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Implementing good laboratory practices and quality control in routine and research laboratories

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► **To cite this version:**

Nopmanee Suvannang, Christian Hartmann. Implementing good laboratory practices and quality control in routine and research laboratories. Engineering school. Laos. 2018. cel-02123672

HAL Id: cel-02123672

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Submitted on 8 May 2019

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Workshop on:

**“Implementing
Good Laboratory Practices & Quality Control
in routine & research laboratories”**

28-30 August 2018 – Vientiane (Lao PDR)

**Mrs Nopmanee Suvannang
Dr Christian Hartamn**

Context

Many important decisions are based on the results of laboratory analysis.

Thus, it is important to have some indications on the quality of the results, i.e. how much your clients can trust your result to make a decision.

Context

Many important decisions are based on the results of laboratory analysis.

Thus, it is important to have some indications on the quality of the results, i.e. how much your clients can trust your result to make a decision.

With globalisation, the lab managers are coming under an increasing pressure:

- (i) to demonstrate the quality of their results and**
- (ii) to demonstrate their results can be compared to results obtained by other laboratories.**

Objectives of the workshop

- 1. Explain the concepts of 'error' and 'good data';**
- 2. present 'Good Laboratory Practices' (GLP);**
- 3. present Quality Control (QC);**
- 4. assess the current procedures of Quality Control in some Lao & Thai routine and research laboratories, and how to improve them;**
- 5. see how develop a regional network of laboratories in order:**
 - (i) to exchange information between members
 - (ii) to link with administration and international partners.

1.
the concepts of 'error'
and of 'good data'

Introduction:

When you cook food, you like to do it correctly, to have good food that everybody like it and enjoy.



Introduction:

When you do chemical analysis, it is the same:



Introduction:

When you do chemical analysis, it is the same:

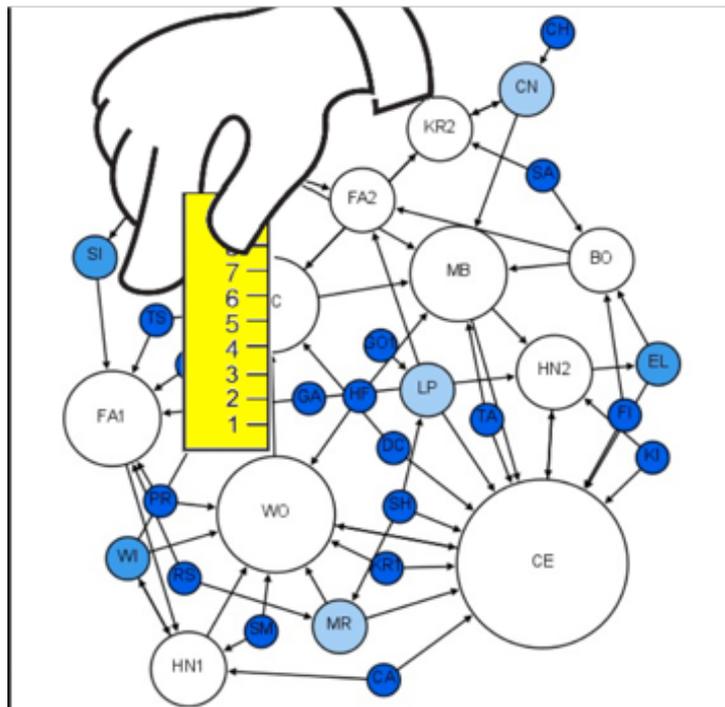
you want good results & happy clients.



How can you get good analytical results?

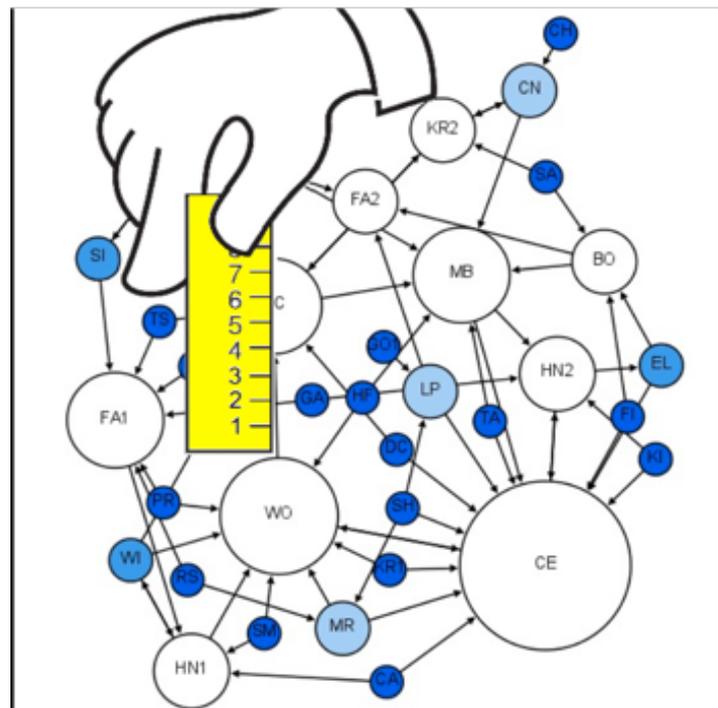
How can you get good analytical results?

Chemical analysis
=
MEASURE what is
inside your sample.



How can you get good analytical results?

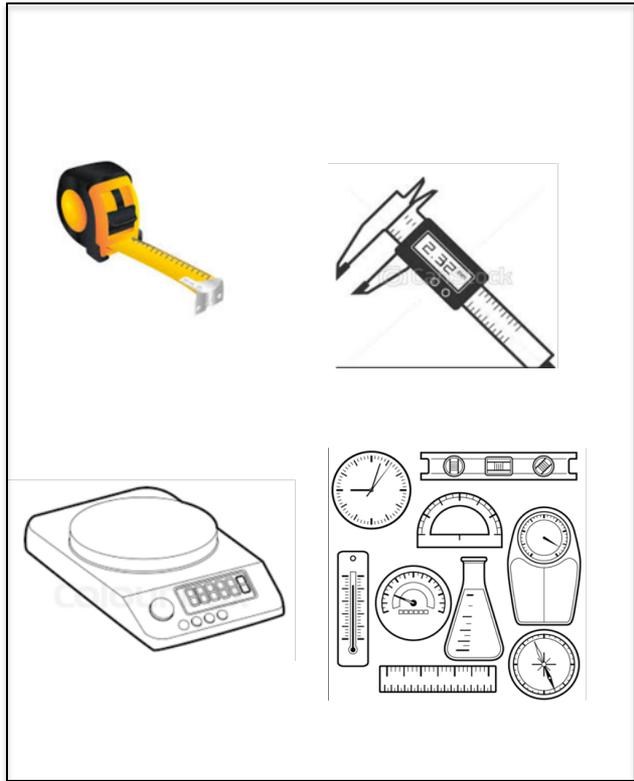
**Chemical analysis
=
MEASURE what is
inside your sample.**



you need firstly to do good MEASUREMENT !

MEASUREMENT:

People → **using** → **Instruments**



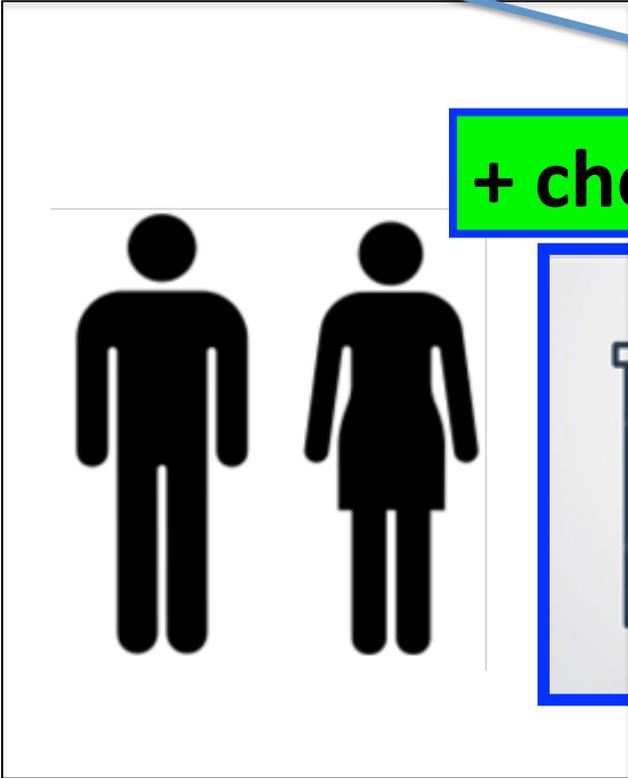
ANALYSIS:

People



doing

+ chemical reactions



ANALYSIS:

People

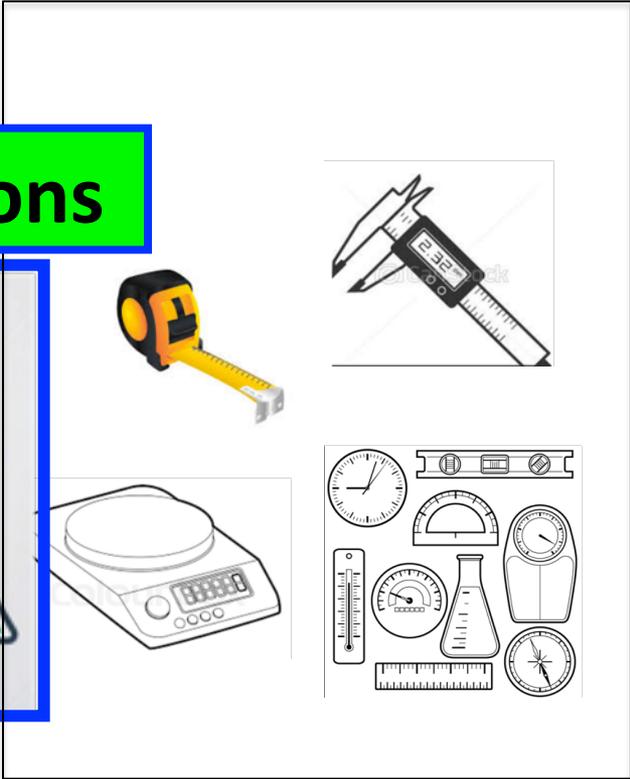
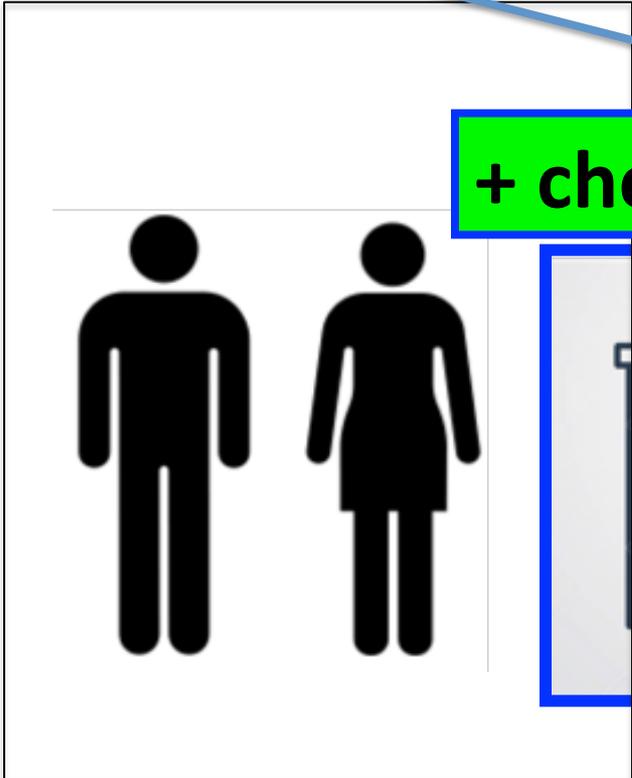
using



Instruments

doing

+ chemical reactions



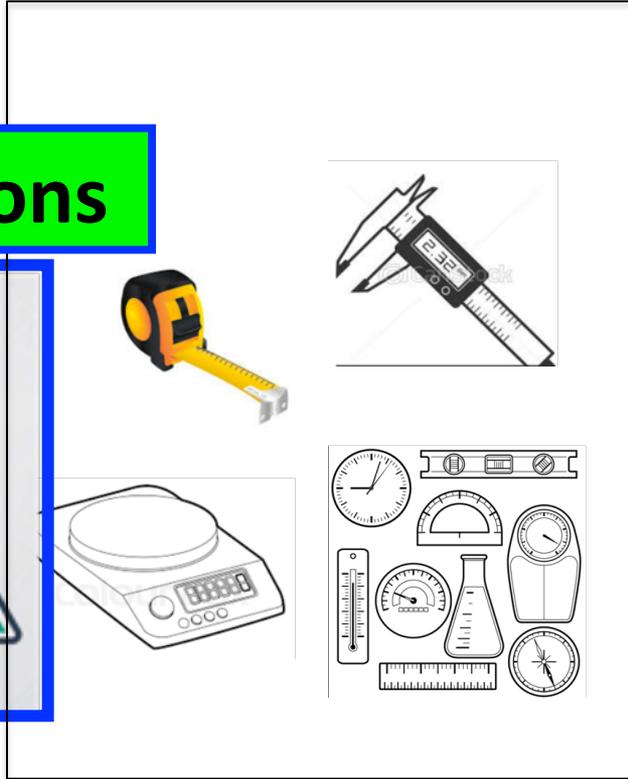
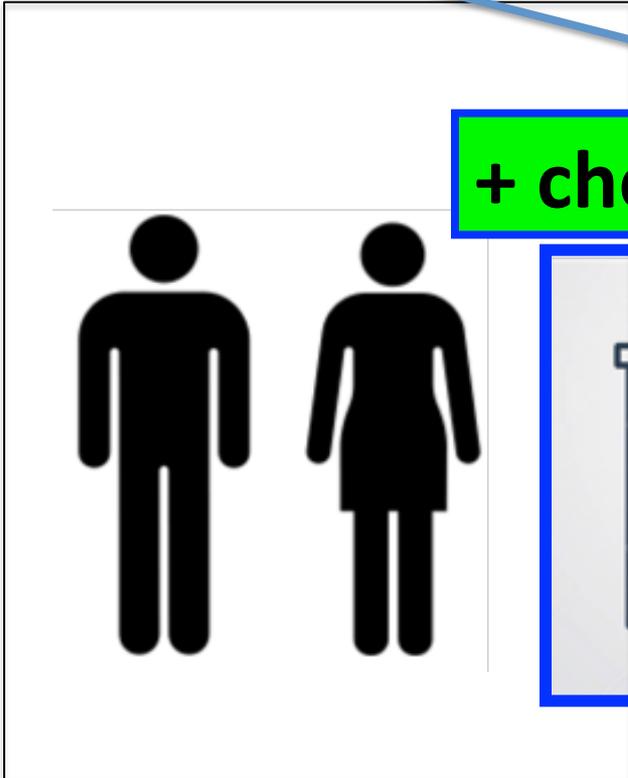
ANALYSIS:

People

using
doing

Instruments

+ chemical reactions



ANALYSIS= a complicate MEASURE

Firstly, let's speak about MEASURES

**Measures seems simple because....
everybody do it in everyday life.**

Firstly, let's speak about MEASURES

Measures seems simple because....
everybody do itit in everyday life.

Everybody can sing, but



Firstly, let's speak about MEASURES

Measures seems simple because....
everybody do it in everyday life.

Everybody can sing, but
not everybody can become a professional singer.



Firstly, let's speak about MEASURES

Firstly, let's speak about MEASURES

Everybody can measure, but...



Firstly, let's speak about MEASURES

Everybody can measure, but not everybody can do professional quality measures.



**If you do measures in a laboratory,
you need to be 'professional',**

and to know about the science of measurement:

METROLOGY.

**To demonstrate that it is not easy to make
professional measure**

**To demonstrate that it is not easy to make
professional measure**

Let's take an example using an egg...



To demonstrate that it is not easy to make professional measure

Let's take an example using an egg...





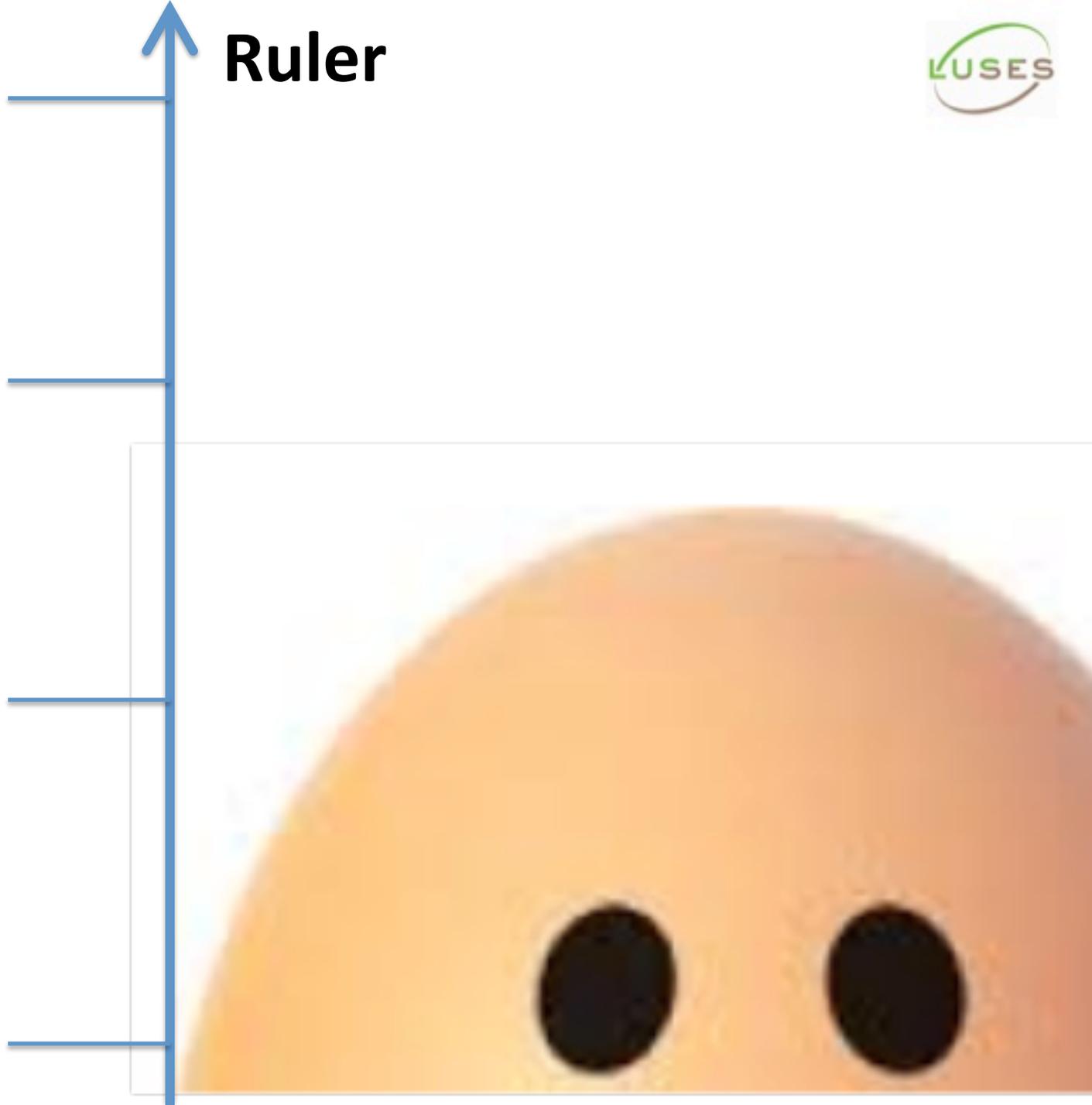
Results...

