organization & Management Responsibility**
- **Quality Management System**
- Document Control
- **Service agreements**
- **Examination by Referral Laboratories**
- **External Services & Supplies**
- **Advisory Services**
- Resolution of Complaints
- **Identification & Control of Non-conformities**
- **Corrective Action**
- **Preventive Action**
- Continual Improvement
- **Control of Records**
- **Evaluations & Audits**
- **Management Review**

➢ Technical Requirements

- **Personnel**
- **Accommodation & Environmental Conditions**
- **Laboratory Equipment, Reagents & Consumables**
- **Pre-examination Processes**
- **Examination Processes**
- **Ensuring Quality of Examination Results**
- **Post-examination Processes**
- **Reporting of Results**
- **Release of Results**
- **Laboratory Information Management**

What we have to do MORE to comply to ISO 15189?

(some examples)

Management -1

- Quality policies and targets
- Management reviews
- Contingency plans

Management -2

- Structured internal audits
- Systems for identifying nonconformities
- Corrective & preventive actions

MAN

- Annual competency evaluation
- Proficiency tests
- Duty list and deputies

What we have to do MORE to comply to ISO 15189?

(some examples)

MACHINE

- Equipment correlation
- Calibration

MATERIAL

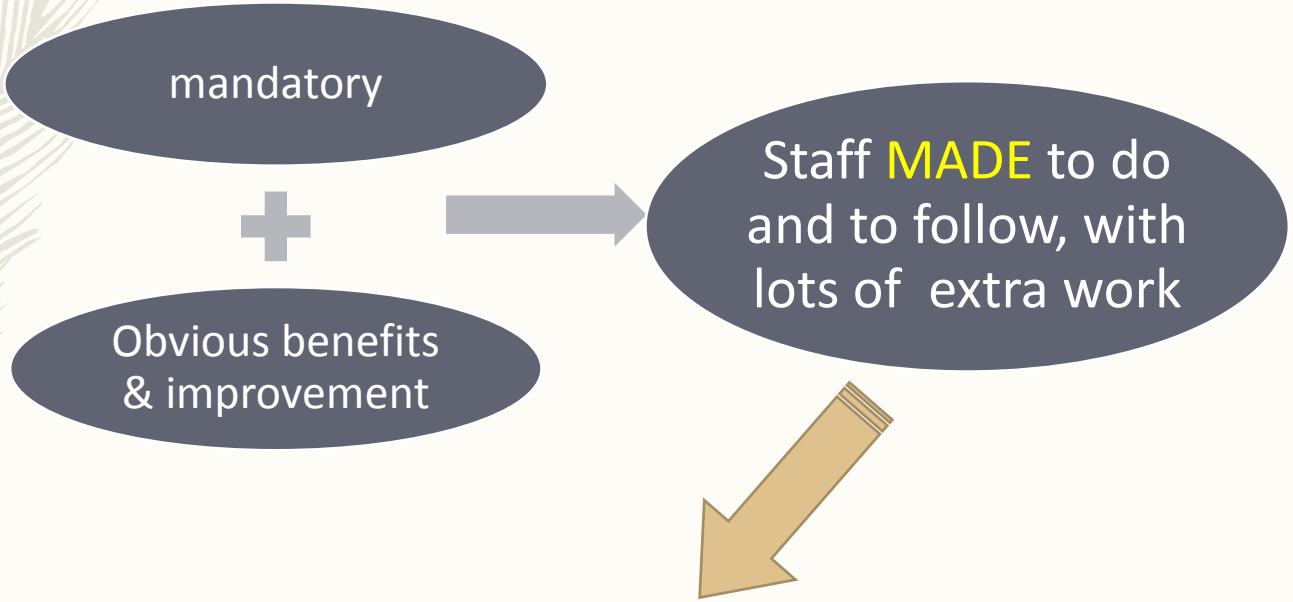
- Reagent evaluation before use
- Supplier evaluation

METHOD

- SOP, from info for clients
- Traceability
- Full documentation & records
- Measurement uncertainty

Cultural change :

