

هيئة التقييس  
لدول مجلس التعاون لدول الخليج العربية  
GCC Standardization Organization



## **ISO/IEC 17025: Lead Assessor of testing & calibration laboratories**

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## ISO/IEC 17025: Lead Assessor of testing & calibration laboratories

*Who's who ?....*

Who am I ?

Laboratory Management Senior Expert (INEXSE Company)

Independent Consultant for major accredited Labs in France

Official Assessor for French Committee of Accreditation (COFRAC)

Official Assessor for Luxembourg Committee of Accreditation (OLAS)

Director of the main analytical lab in France for 5 years (400 people)

Director of analytical Lab in Pasteur Institute for 15 years

Expert for WHO, EC, AFNOR and CEN, IOW, FAO and World Bank

## Summarize

Sunday	Introduction and Management requirements
Monday	Management and Technical requirements
Tuesday	Technical requirements
Wednesday	Exam and correction
Thursday	Visit of the lab and Game

## Scope and topics

- Know the major topics of Management and Technical requirements
- Be able to define a non-conformity (NC) correctly
- Be able to validate the answer of the lab to NC
- Be able to study a case in audit situation

Formal slide exhibition

Numerous examples of (potential) NC

Study of cases, Study of pictures

Study of answers from the lab

Audit simulation

## Introduction :

What is the difference between accreditation and certification ?

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### Certification

insurance, given by a third party, that a product, a service, or a system, is **conform** to specific requirements.

*This insurance is formalized by a written document (certificate)*

## Introduction :

What is the difference between accreditation and certification ?

### Accreditation

Recognition, given by a third party, of the **competency** of an organization in a dedicated field of activity.

*Giving credit is giving confidence*

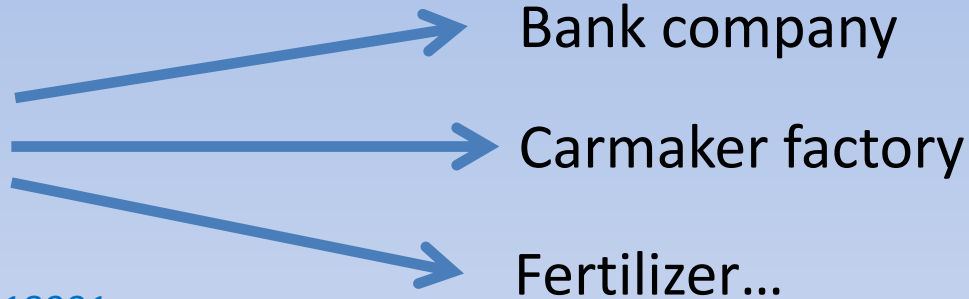


## ISO/IEC 17025: Lead Assessor of testing & calibration laboratories

### Introduction :

Certification

*ISO 9001, ISO 14001, ISO 18001*



*EMCO Qatar is 9001 certified*

Accreditation

*ISO 17025, ISO 15189*



**LABS**

*PO4 analysis in fresh water according to ISO 6878 is accredited*

## Introduction :

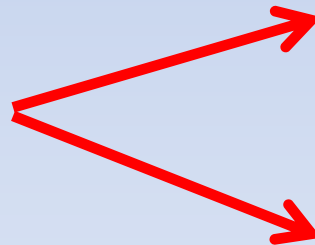
**Certification**



Conformity to a reference document  
(standard)

*ISO 9001, ISO 14001*

**Accreditation**



Conformity to a reference document  
(standard)

Assessment of knowledge  
(competency)

*ISO 17025*

## Introduction :

What is (are) the reason(s) why your lab should be accredited ?

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What is (are) the reason(s) why your lab should be accredited ?

- Give confidence in the work we do
- Increase the relationship with our customers
- Need for international recognition
- Facilitate the deal between countries

## Introduction :

What is (are) the reason(s) why your lab should be accredited ?

- Enhance the general level of knowledge of the lab
- Bring an obvious bonus to a competitor
- Label an unknown activity
- It's the latest fashion