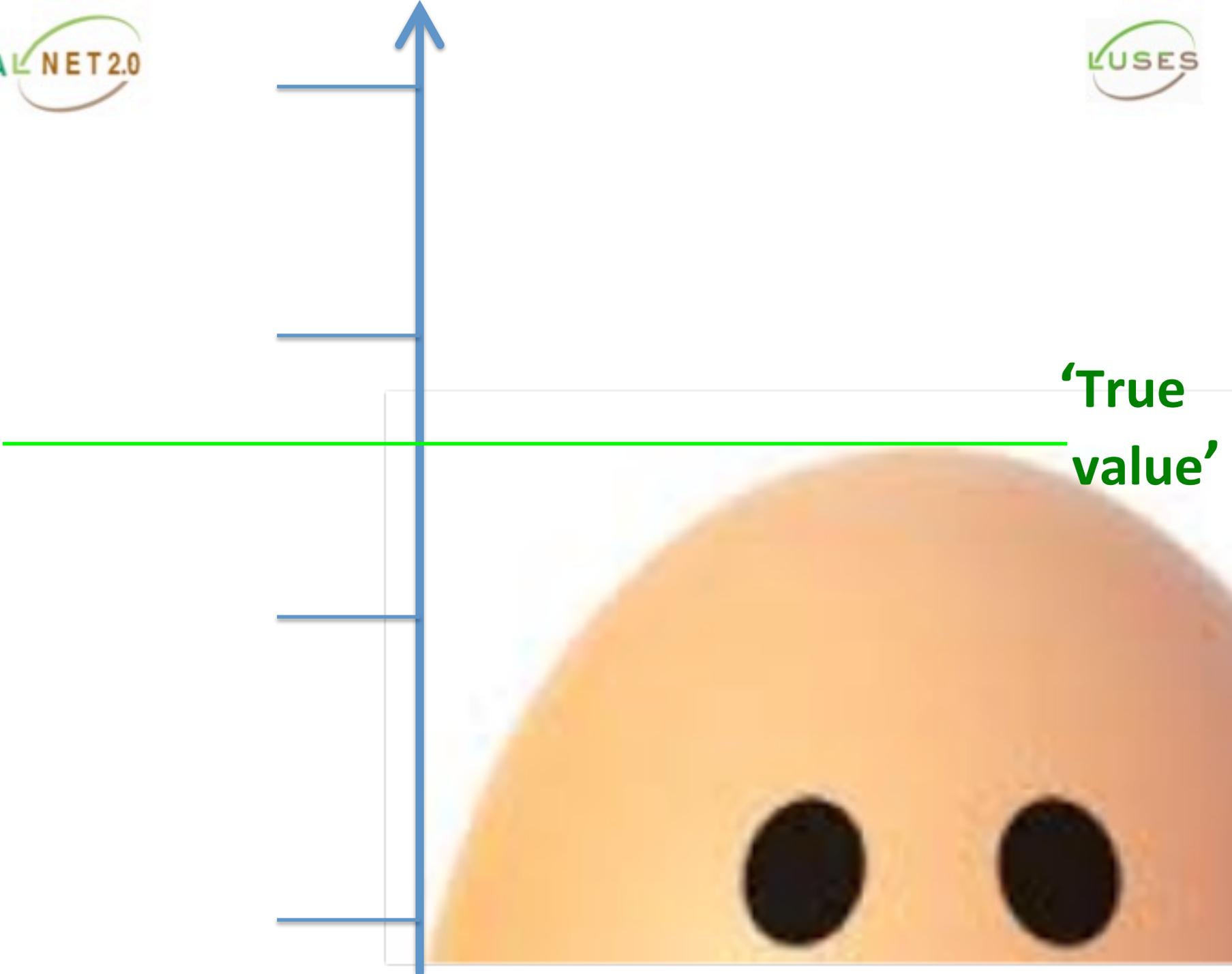


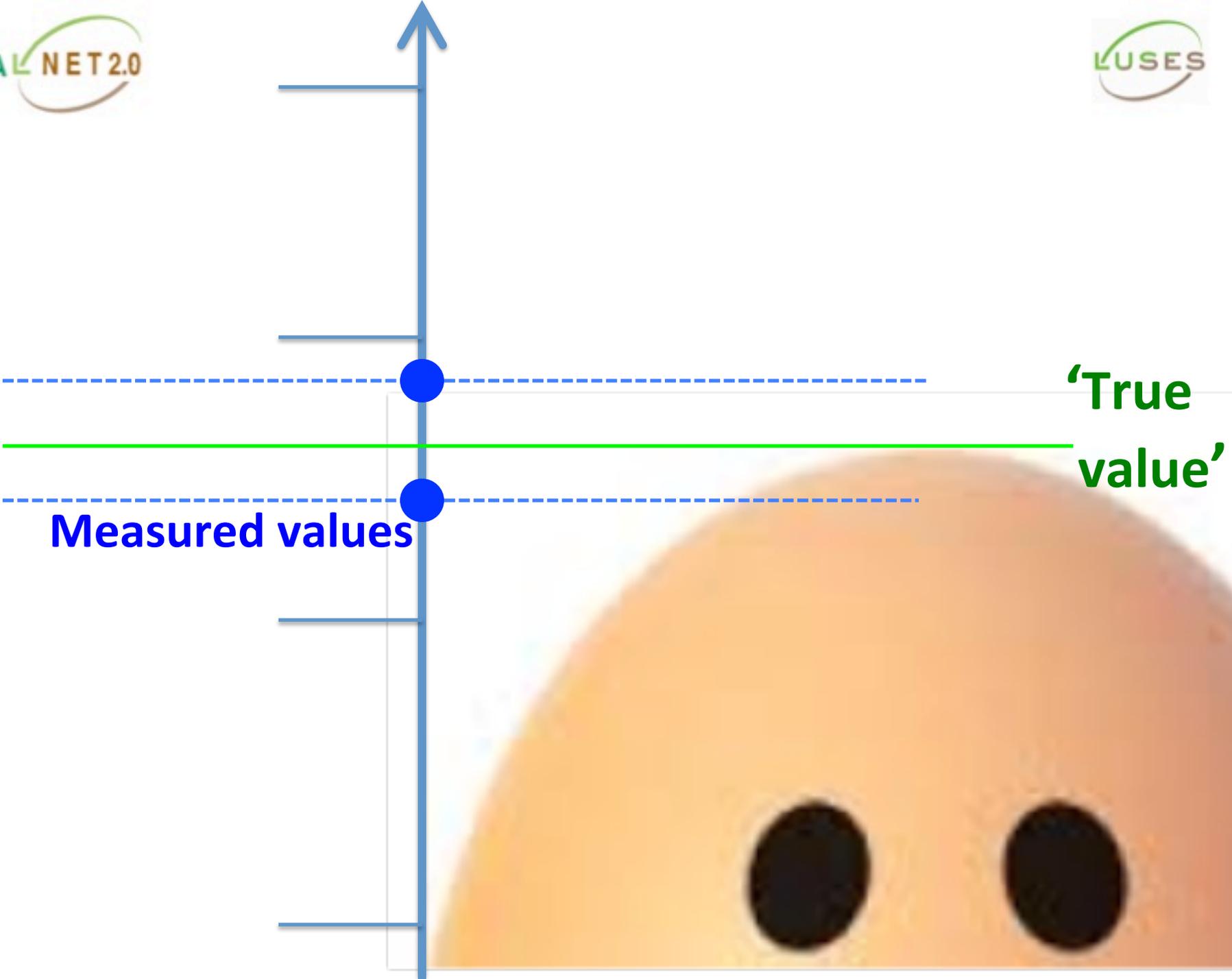
for one egg, one ruler,
but different people==> different measures.

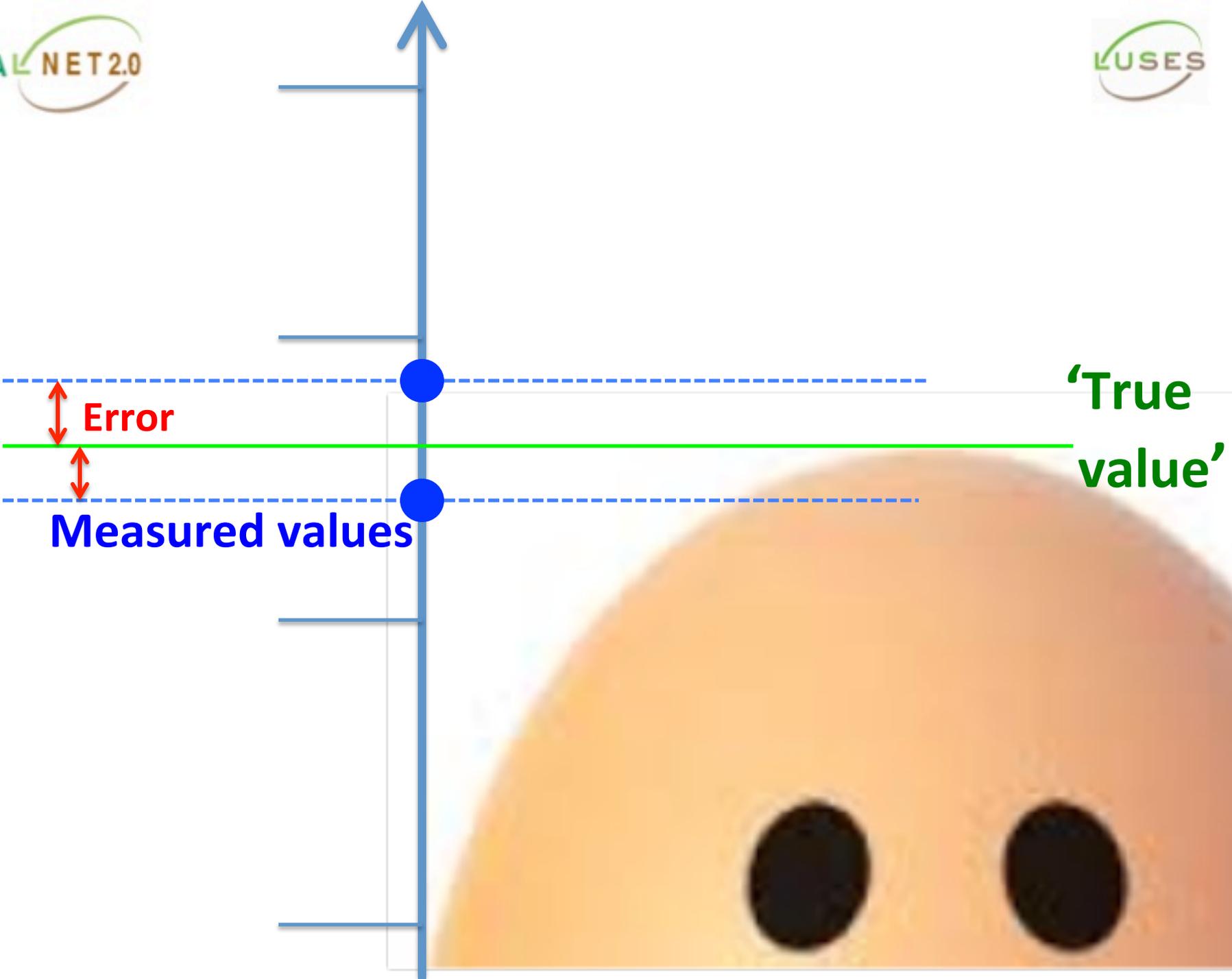
What happened?

Ruler





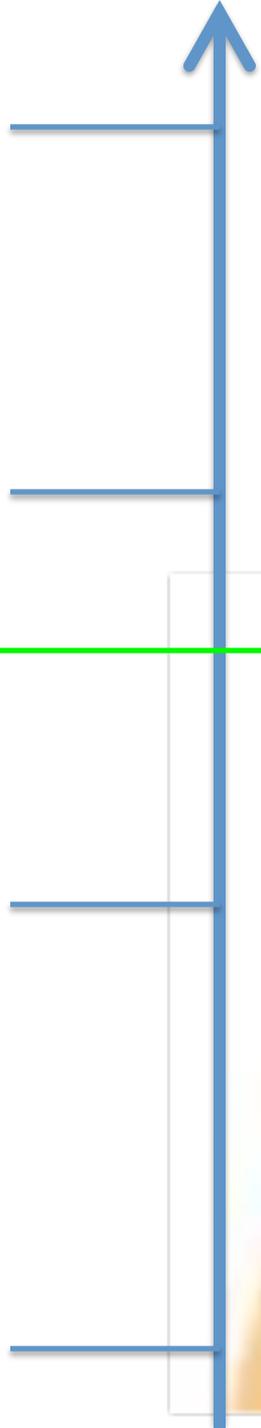




'True value'

Error

Measured values

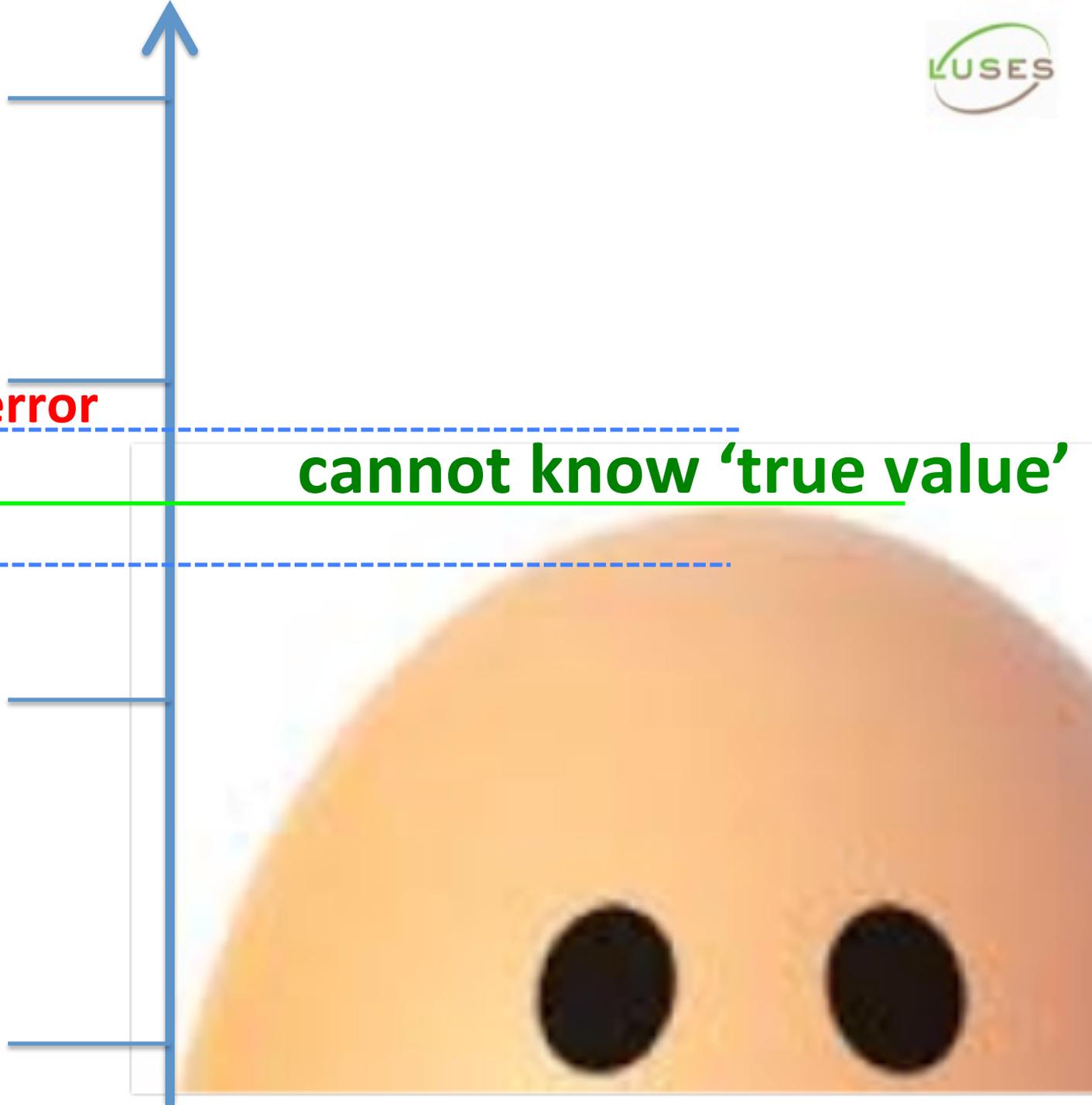
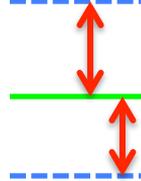


cannot know 'true value'

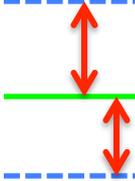


cannot know error

cannot know 'true value'

