



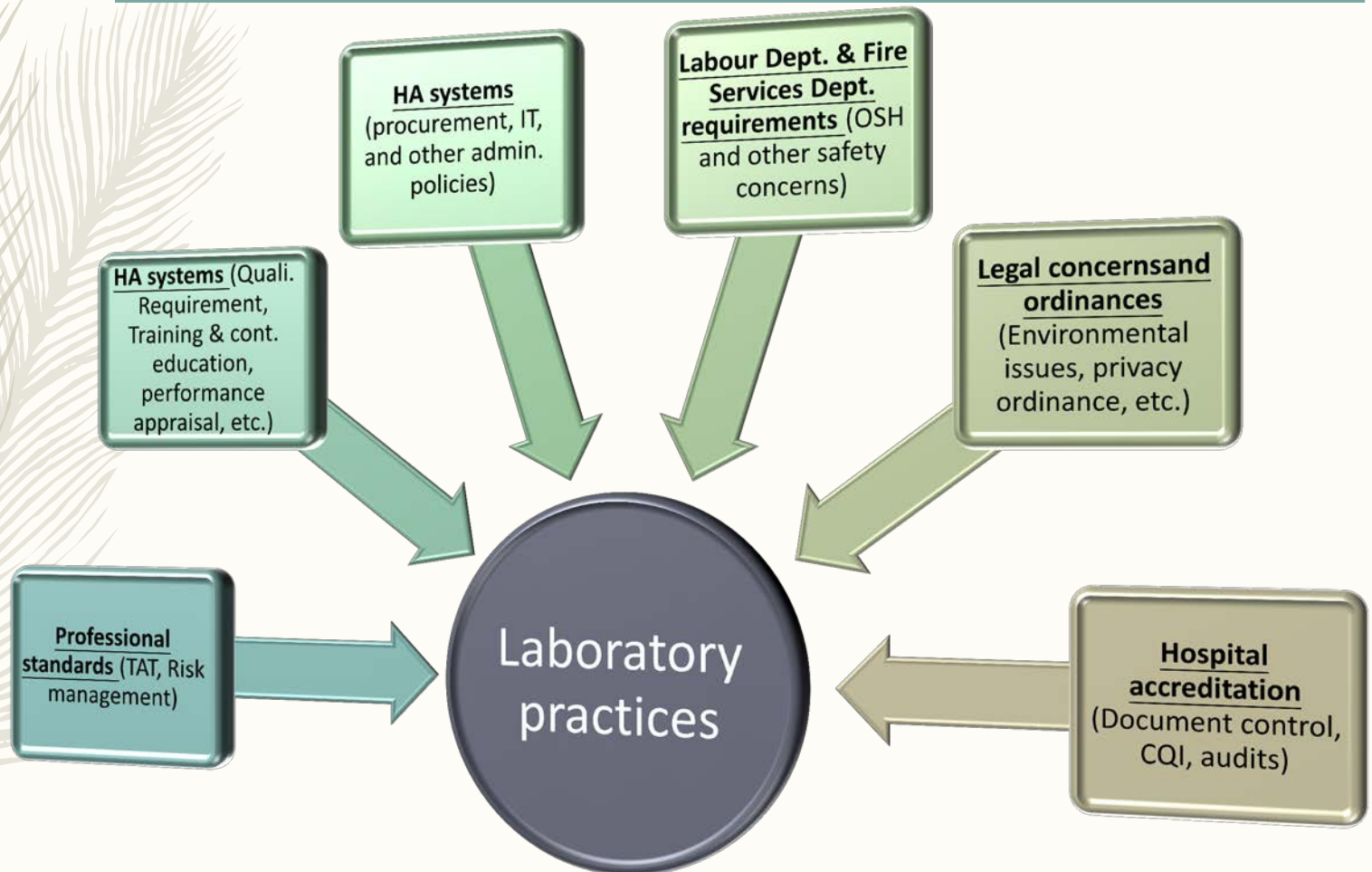
Culture in
laboratory :

A change after
accreditation

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How was the lab before seeking accreditation ?



How was the lab before seeking accreditation ?