ex : in France 1 ENV Lab accredited in 1990  
130 Labs in 2013

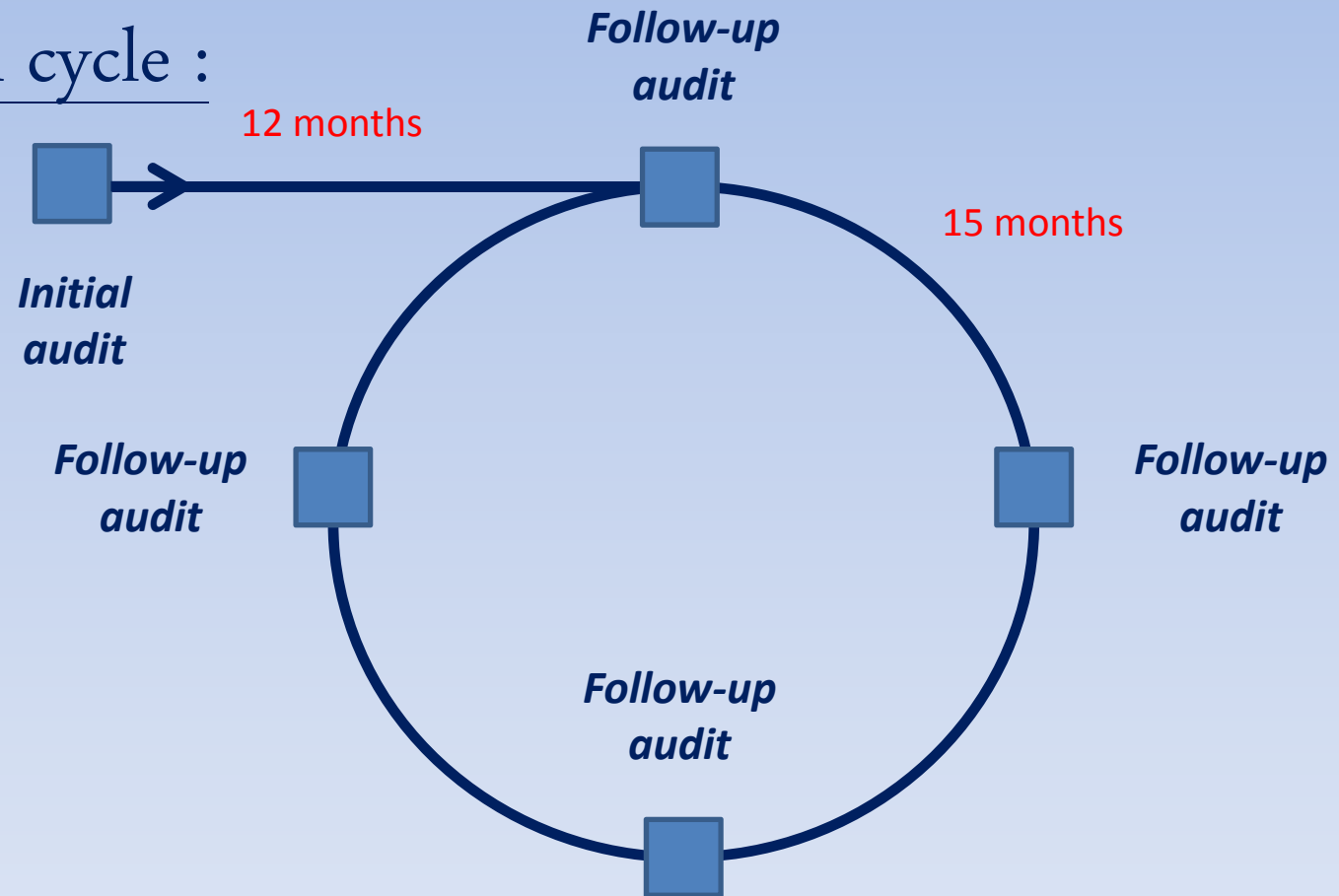
## Introduction :

What is (are) the reason(s) why your lab should be accredited ?

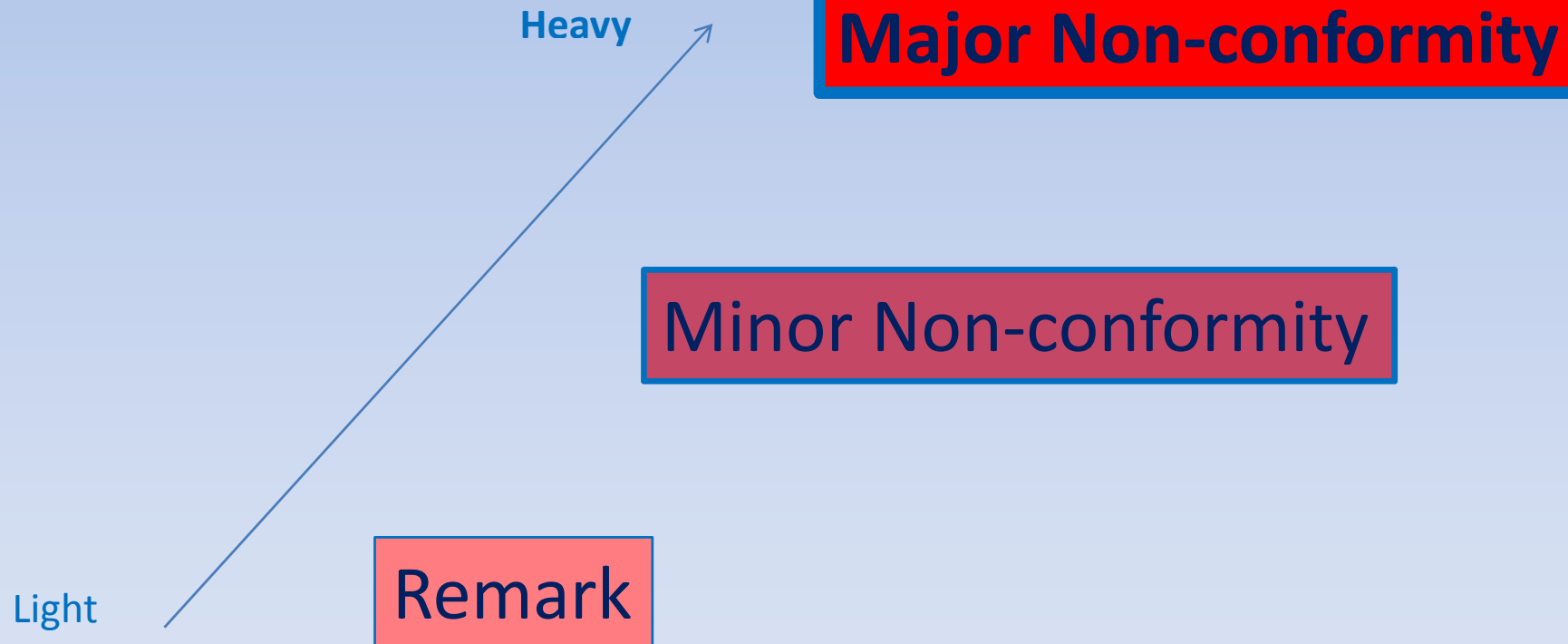
- It protects the lab
  - ex : client's complaint
  - when appearing in court
- It's the only way to keep working
- Should promote the motivation of the personnel through a team project of (re)organization and competency promotion