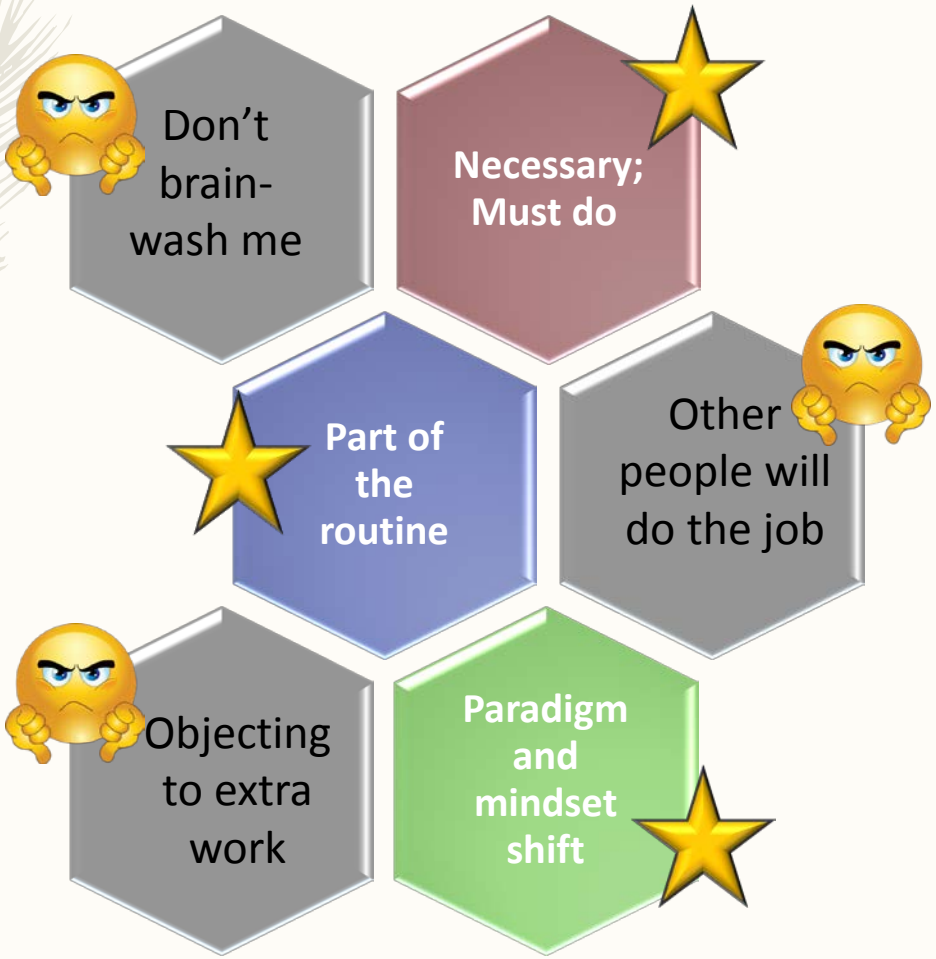
At the beginning :



Some time after being accredited :

Are the quality management system elements now part of the daily work ?

Changes needed :



Role of lab accreditation in the cultural change

- Lab accreditation

  = recognition of the compliance to the set standard by an AUTHORIZED THIRD PARTY

Benefits with respect to lab managers

- Systematic approach and clear guideline for each essential elements in quality management
- Better documentation of all useful records
- Traceability to investigate and review for incidents
- More alert to risks and with proactive preventive actions in place
- Increased assurance of lab result accuracy and staff competence
- Continual Improvement concept better received
- More sharing and learning opportunities

Benefits with respect to staff

- **Systematic approach** of competence-based training
- **Status** and prestige to work in an accredited lab
- **Professionalism** in having wider knowledge other than the technical knowledge for lab work, such as :
  - Standards and ordinances and regulations
  - Quality assurance and quality control and verification
  - Proficiency tests
  - 5S, lean management, etc.

Story of an incident investigation

Demonstrating the benefits of good quality management

- A case of specimen mix-up of breast biopsies
- Root cause :
  - Opened specimen container could not be easily distinguished from new ones
  - Used container with a small piece of biopsy (malignant) was mistakenly thought as an unused one and recapped, and re-used for another patient (non-malignant) several days later.
- Confirmation :
  - DNA from 2 different patients found in the same one specimen container.