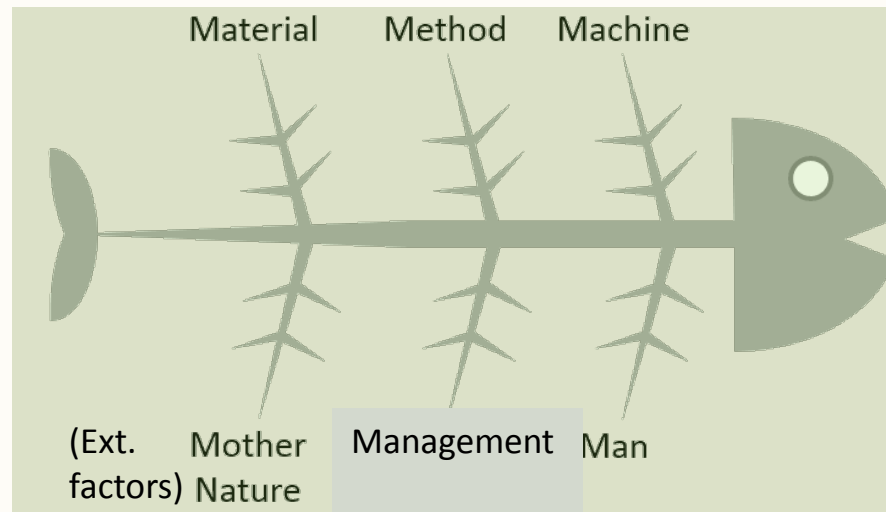
**Not bad,
but greatly depends on a
highly competent leader
to put all the things
together**



The diagram features a central circular node labeled "Laboratory practices". Surrounding this central node are six rectangular boxes, each representing a different area of influence. Arrows point from each of these boxes towards the central node, indicating that all these factors contribute to the laboratory's practices. The boxes are: "Professional standards (TAT, Risk management)" at the bottom left; "Hospital accreditation (Document control, CQI, audits)" at the bottom right; "Local, state, & federal regulations (Environmental issues, private ordinances)" at the top right; "OSHA requirements (OSH and other safety concerns)" at the top; "Procurement, IT, and other admin. policies" at the top left; and "Requirements (Training, performance, etc.)" on the left side.