## ISO/IEC 17025: Lead Assessor of testing & calibration laboratories

### Accreditation cycle :



## Non conformity weight :





## Non conformity weight :

- Impact on the final result
- Do not match with major requirements

**Major Non-conformity**

- Do not match with minor requirements
- Default of formalization

**Minor Non-conformity**

- No impact on the organization, but this tool is used by the assessor to ensure the necessary change will be made.

**Remark**

## Behaviour of the assessor (auditor) :

*The assessor is an expert, and considered as a **reference**.*

- ☐ He/she is the representative of an official organisation
- ☐ He/she must be **impartial**. Its judgment must target a SYSTEM and not the PEOPLE
- ☐ He/she must be **fair**
- ☐ He/she must assess the **consistency** (coherence) of the system
- ☐ He/she must not try to compare with its own requirements

## Description of a non-conformity (NC) :

*The NC is used to report to the accreditation body committee.*

- ☐ It must be **factual**
- ☐ It must never be **nominative** or **comparative**
- ☐ It must be **clear**
- ☐ It must not contain any **opinion** or **advice**
- ☐ It must be **accurate**
- ☐ It must give detail of the **risk assessment** of the fact

## Exercise 1 on non-conformity (NC) :

“ The lab should increase the number of bench in its technical rooms to ensure more comfortable work for its personnel.”

**NC ?**

Exercise 2 on non-conformity (NC) :

“Mrs Naima is in charge of the tests, as well as deputy for Metrology correspondent and deputy of the Quality correspondent. This accumulation of tasks for the same personnel is uncomfortable as inefficient.”

**NC ?**

Exercise 3 on non-conformity (NC) :

“This lab operates control of the balances once a year, while the other labs generally do it once a month.”

**NC ?**

Exercise 4 on non-conformity (NC) :

“The Quality Manager is in charge of regular control of the list of “opened” non conformity which has to be operated once a month, but during her last seek leave, she delayed this operation and controlled the list only once for the next two months although it should be done monthly.” **Acceptable NC ?**

Exercise 5 on non-conformity (NC) :

“The document ref LAB/CHEM/REC-002 used as a record for the daily control of the temperature of the fridge N° F/CHEM 001 has been initially used on 21/02/2013. The validation of the template of this document has been validated by the Quality Manager on 06/03/2013.” **Acceptable NC ?**



Exercise 6 on non-conformity (NC) :

“The Emirati accreditation body will never accreditate a company which doesn’t accept that its customers visit its lab.” **NC ?**

Exercise 7 on non-conformity (NC) :

“An internal NC (ref LAB/BIO/NC-021) has been formalized and correctly solved two days later. The QM didn't sign it up yet (after 3 months).”

**NC ? If yes, kind of NC ?**

Exercise 8 on non-conformity (NC) :

“The lab didn’t send its Quality Manual to the assessor three weeks before the date of audit, in accordance with the requirements of the accreditation body.” **NC ? If yes, kind of NC ?**

Exercise 9 on non-conformity (NC) :

“Mrs Aicha is more competent than Mrs Warda.”

**NC ? If yes, kind of NC ?**

Exercise 10 on non-conformity (NC) :

“Sometime, the lab accepts samples with no form from some of its clients.”

**NC ?**