- What helped to free the lab from the accusation of specimen mix-up

A glimpse of the routine work in an accredited lab

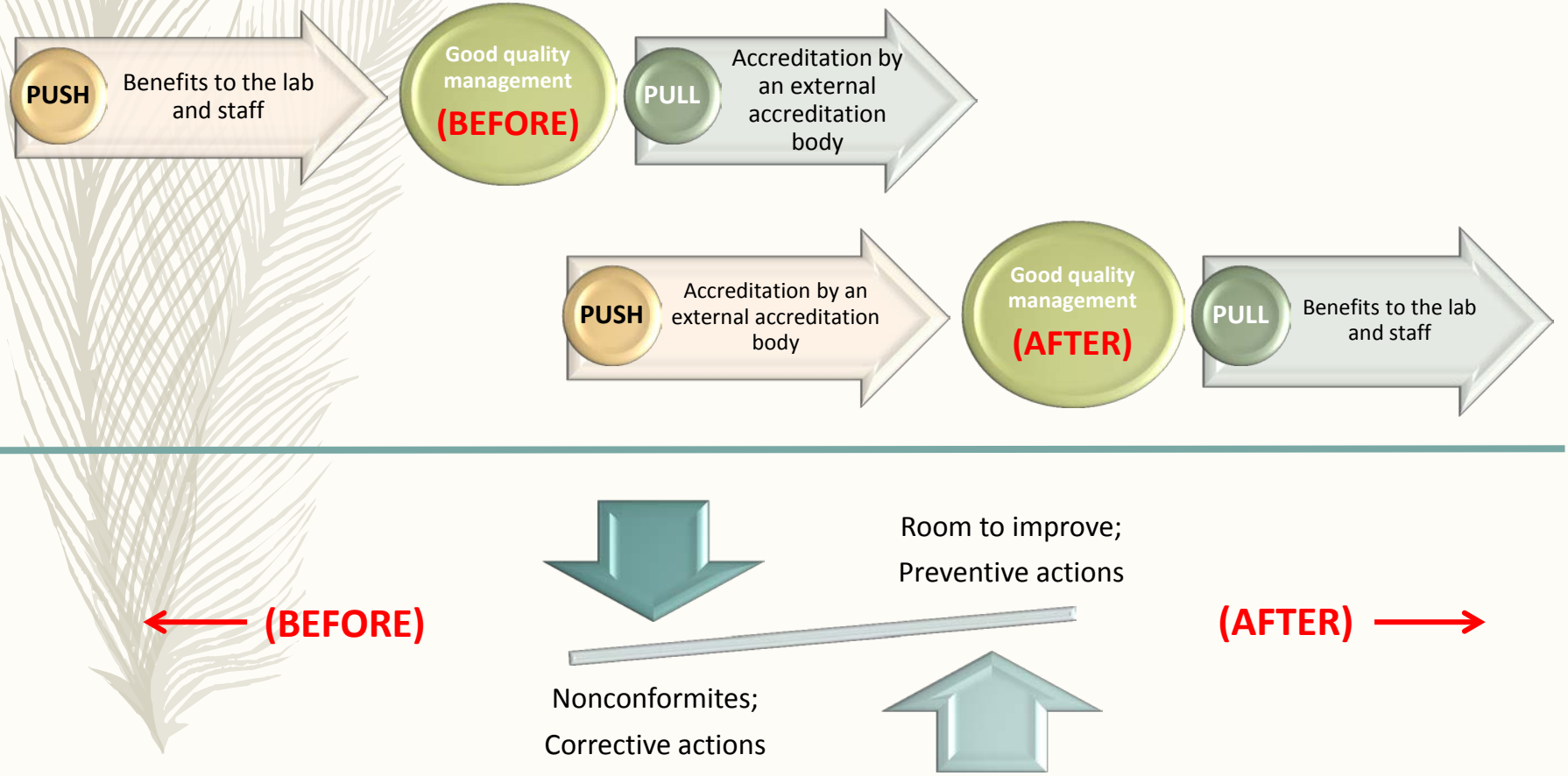
- **Forms and logsheets**

  100+ for each lab

- **SOP**

  ~ 100 for each lab

What have been achieved ?