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

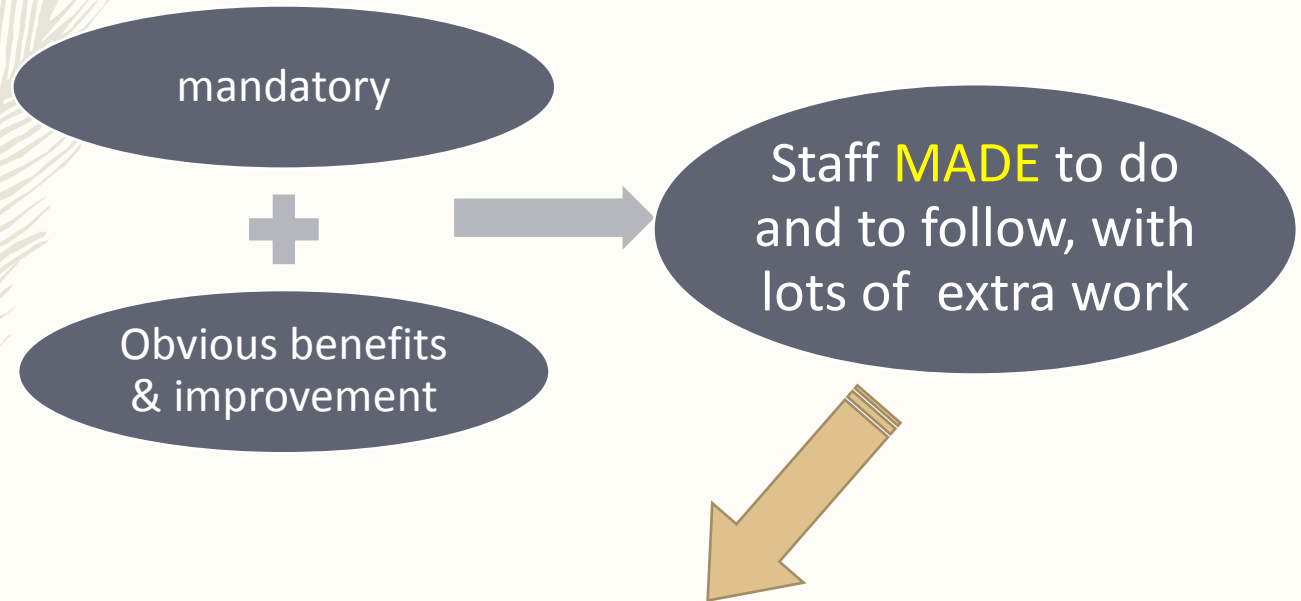
Traceability

Full
documentation
& records

Measurement
uncertainty

Cultural change :

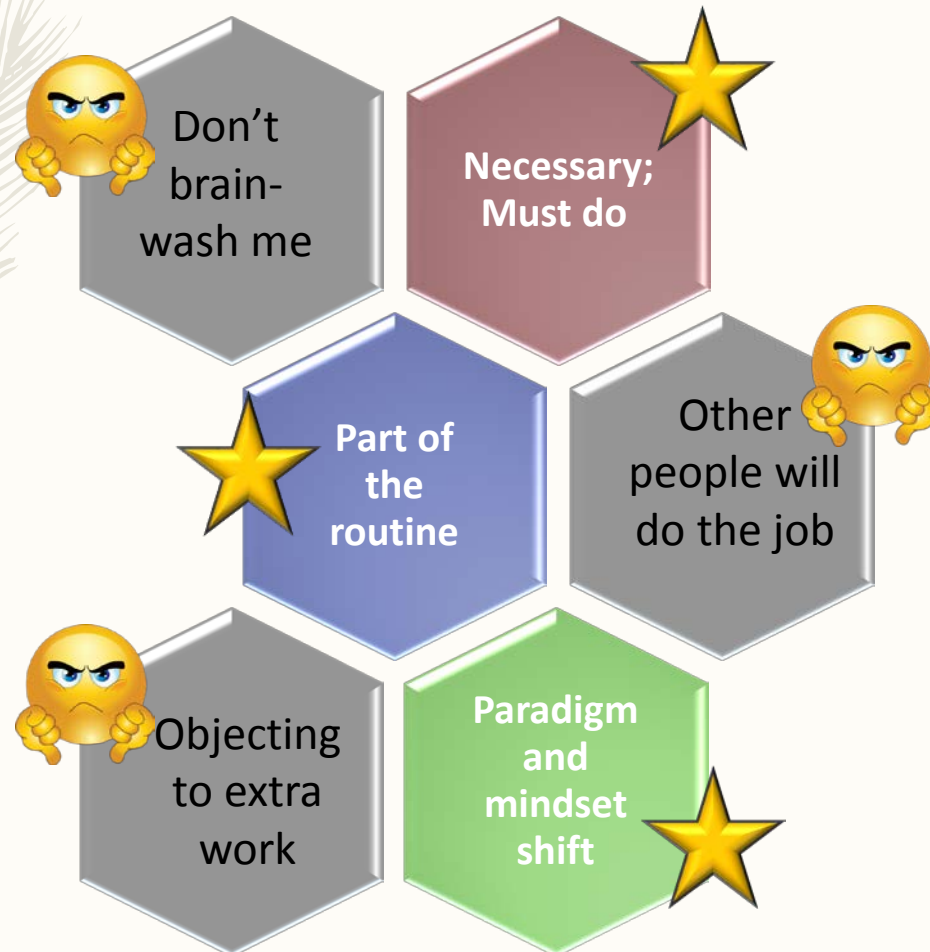
At the beginning :



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

Specimen retention


- Such that residual materials were available for DNA studies
- Such that all the remaining materials from cases processed before and after the index case could be retrieved