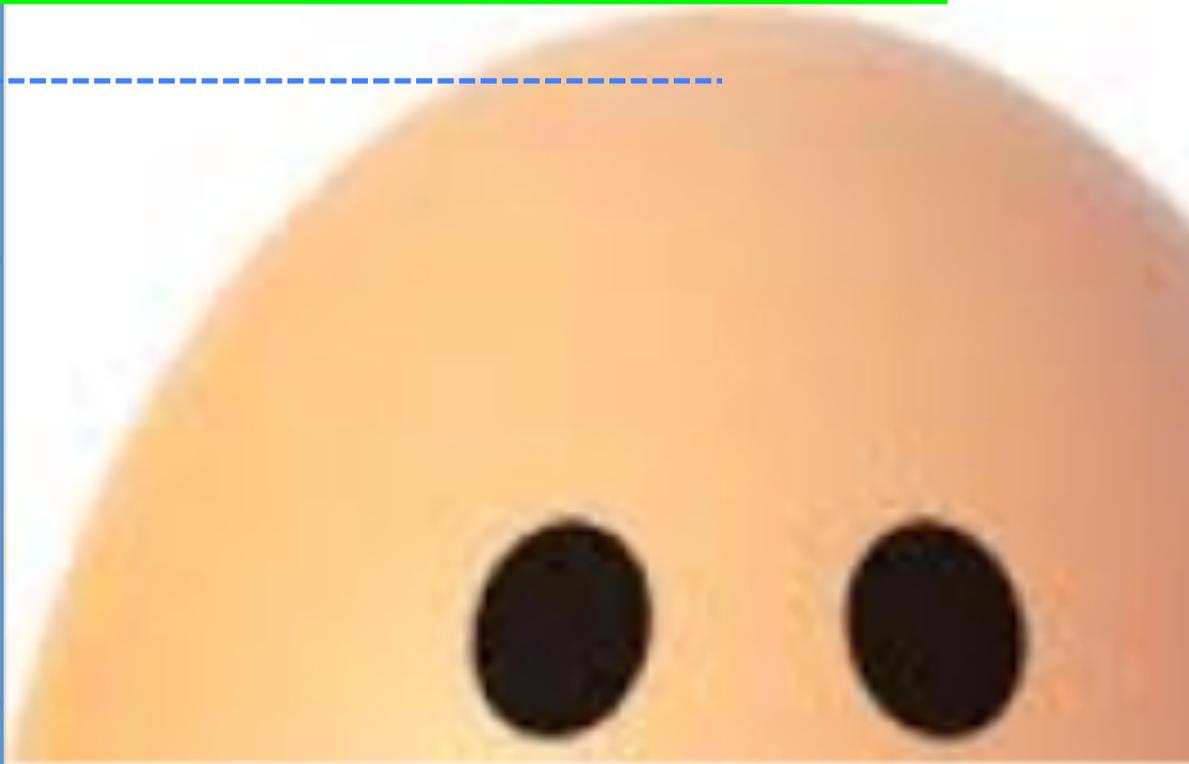


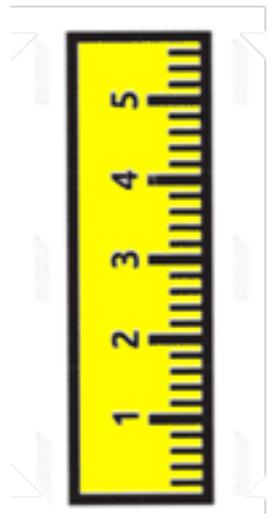
cannot know error



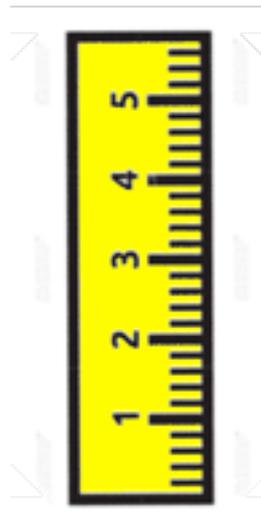
cannot know 'true value'

can only
minimise
the errors...



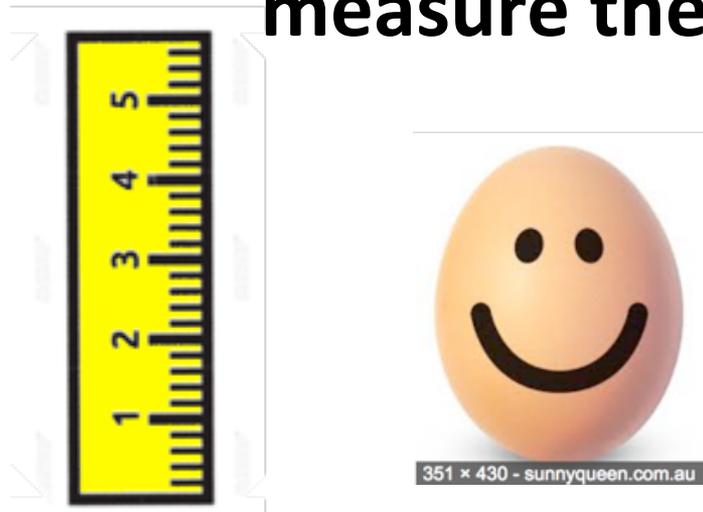


the egg has one size but...
we have different measures!



**METROLOGY teach us that
all measures contain errors.**

measure the egg....



METROLOGY teach us that
all measures contain errors:

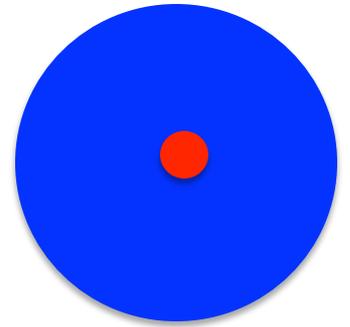
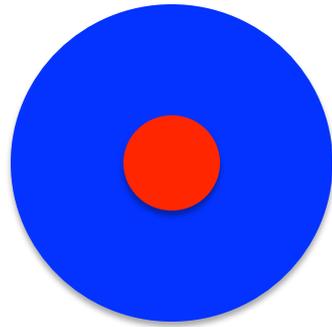
measure = true value +/- error

measure the egg....



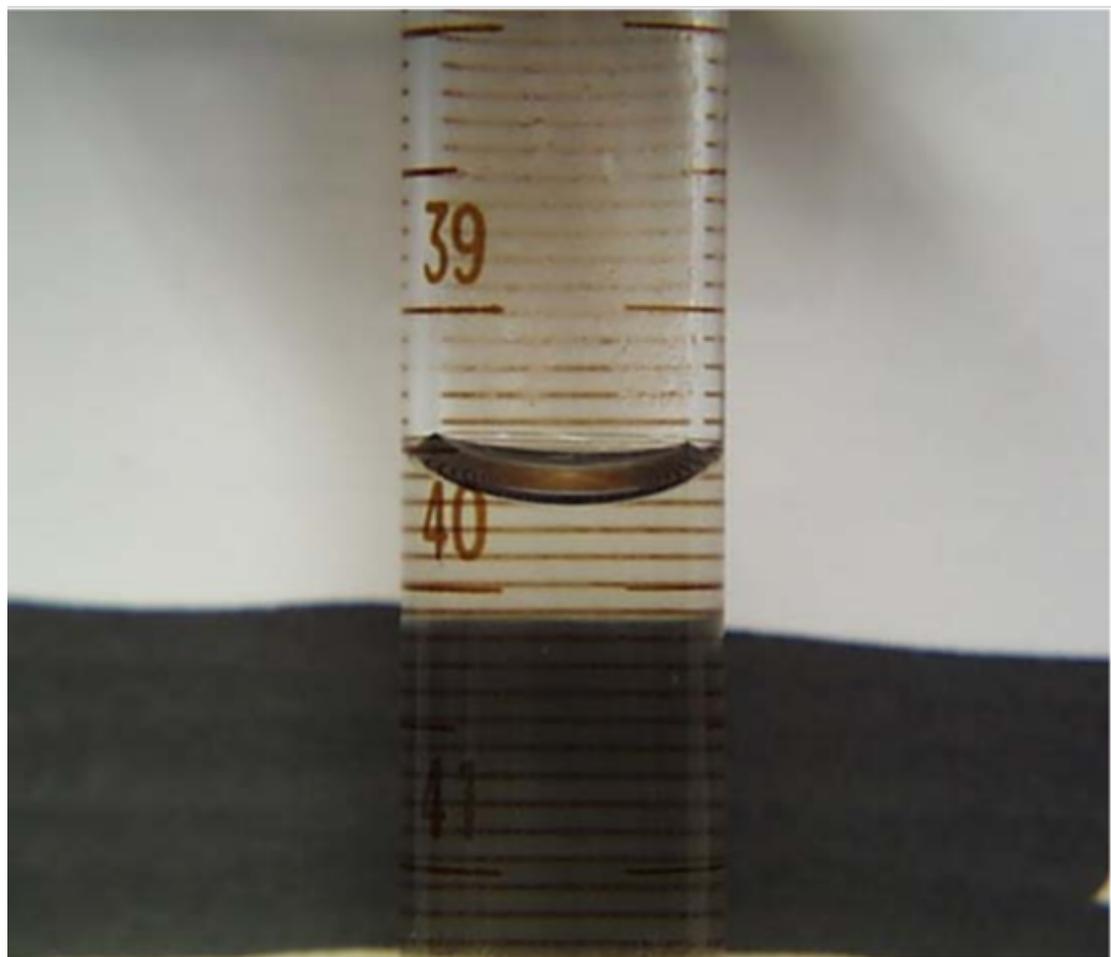
METROLOGY teach us that
all measures contain errors:

good measure = minimal error...



**Secondly, let's speak about
MEASURES in the laboratory...**

let's take the example of a burette



[Figure 20](#): Liquid in a Burette

How much do you read?

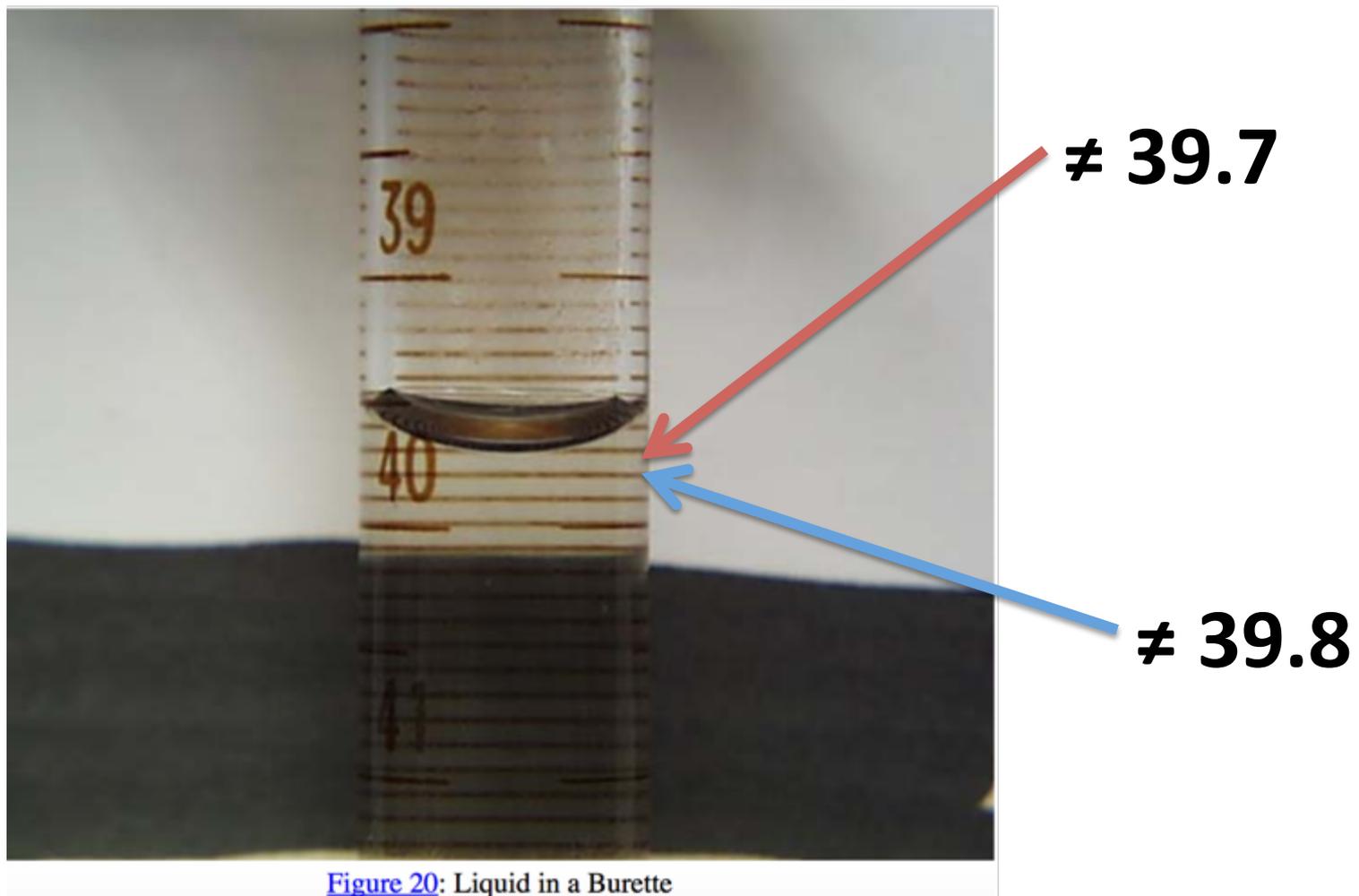
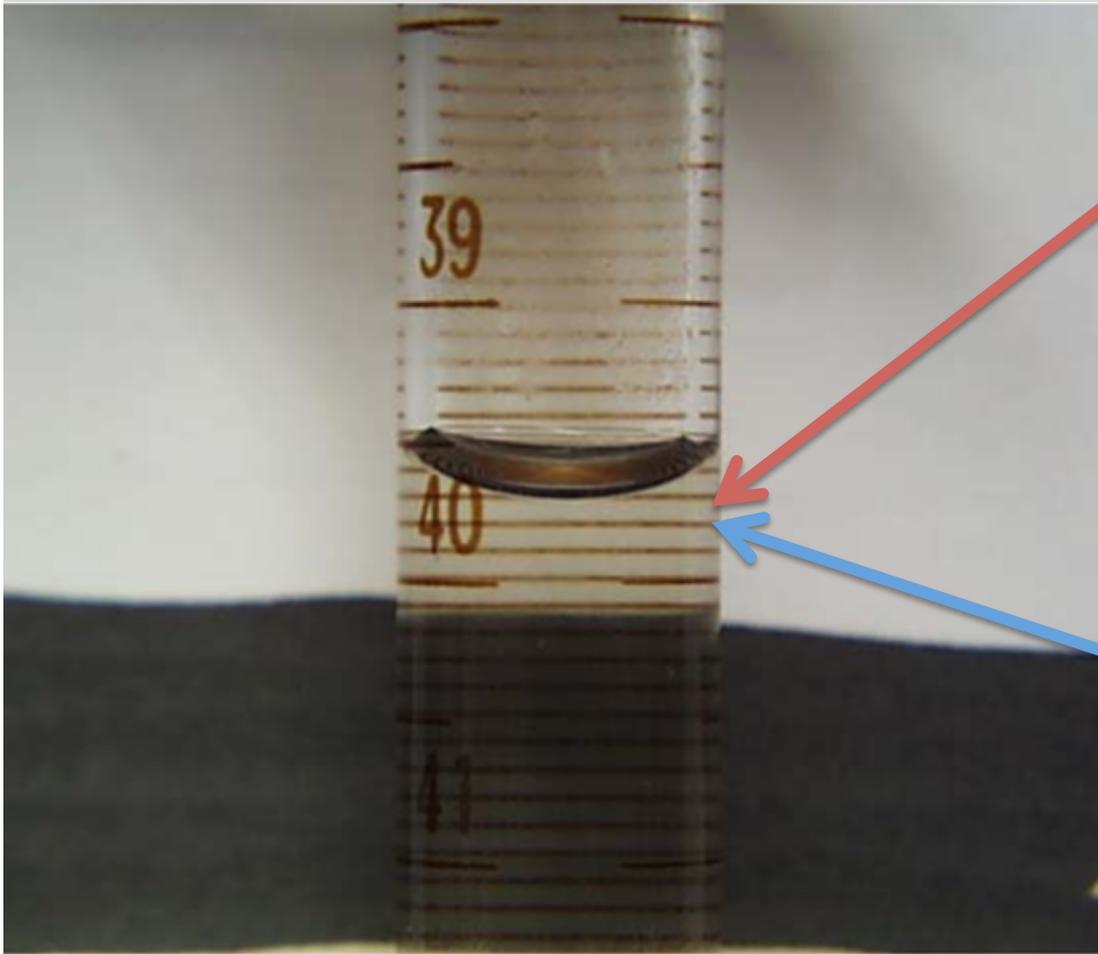


Figure 20: Liquid in a Burette



39.71?

≠ 39.72?