Way to consider further improvement in an accredited lab

Culture of quality management in mind and in life

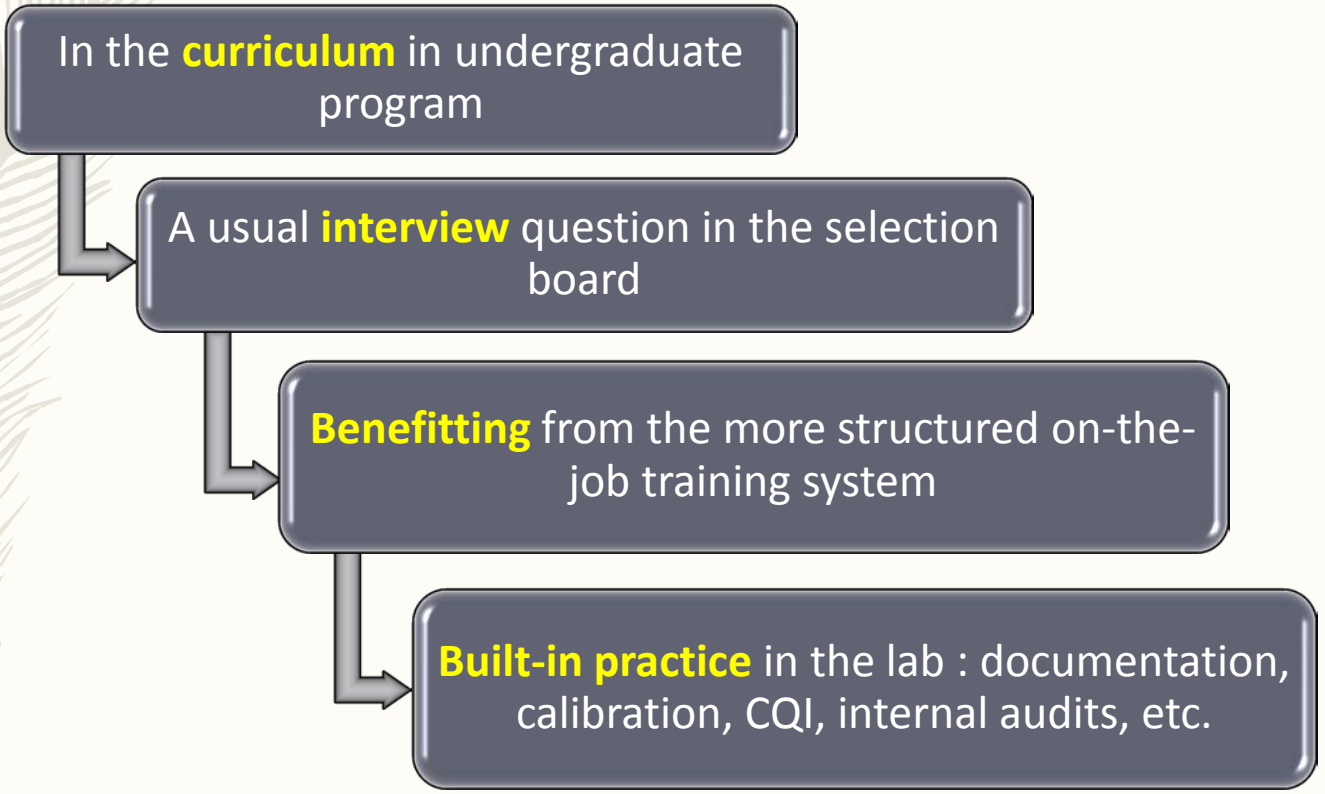
– Example : the need of calibration

Really 38°C outside on the road ?
The device **CALIBRATED** ?

Really 7°C outside on the road ?
The device **CALIBRATED** ?

Ultimate outcome to expect:

More significant influence to be on the new team members



Thank You !