Specimen reception

- No ambiguity in labeling and identification

Traceability in all processes

- Facilitated investigation and evidential for the absence of the mix-up faults



A glimpse of the routine work in an accredited lab

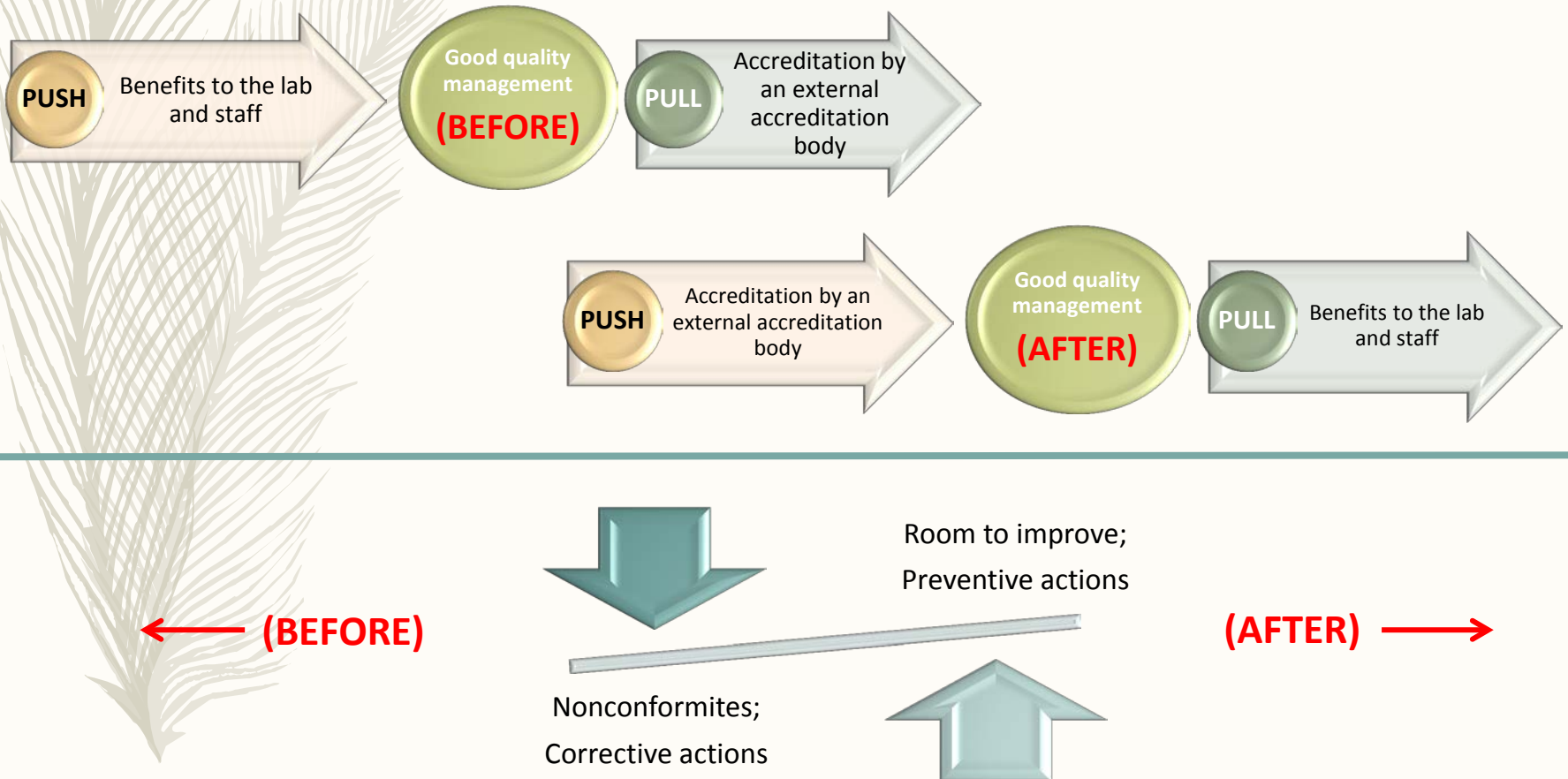
– Forms and logsheets

100+ for each lab

– SOP

~ 100 for each lab

What have been achieved ?



Way to consider further improvement in an accredited lab



Traceability
necessary

• ?
Computerization

smarter way
to meet all the
requirements

• Lean
management

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



In the **curriculum** in undergraduate program

A usual **interview** question in the selection board

Benefitting from the more structured on-the-job training system

Built-in practice in the lab : documentation, calibration, CQI, internal audits, etc.



Thank You !