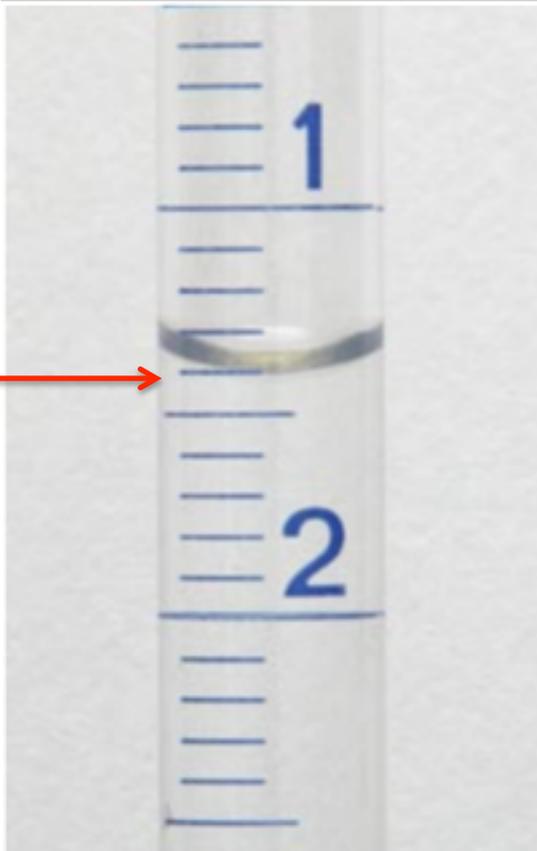
Figure 20: Liquid in a Burette

anyway my result will contain an error

Another example:

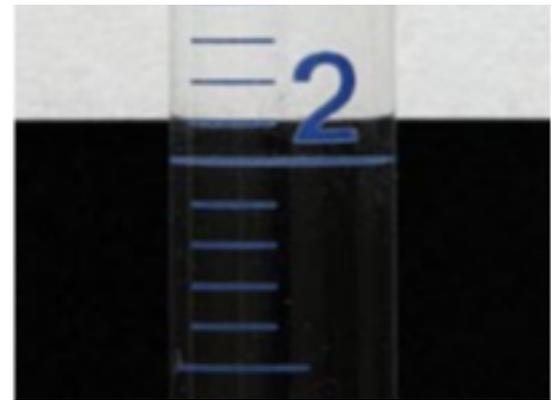


1.40 →

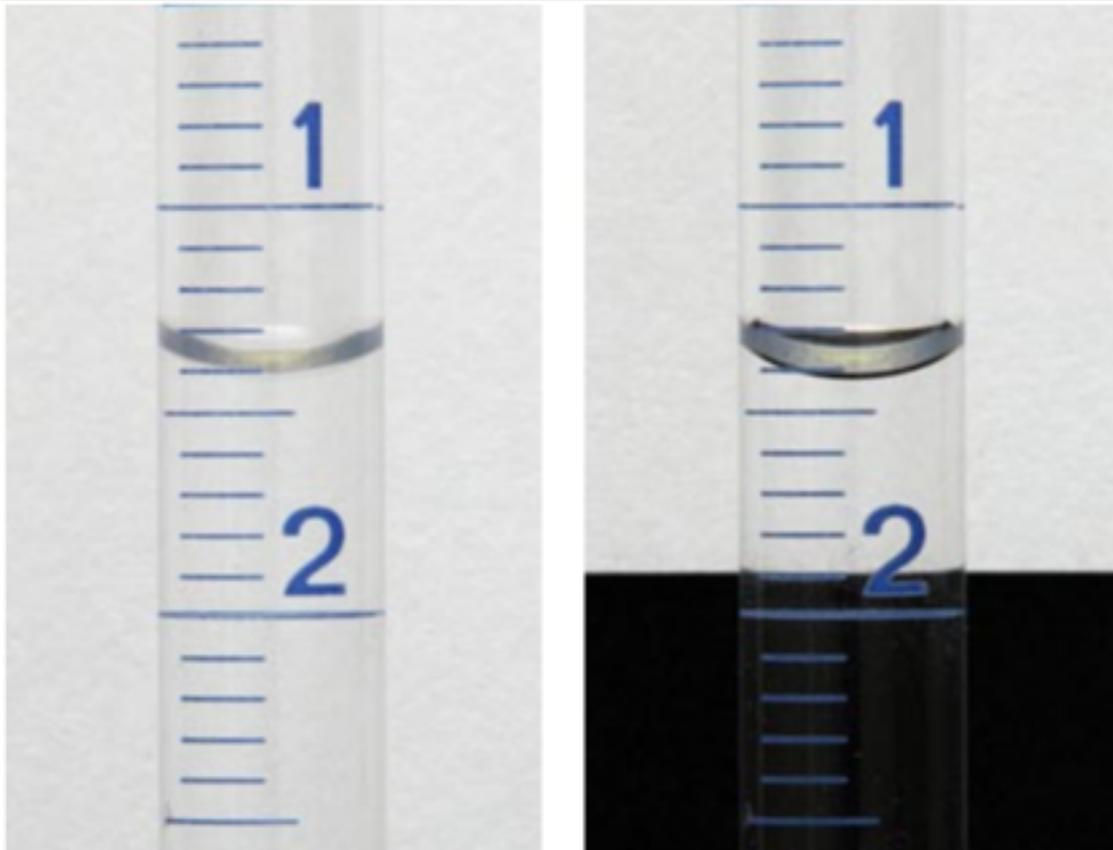


Error:

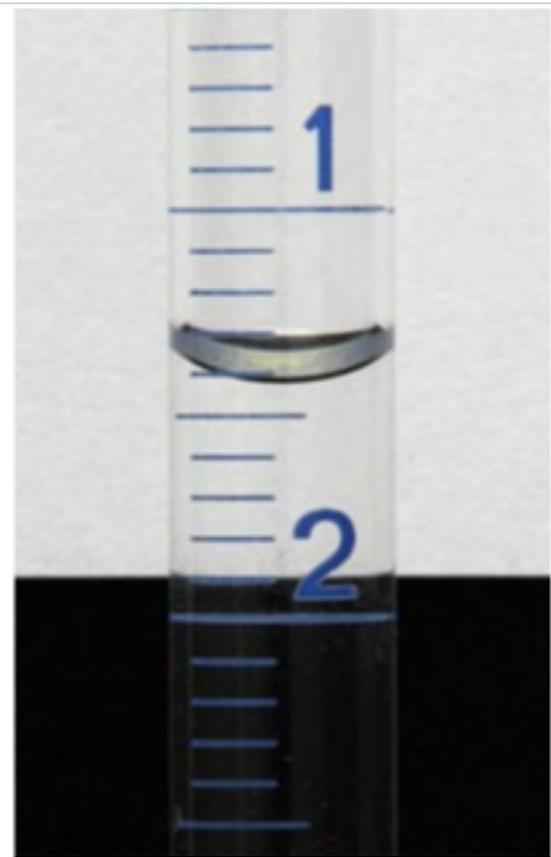
1.40



1.40



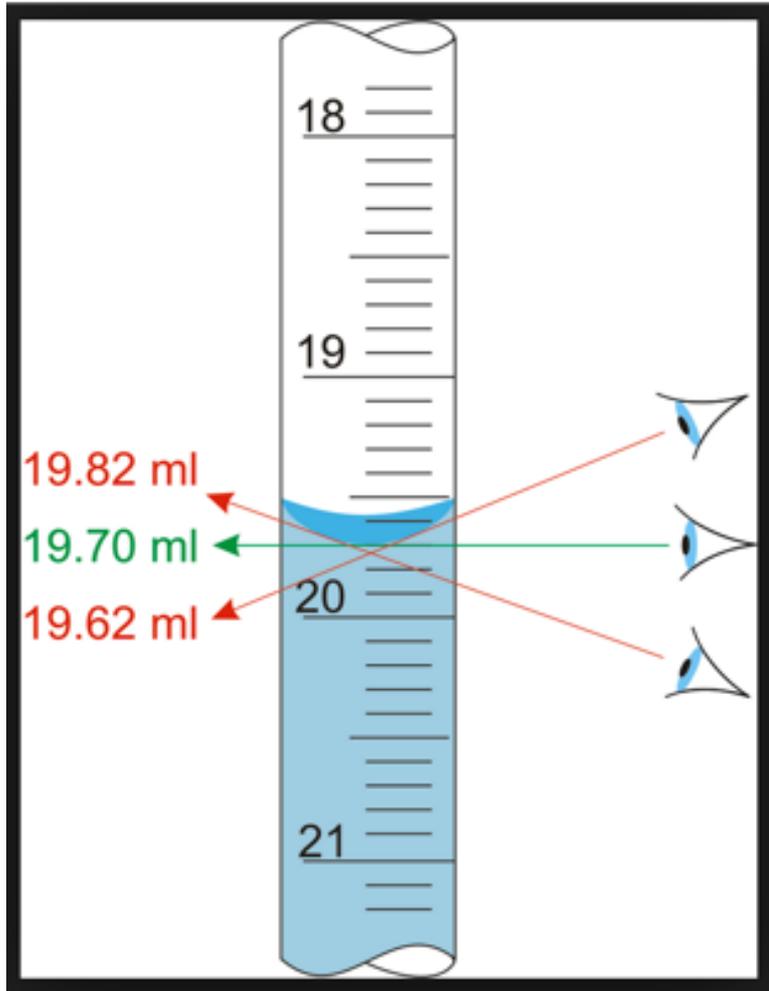
1.40



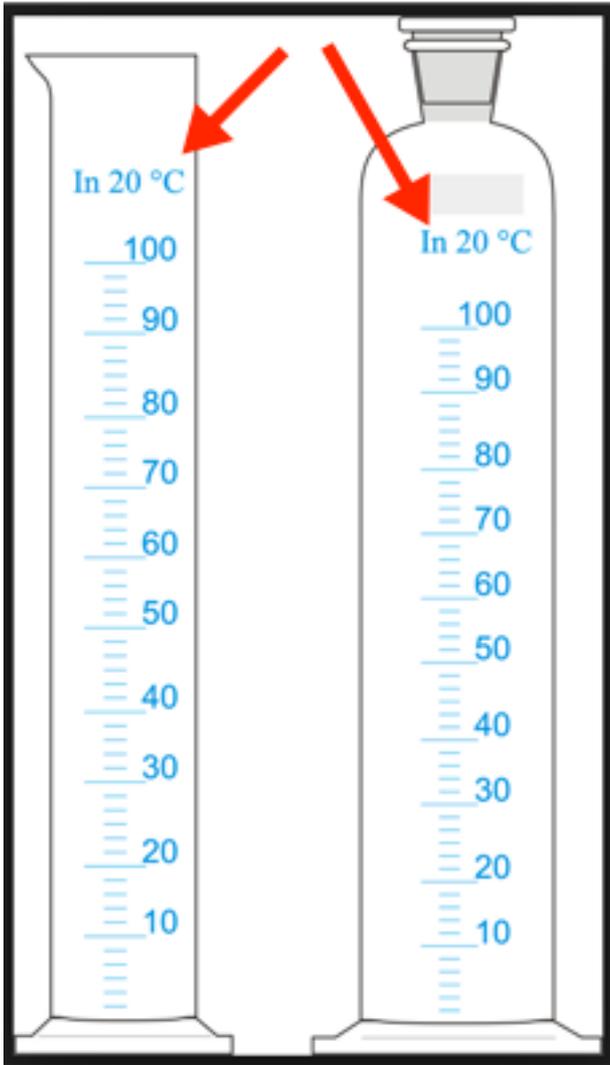
≠ 1.40



Error: coming from people



Error: coming from working conditions



Your objective:

**to get as close as possible from
the true value,**

that you can NEVER reach...

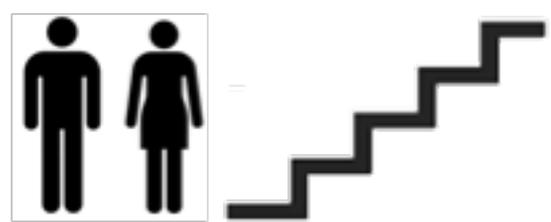
True value = middle of the target..



If you are a beginner:



SUCCESS



If you are a beginner:



you have to improve!

SUCCESS





after some training:

**after some training:
you can improve, having arrows together**



**after some training:
you can improve, having arrows together
but still not in the center, of the target**



**after some training:
you are more PRECISE**



after more trainings:

after more trainings:
PRECISE and ACCURATE!



after more trainings:
PRECISE and ACCURATE!



SUCCESS

congratulations



but if you stop training...

random again....



random again....



To describe the quality of analyses:

Precision: the closeness of the replicates.

Accuracy: the closeness to the "true" value.

Precision:

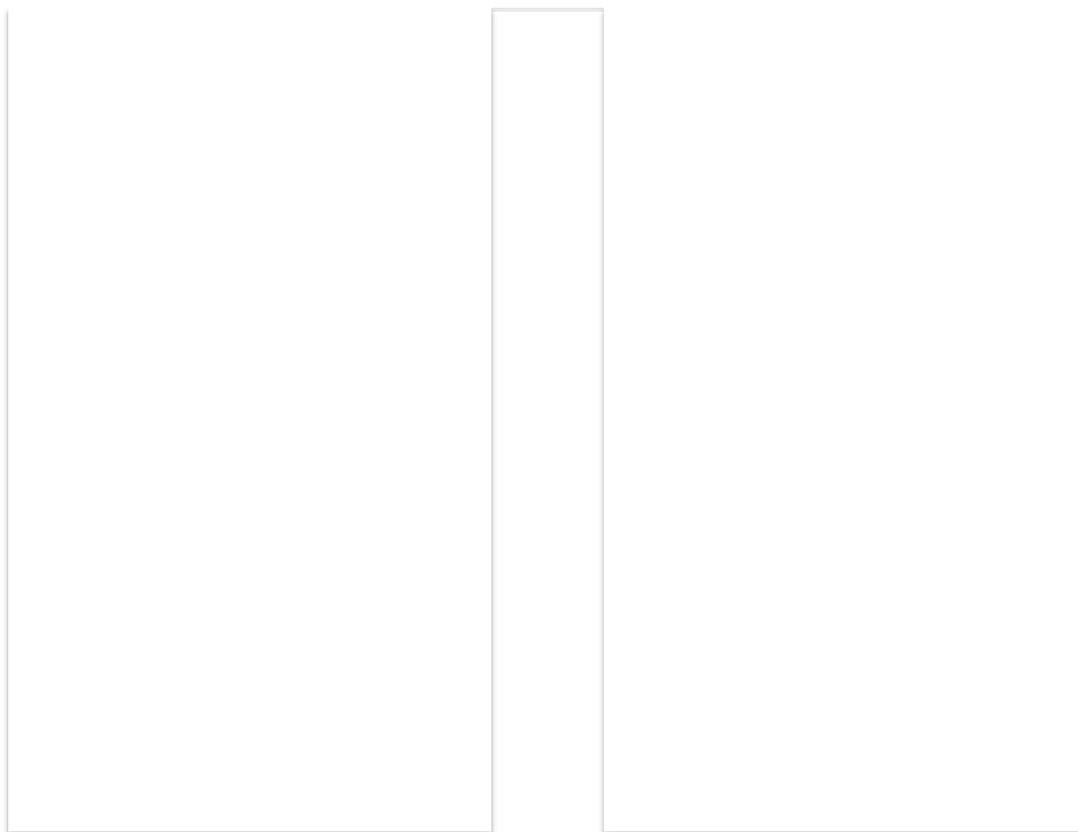
high

low

Accuracy:

high

low



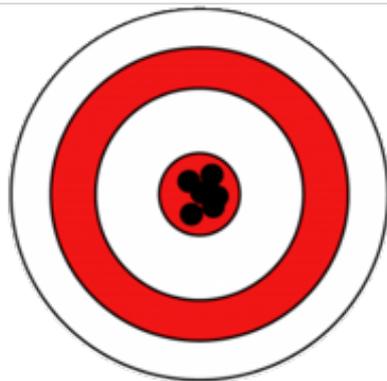
Precision:

high

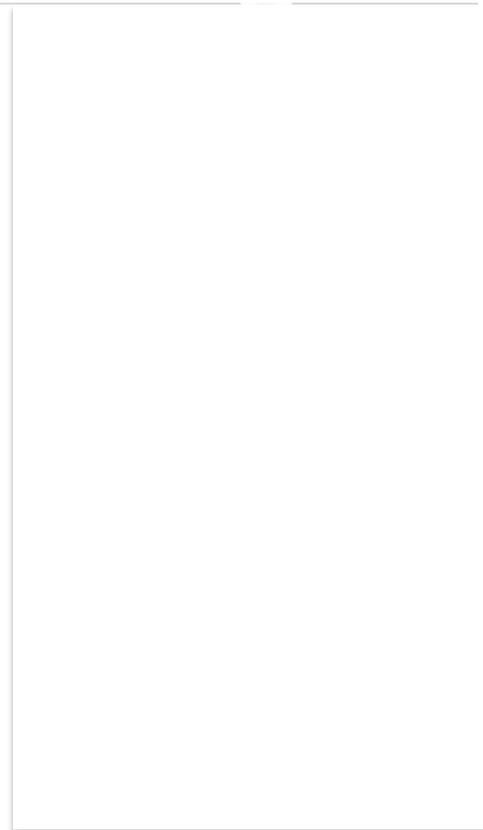
low

Accuracy:

high



low



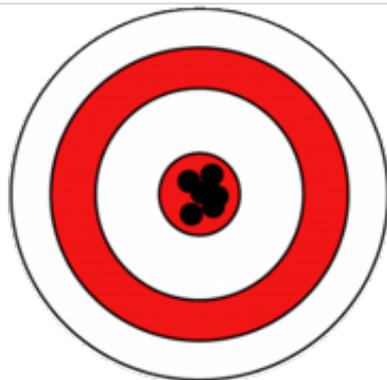
Precision:

high

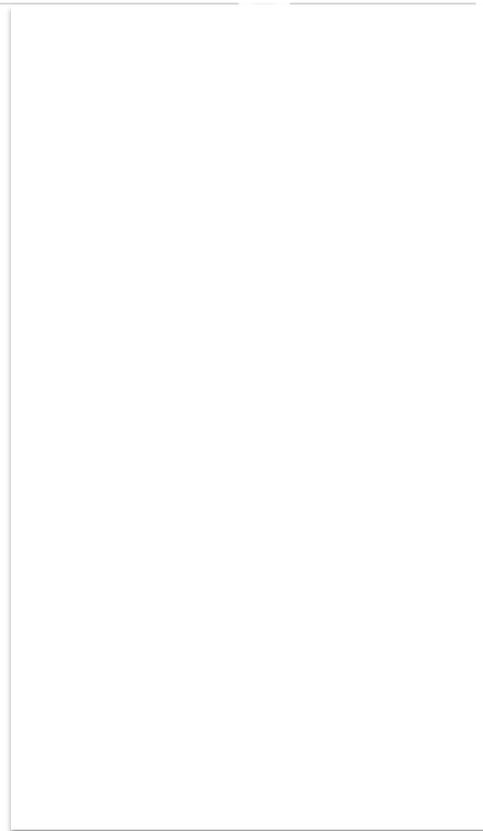
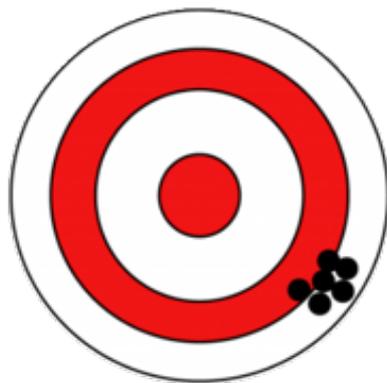
low

Accuracy:

high



low



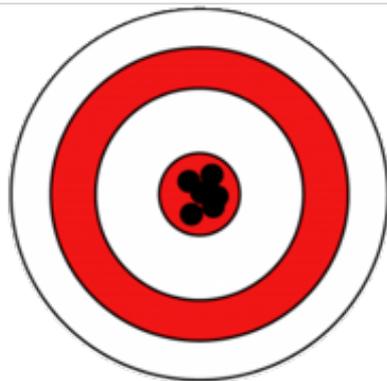
Precision:

high

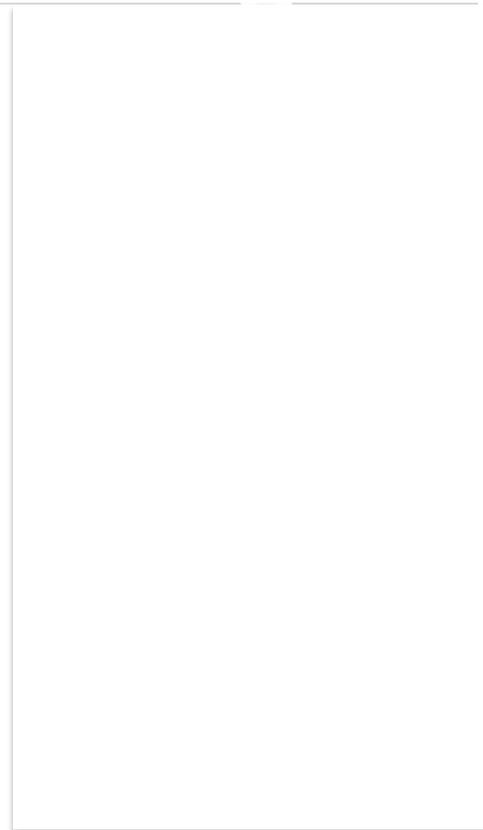
low

Accuracy:

high



low



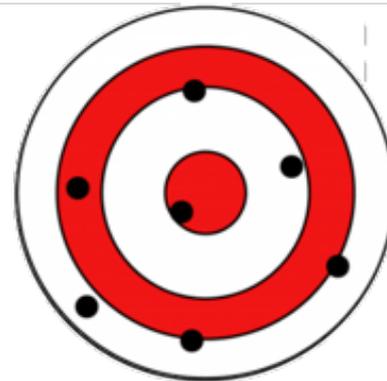
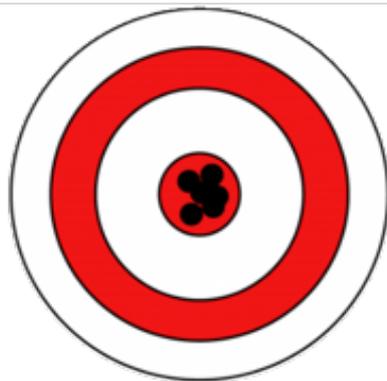
Precision:

high

low

Accuracy:

high



low



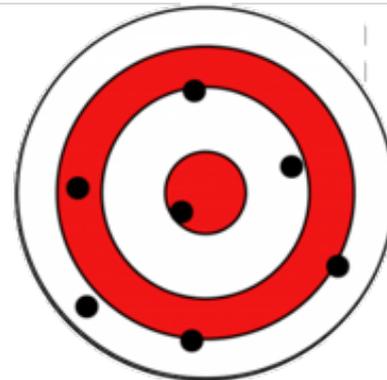
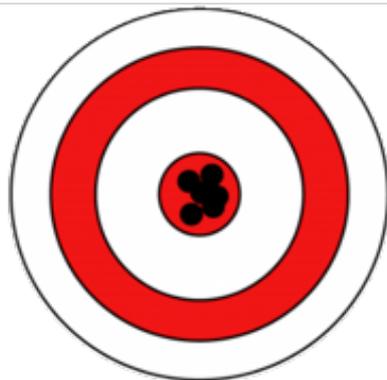
Precision:

high

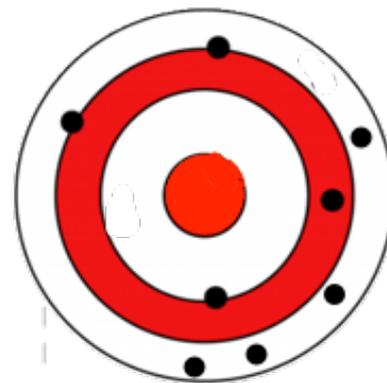
low

Accuracy:

high



low



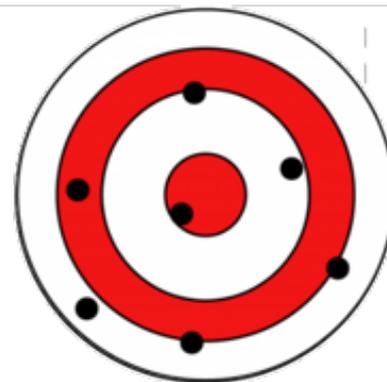
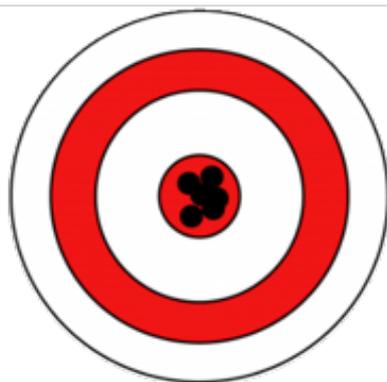
Precision:

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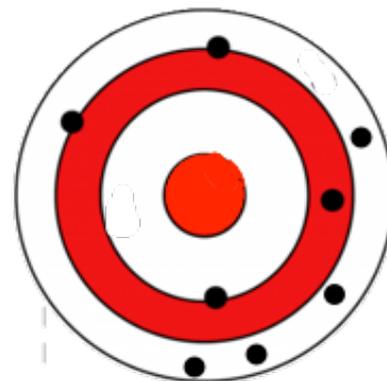
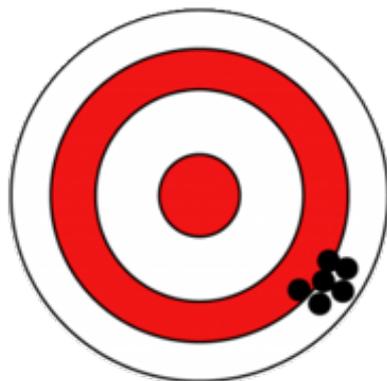
low

Accuracy:

high



low





Accuracy and precision in every day life.....



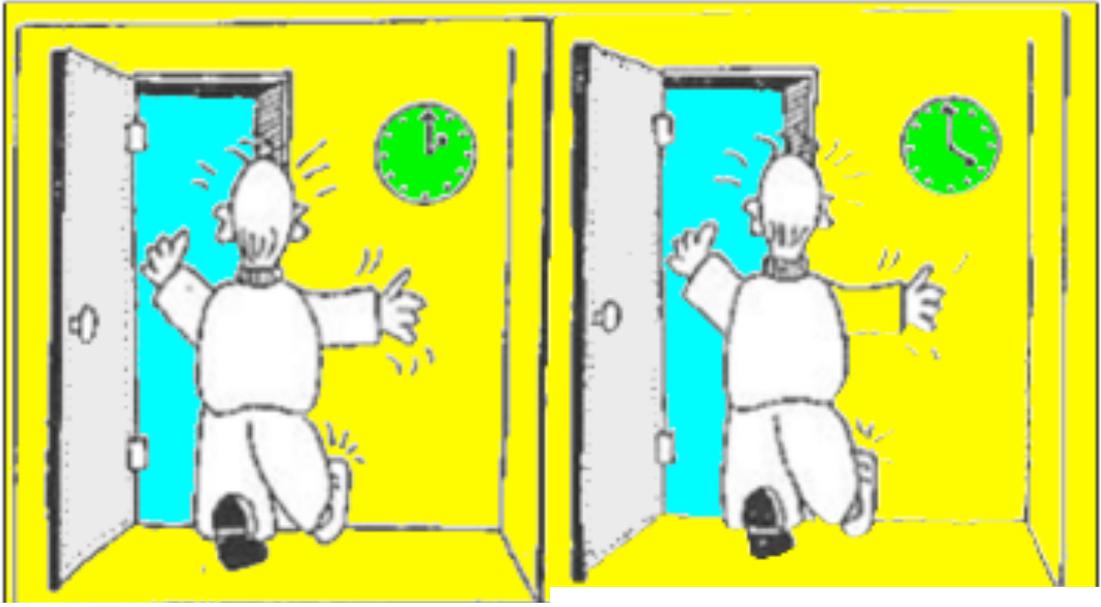
Accuracy and precision in every day life

going threw a door with:
high precision
but low accuracy

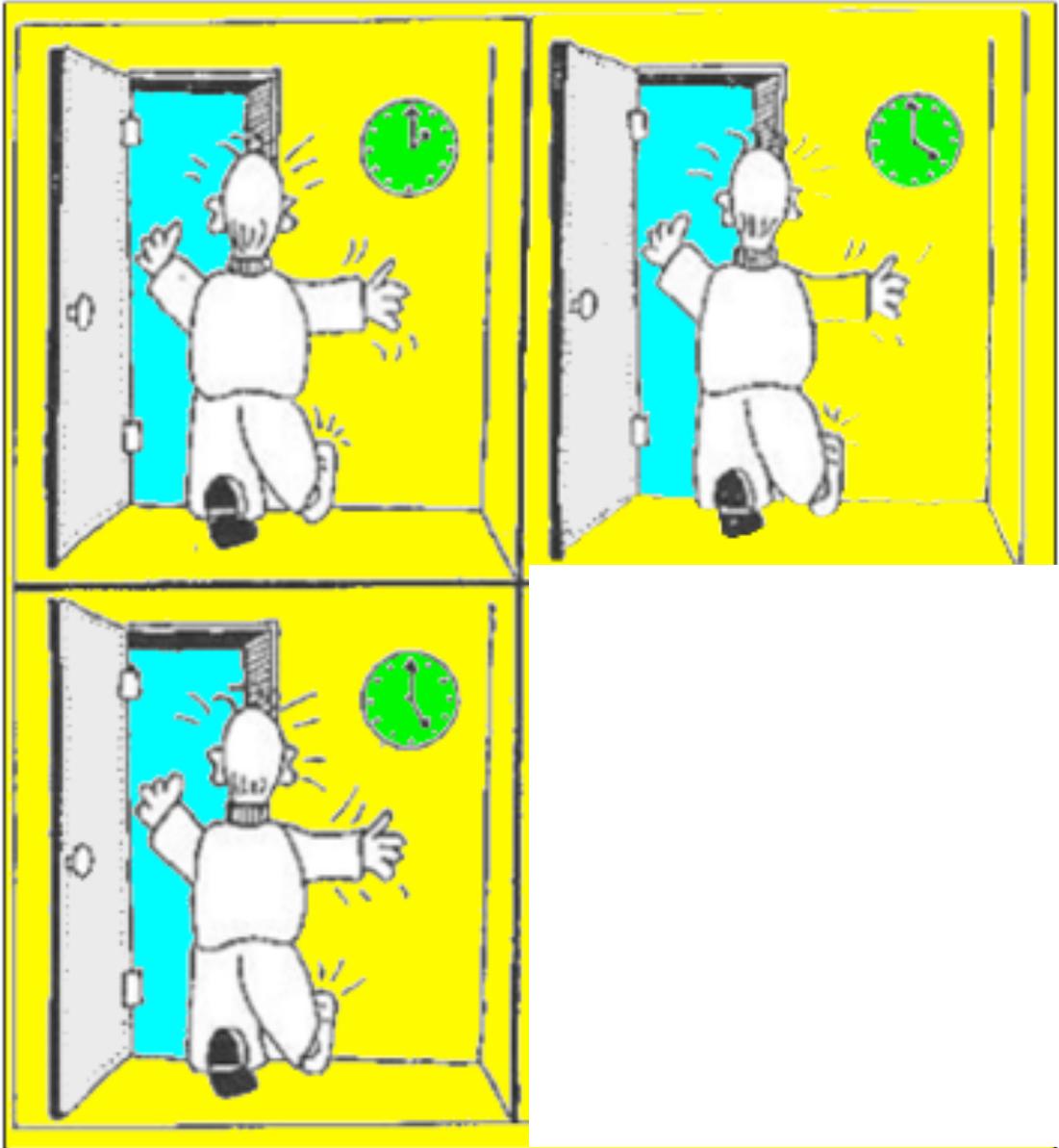
Accuracy and precision in every day life....



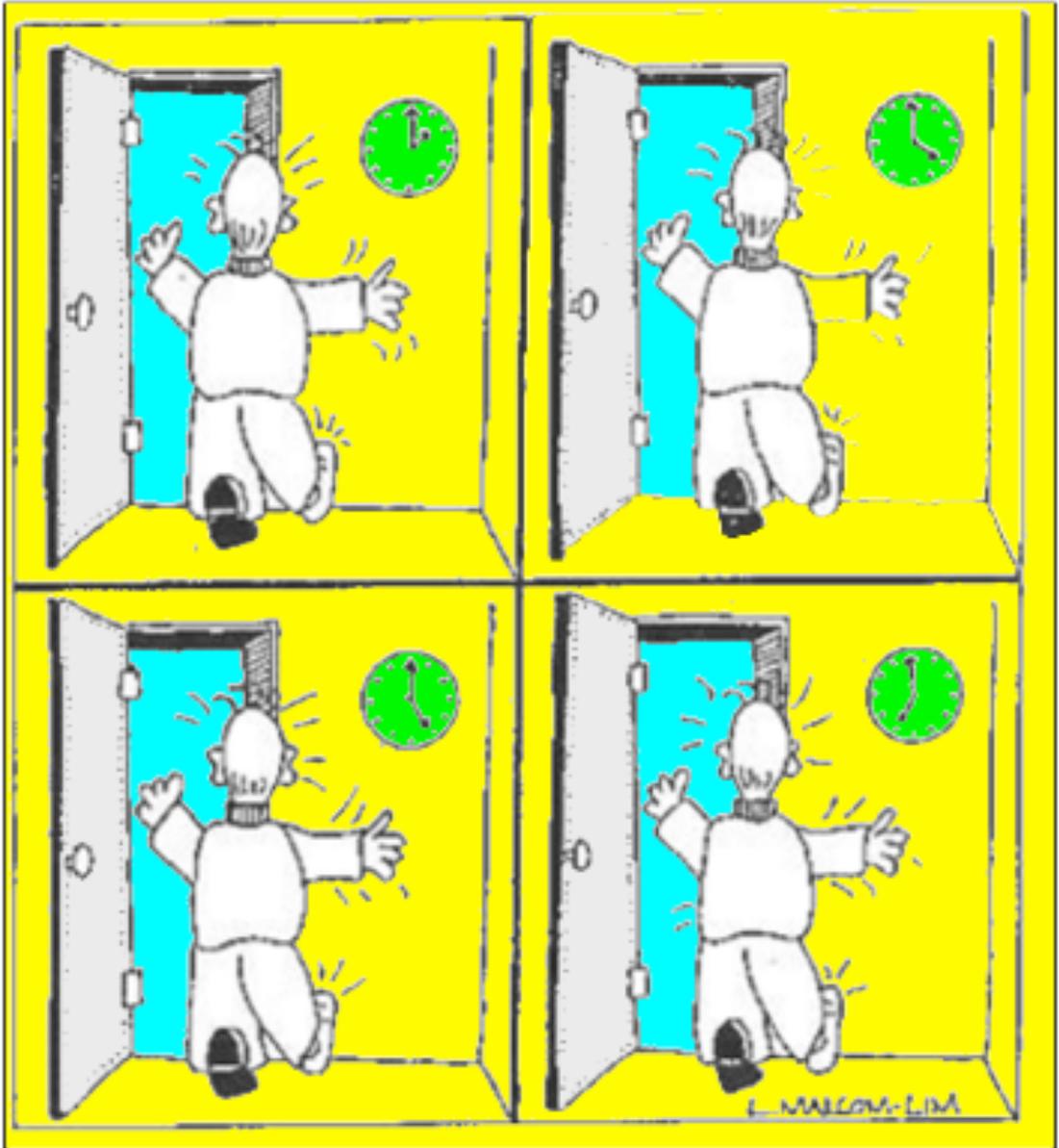
Accuracy and precision in every day life....



Accuracy and precision in every day life



Accuracy and precision in every day life





**Your measures will ALWAYS
ALWAYS
ALWAYS
ALWAYS**

contain errors!

- 1. Limit the errors to a certain range**
- 2. Detect the errors that exceed the range**
- 3. Correct the errors if they are excessive.**



Accuracy and precision with machines.



**When you take a measure, you make an error:
This error cannot be avoided whatever the instrument....**



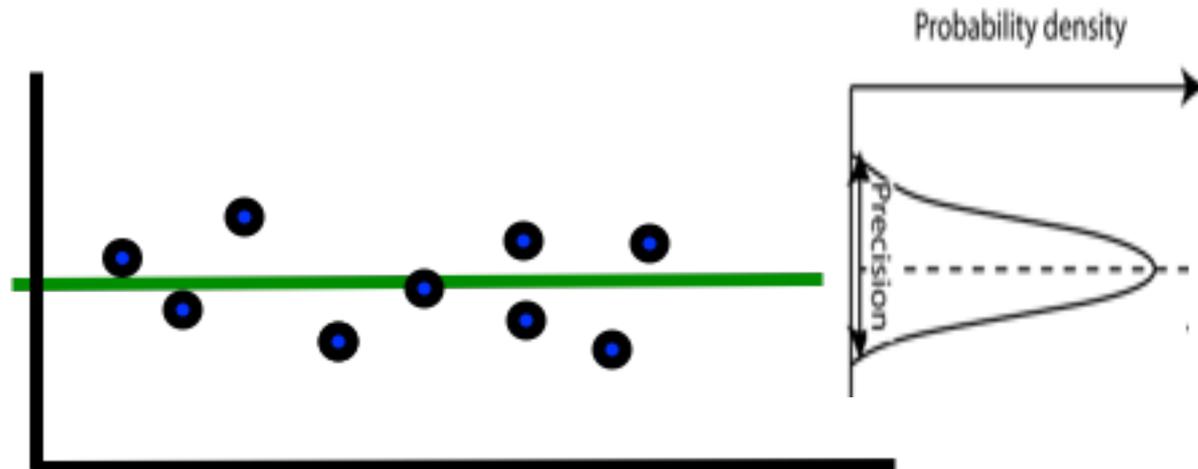
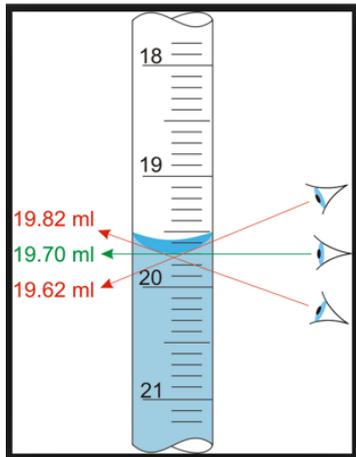
Error:

**the difference between your
result and the "true" value.**

Analytical errors can be of 2 categories:

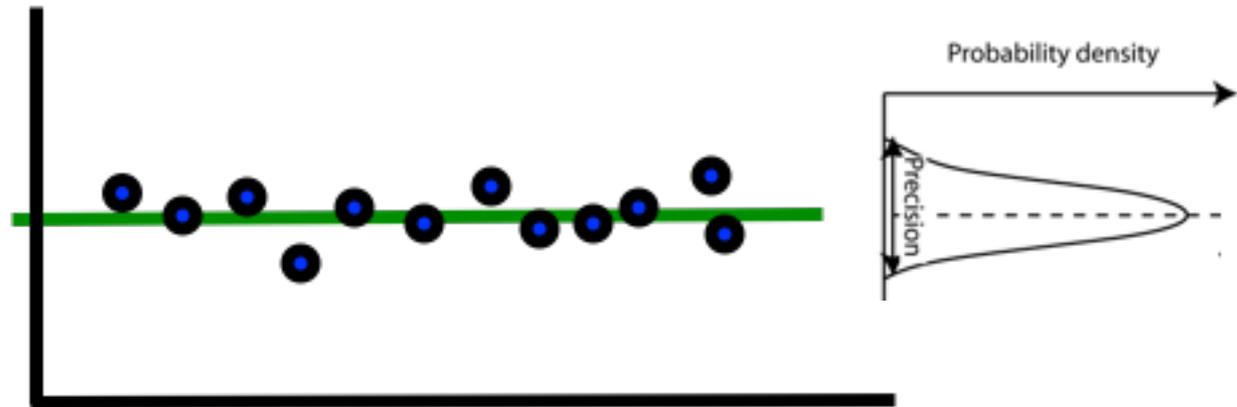
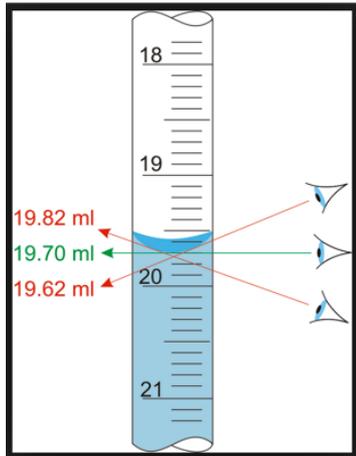
Analytical errors can be of 2 categories:

1. Random or 'unpredictable' deviations between replicates



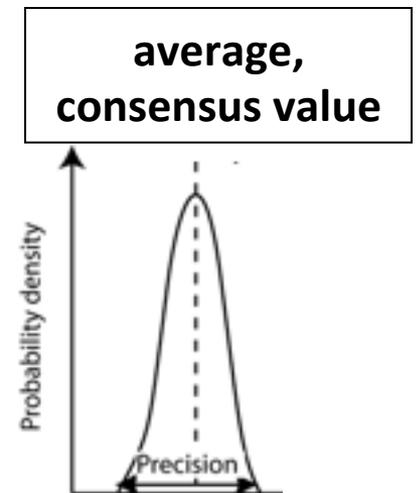
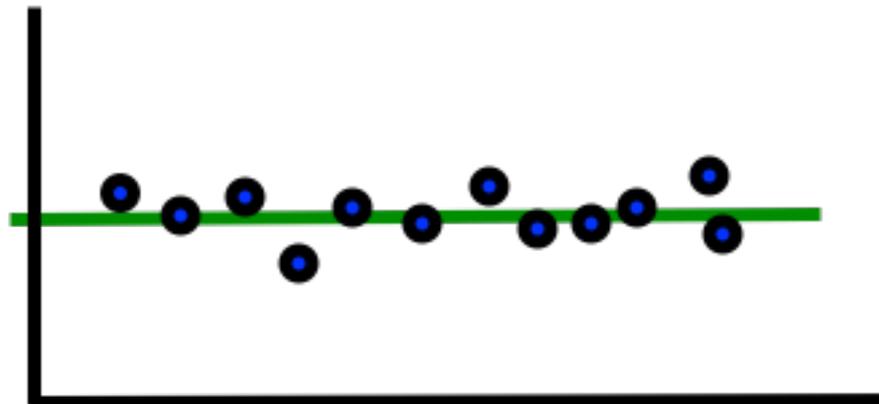
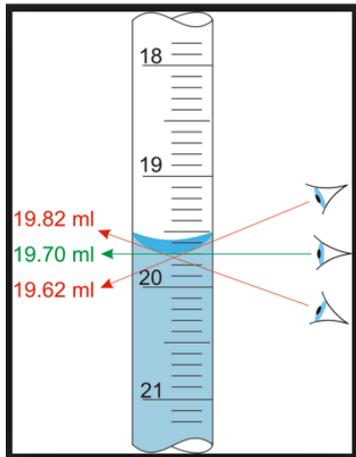
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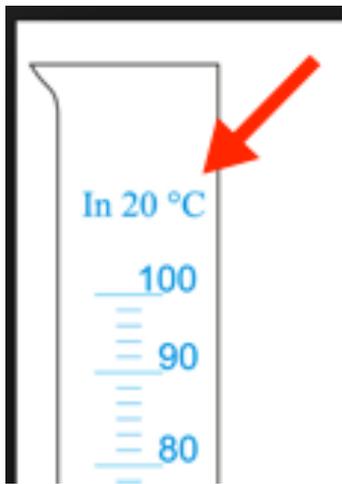
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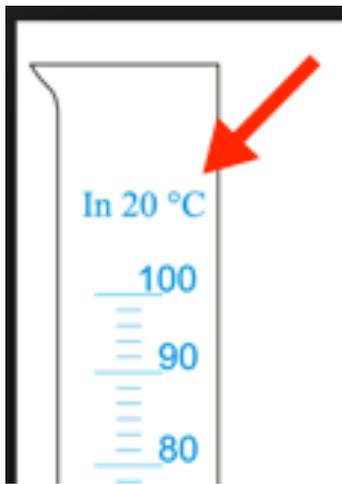
Analytical errors can be of 2 categories:

2. Systematic or 'predictable', regular deviation from the "true" value.



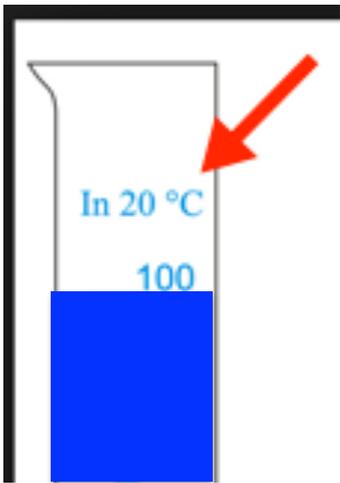
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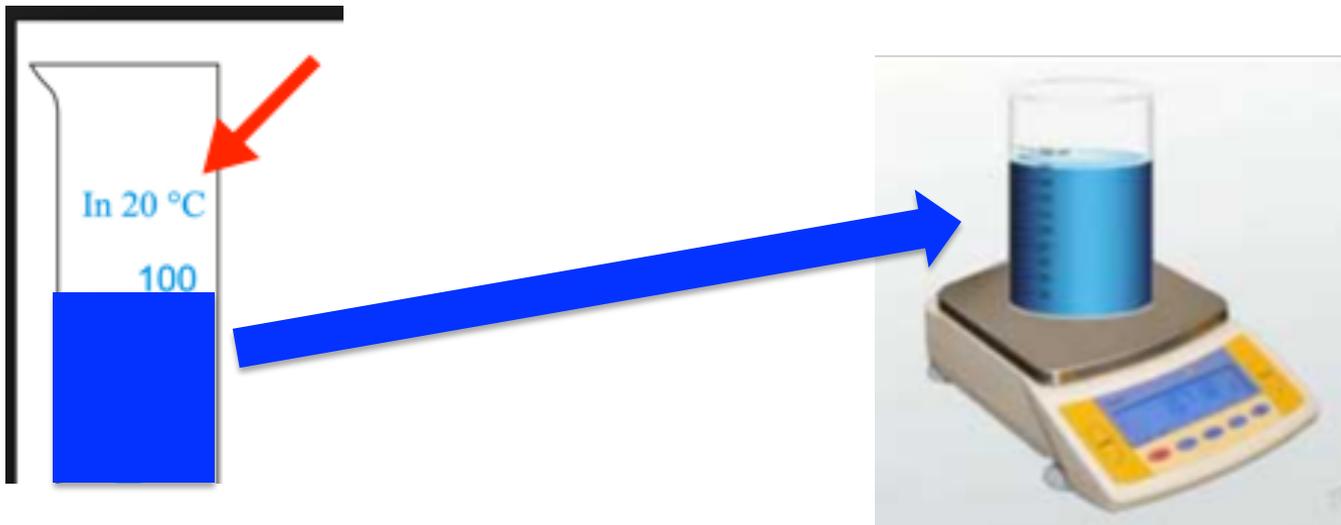
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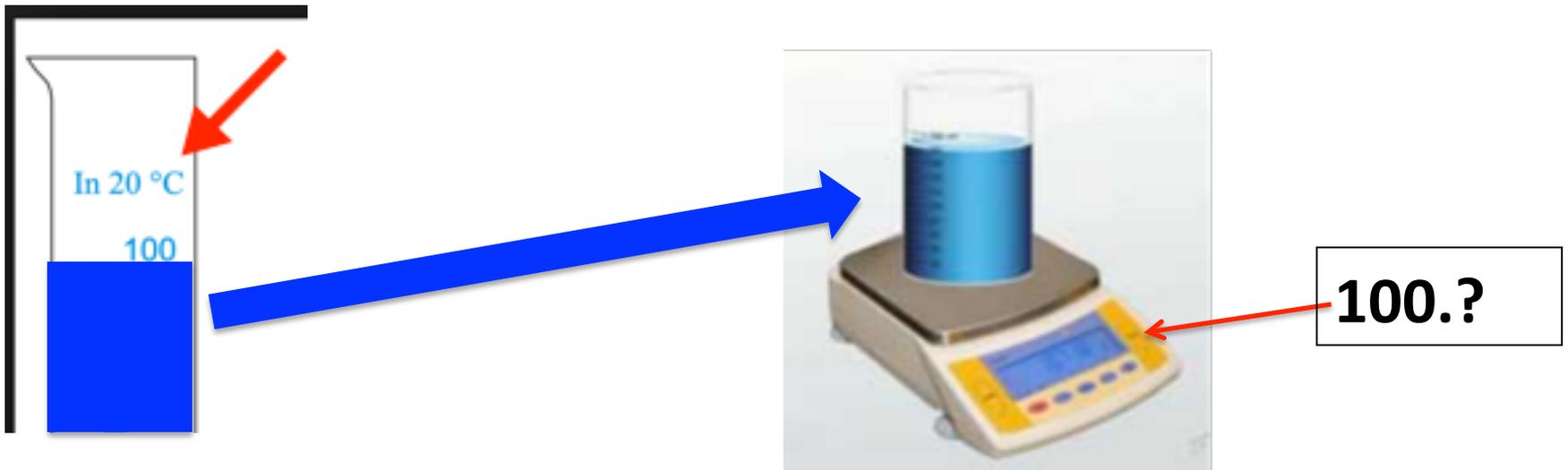
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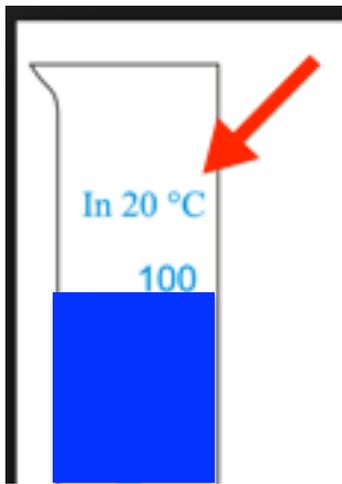
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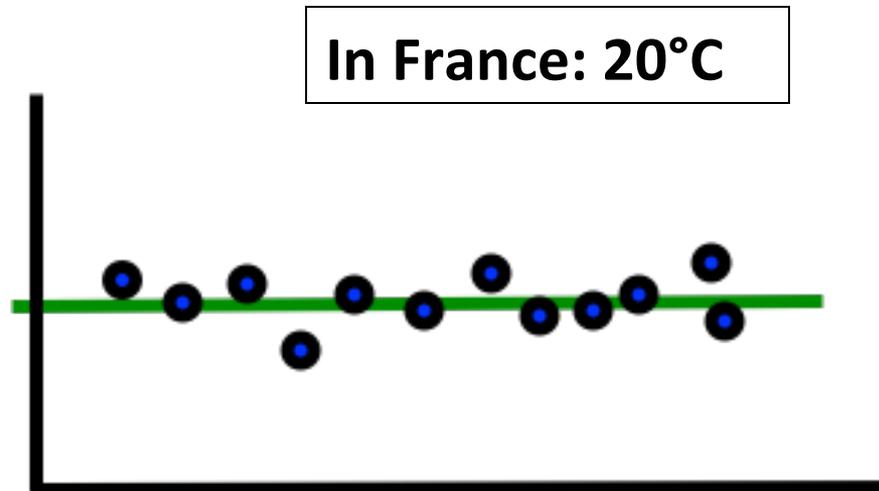
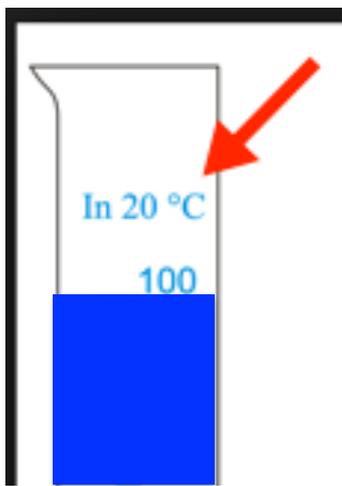


In France: 20°C

100 mL

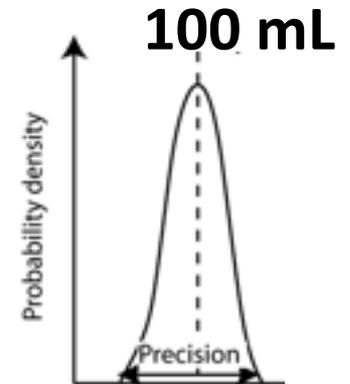
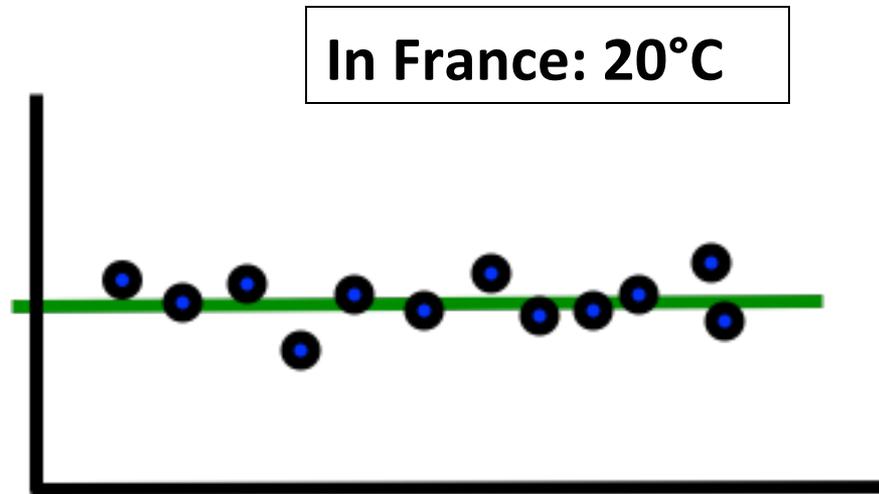
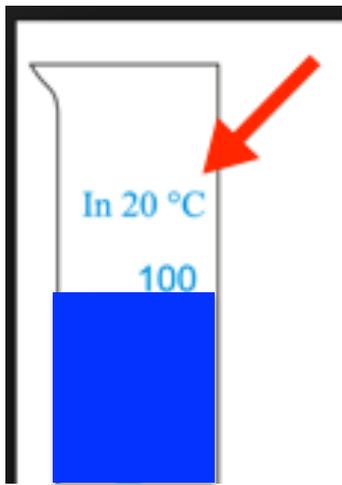
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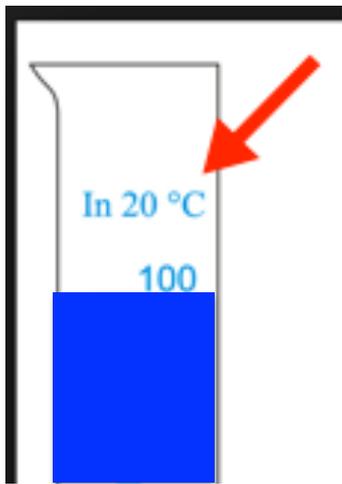
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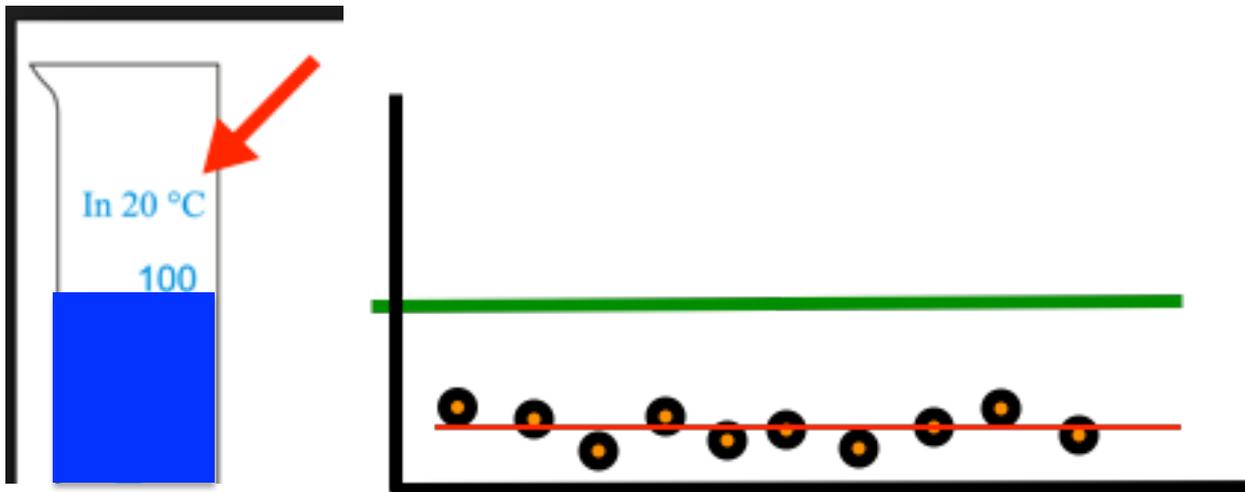


100 mL

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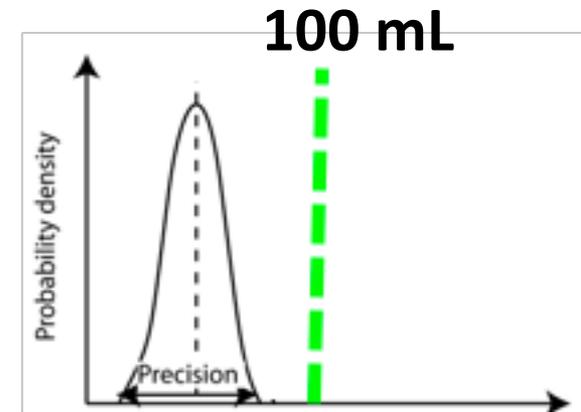
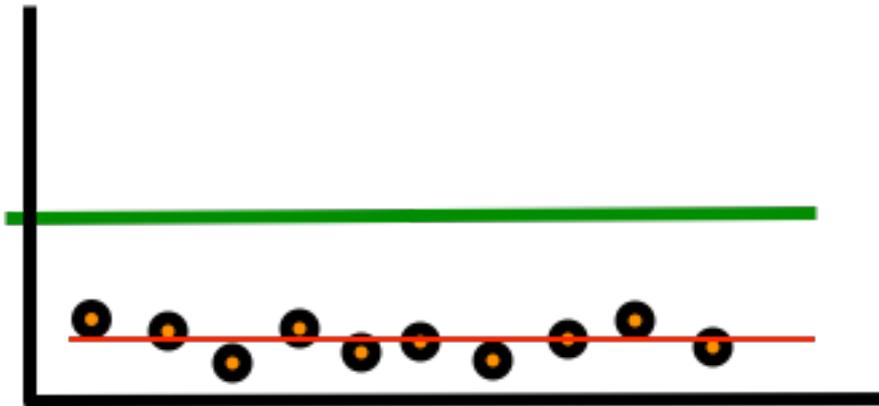
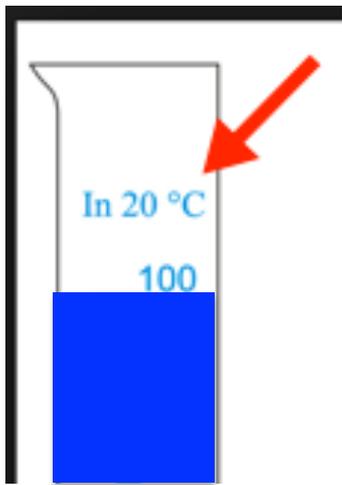
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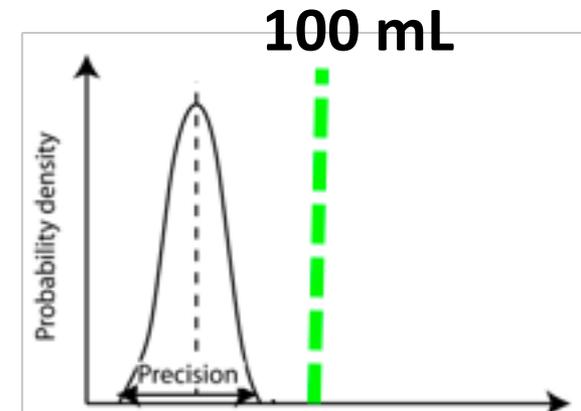
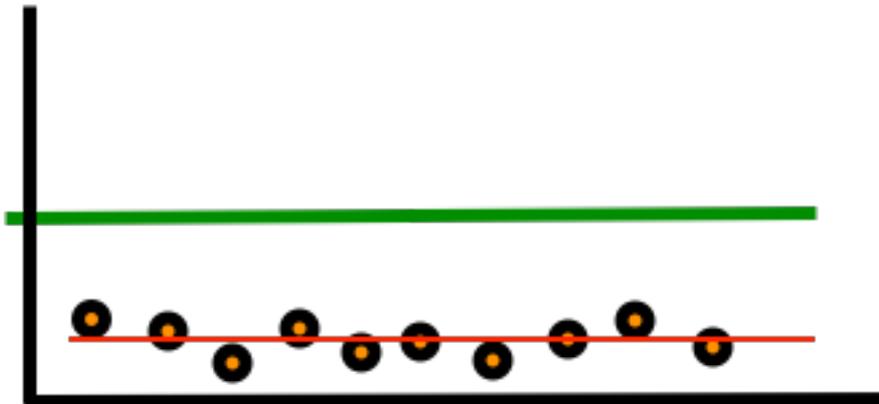
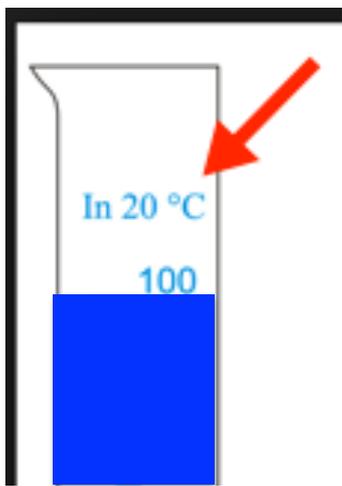


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In Lao PDR: 35°C (glass expansion)

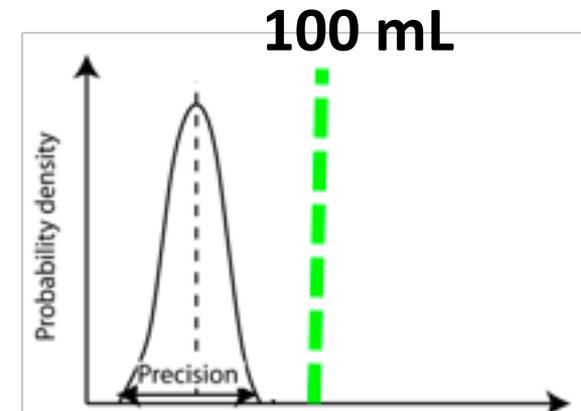
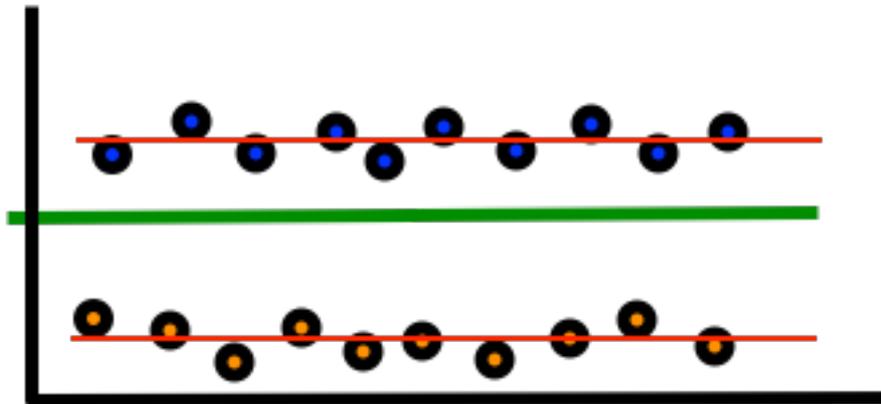
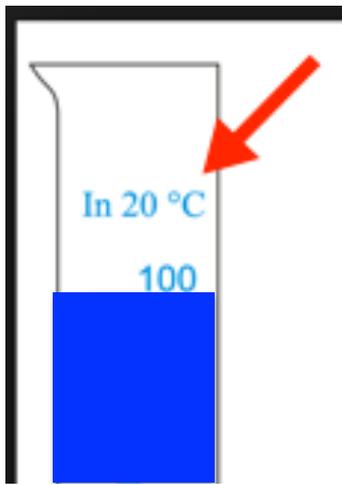


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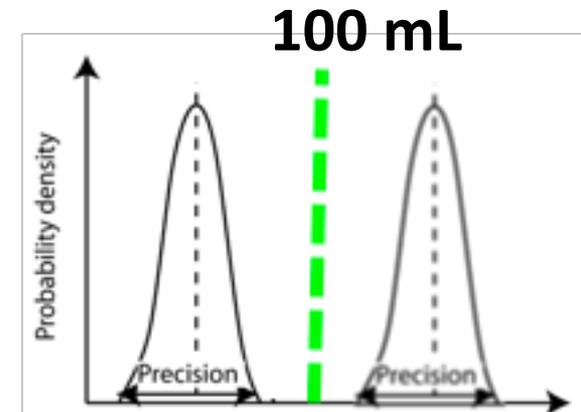
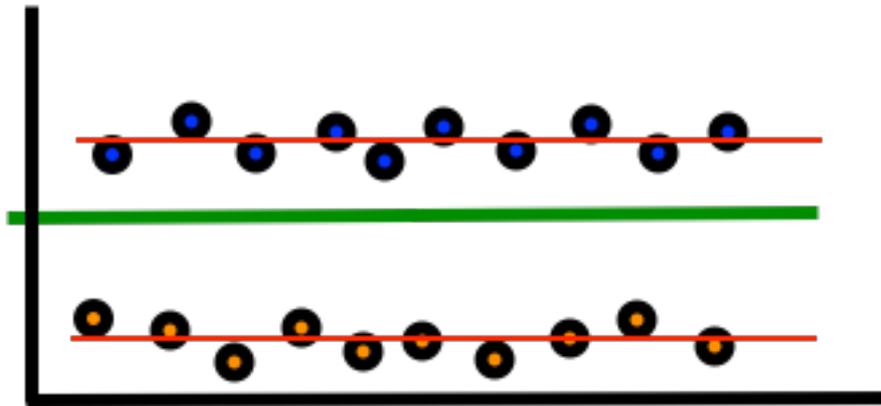
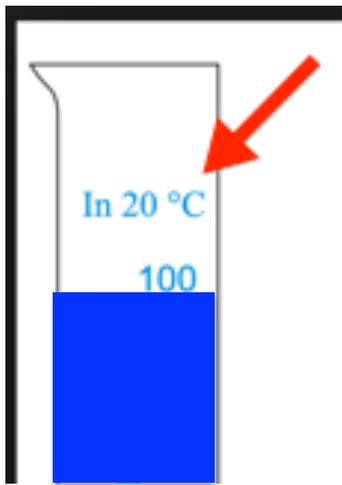


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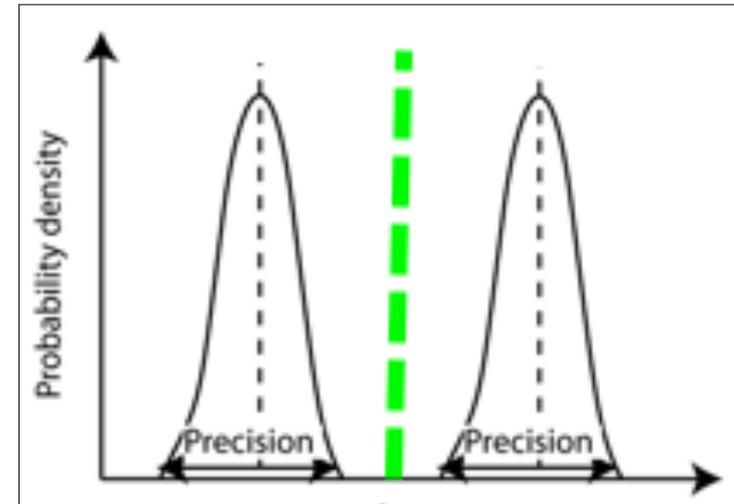
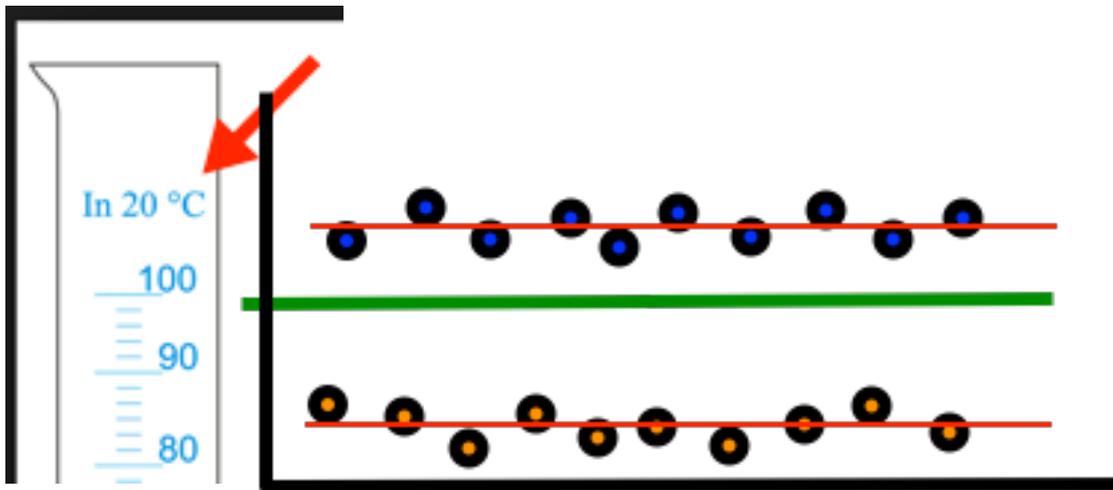
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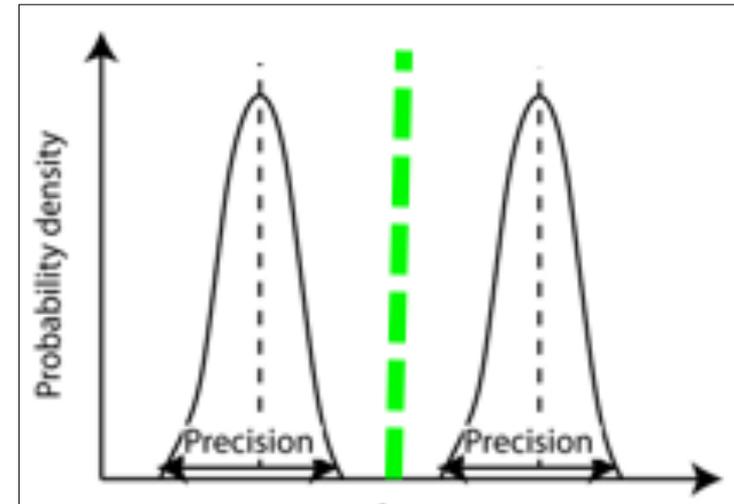
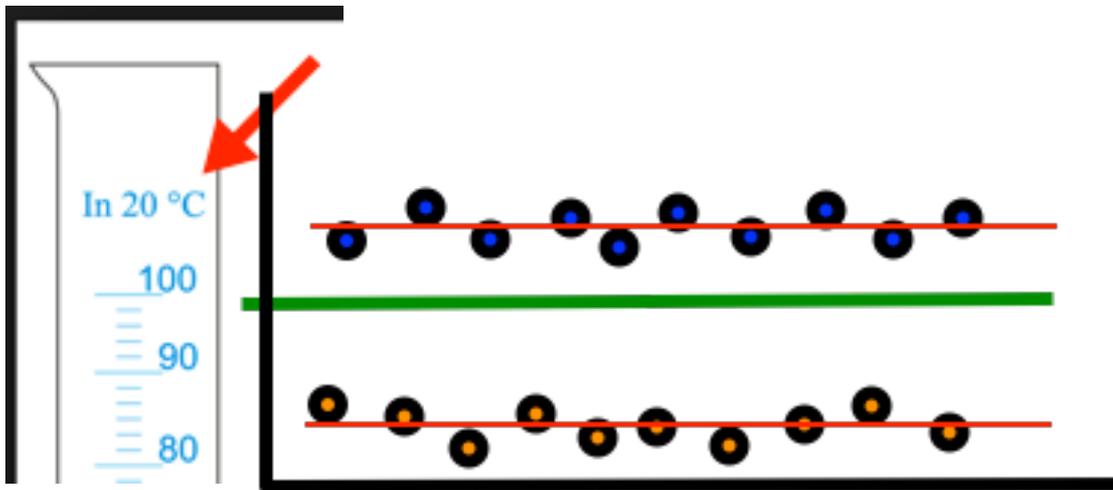
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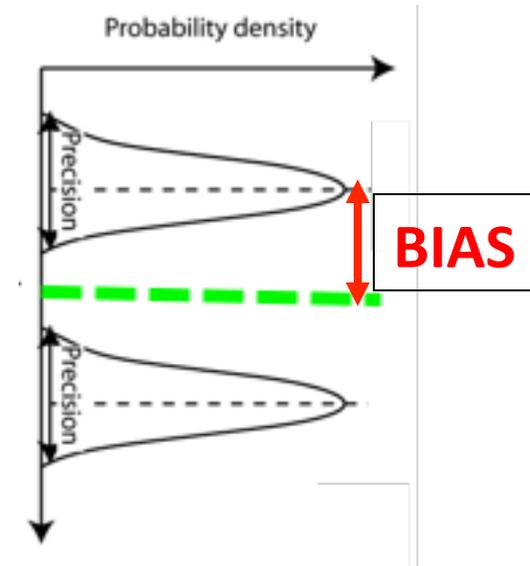
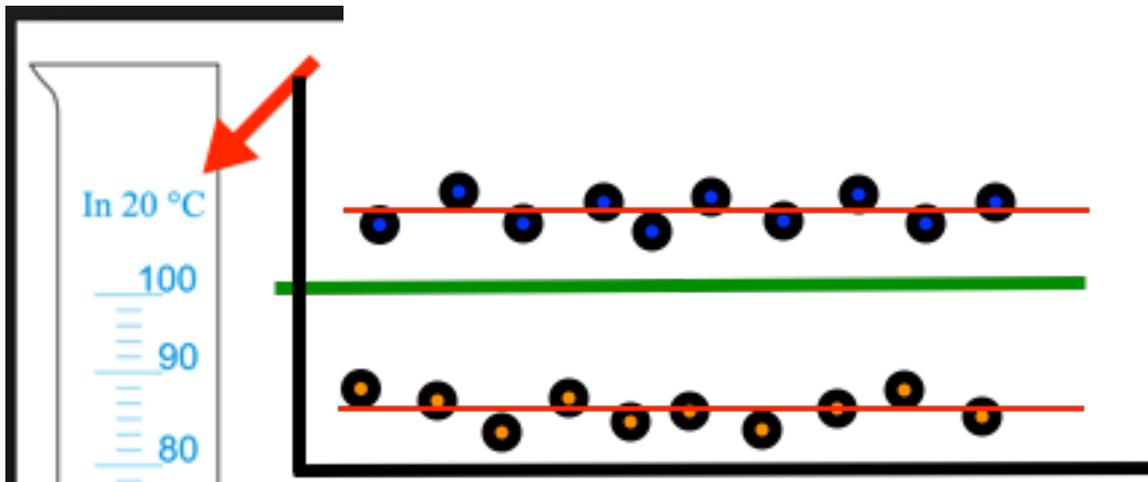
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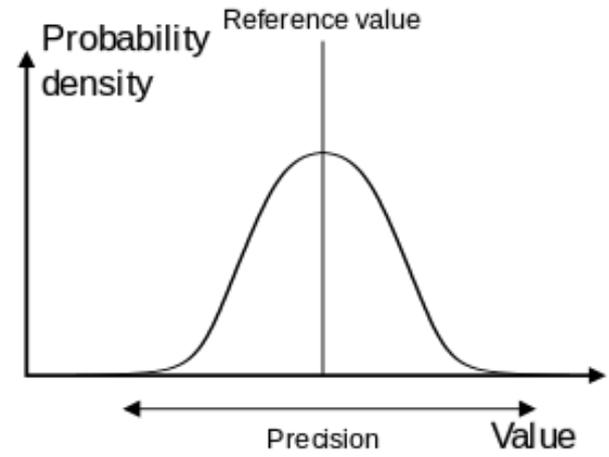
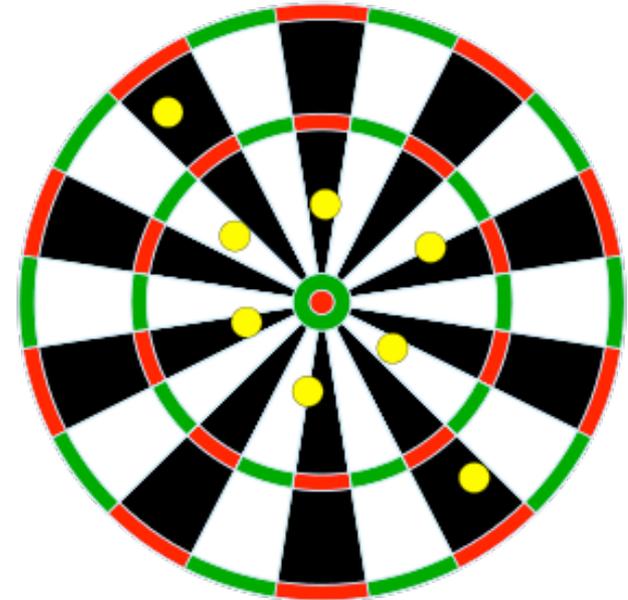
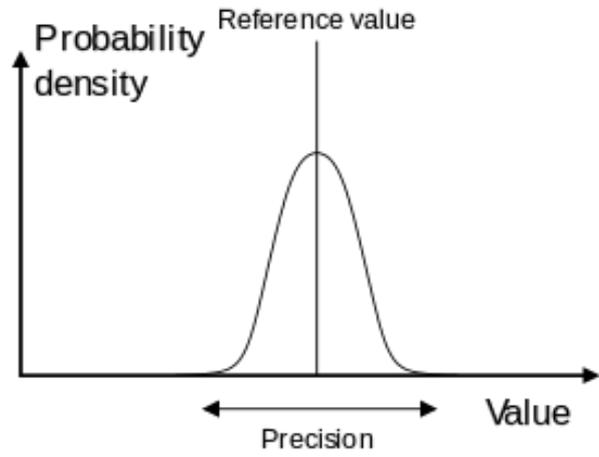


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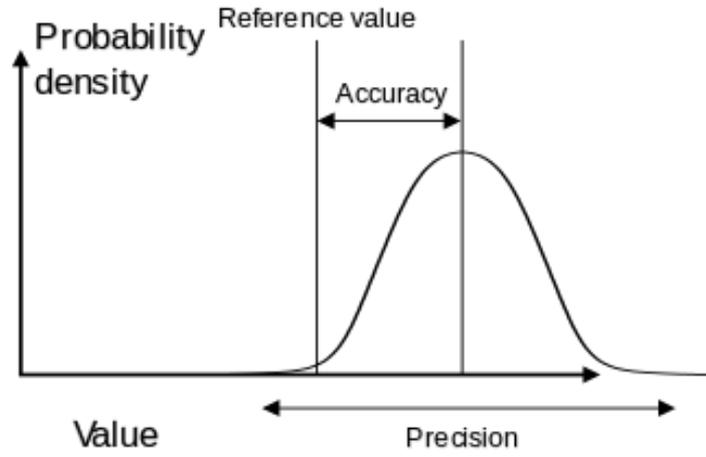
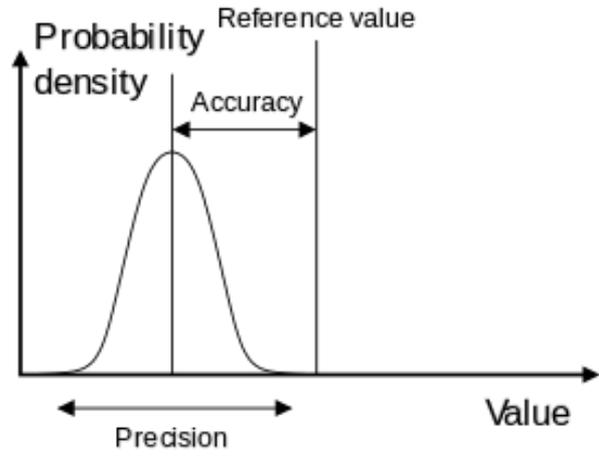
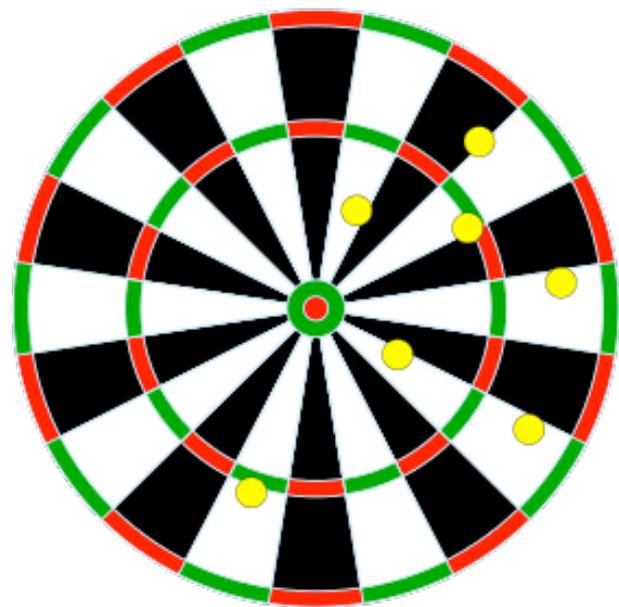
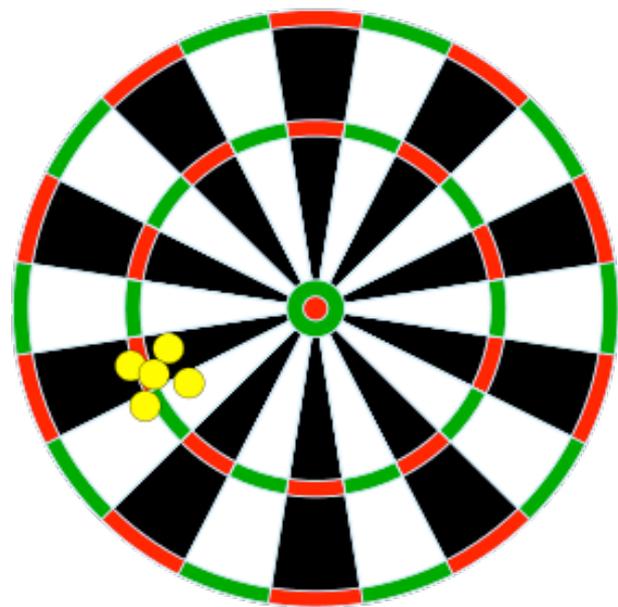
Yes



Precision Value

Precision Value

No



Analytical errors can be of 2 categories:

- 1. Random (or 'unpredictable' deviations between replicates)**
- 2. Systematic (or 'predictable' regular deviation from the "true" value),**

Error:

**it is an idealised concept:
errors cannot be known exactly.**



you must **always** keep in mind:



you must always keep in mind:

**Despite all efforts,
you cannot avoid
errors.**

you must always keep in mind:

**Despite all efforts,
you cannot avoid
errors.**

**= all results will always
contain an error !**

You will always have errors.

**Good Laboratory Practices,
will limit the errors.**

You will always make errors.

**Good Laboratory Practices,
will limit the errors.**

**Quality Control (QC) help you
to *detect* the remaining errors.**

Very important !



**Some characteristics do not have a
'true' value !!!**

The diameter of a planet, etc...

In soil science, several characteristics have no 'true' value' !!!

In soil science, several characteristics have no 'true' value because the results strongly depends on the analytical method !

(e.g. cation exchange capacity, phosphore, etc.).

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(e.g. cation exchange capacity, phosphore, etc.).

It does not mean you cannot measure these characteristics,

but it means that you always have:

- to indicate which method you have used,**
- use similar methods if you want to compare results.**

(soil mapping, etc...)

II – Description of GOOD LAB PRACTICES.

'GLP'

**= low-cost basic measures that will improve
the performances of your laboratory.**

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= low-cost basic measures that will improve the performances of your laboratory.



This process can be successful only with:

1. a change in daily attitudes & practices,
2. a change that all the staff must adopt.

GLP tries to correct 'old habits' by **providing written documents for all important actions.**

The success of GLP also depends on the cooperation, participation, involvement and contribution of all laboratory staff.

Benefits of GLP:

- **minimize errors**
- **improve efficiency** (thus reducing costs)
- **allow quality control** (tracking errors & their origin)
- **stimulate and motivate all the staff.**

What are the:

**Good Laboratory Practices?
(GLP)**

What are the:

**Good Laboratory Practices?
(GLP)**

**the laboratory structure:
nested activities.**

The laboratory structure: nested activities.

Management

Technical elements

Reagents, instruments, etc..

Analytical tasks

pH, NPK, etc..



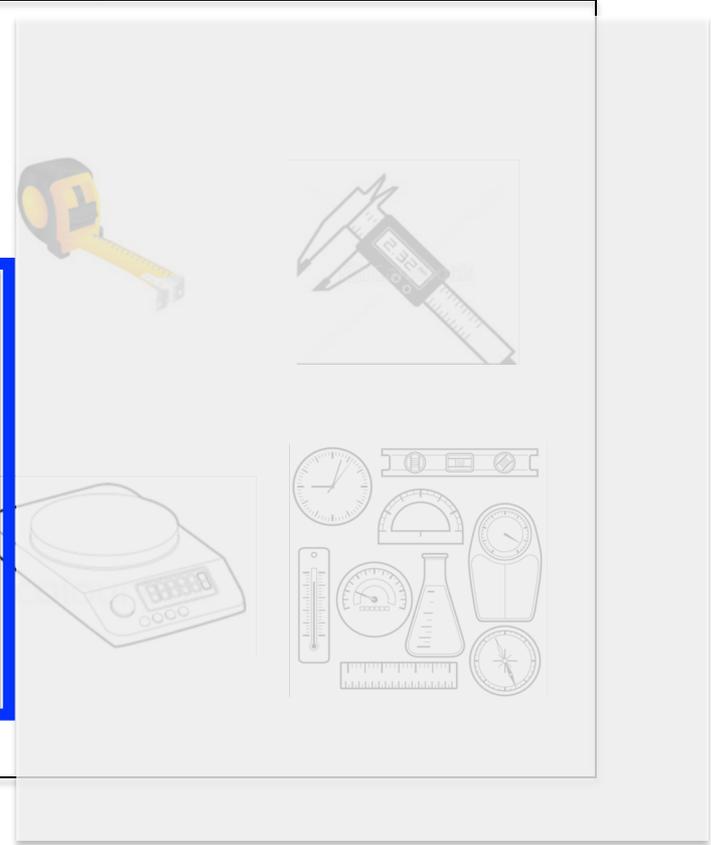
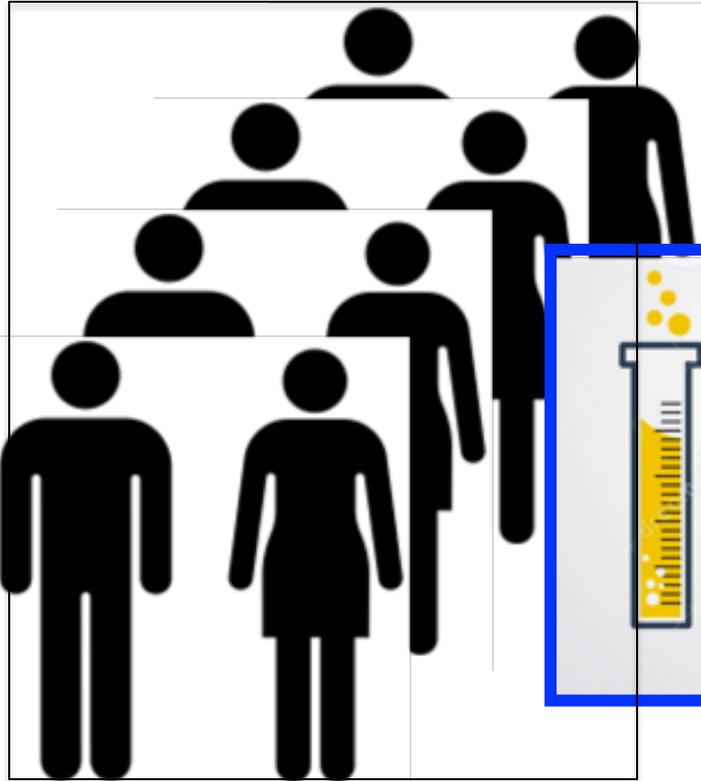
Analytical tasks

pH, NPK, etc..

People

+ chemical reactions +

Instruments



Staff but also...
students

every body must work the
same way.... how? SOP !

with GLP you need:
STANDARD OPERATING PROCEDURES
(SOP)

**The objectives of a SOP is
to do all the important operations:**
(i) correctly,
(ii) always in the same way.

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Detailed, written instructions to achieve uniformity of the performance of a specific function.

Repeated application of unchanged processes and procedures, and their documentation.

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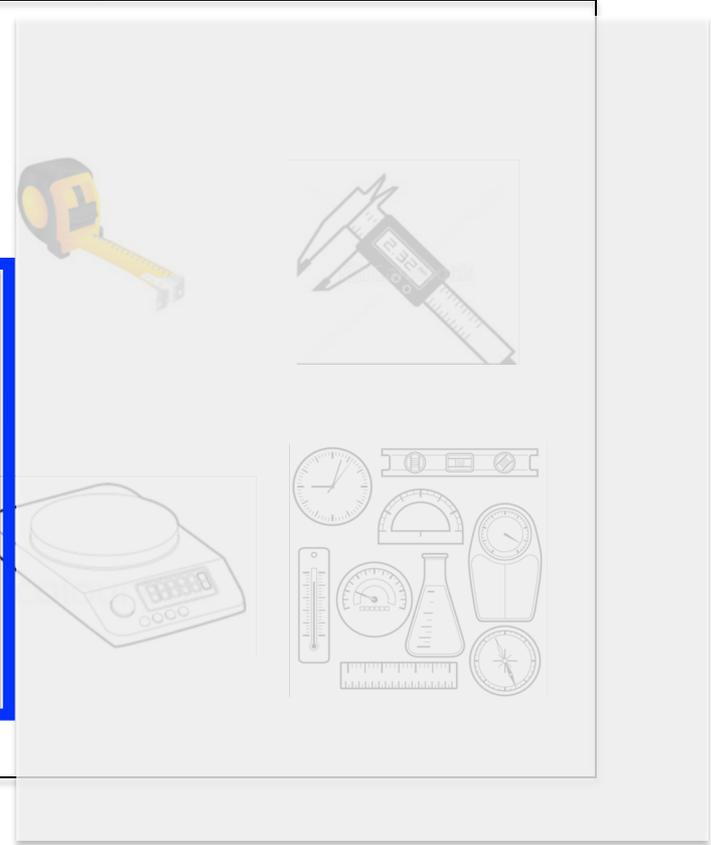
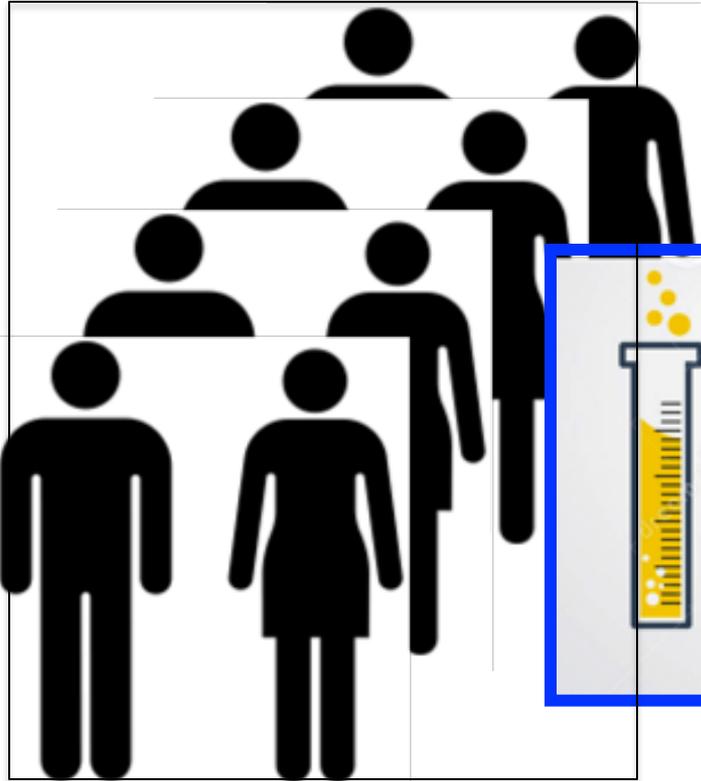
SOP are mandatory instructions!

You have to strictly follow a SOP, not to adapt it.

People

+ chemical reactions +

Instruments



Staff but also...
students

you need skilled people !!!



SOP...

did not follow the SOP...instead of 170 km/h



240 km/h ! felt out of the tracks.

of course in soil analysis they are no dramatic consequence but my objective was to demonstrate that even in case of high risk, human do not like to follow SOP...

And because in Soil science there is no dramatic consequence, there is a high probability not to follow the SOP.... you cannot change it, you must DETECT IT....

The objectives of a SOP is to do all the important operations:

(i) correctly,

(ii) always in the same way.

Thus, a SOP is a mandatory instruction!

You have to strictly follow a SOP, not to adapt it.

A SOP should be available at the place where the work is done".

SOPs should be kept as simple as possible, particularly in the beginning.

you decide the SOP for your lab
or you have to follow the SOP of a network if
you are involved in a larger network.

DALAM can decide to do what it wants

But now they are international accreditation and customers want to know you
fit with international rules.

For example Chinese, Thai, Australian company, etc... want to be sure your data fit
with what they know....

A good example is Carbon and ORGANIC MATTER

If you work for chicken food, you have to do like the industry of chicken food is
used

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- 6.3.2 SOPs provide a source of information to which analysts, carrying out a particular operation, can refer in order to ensure a consistent approach. A closely followed, well written SOP can improve the consistency of data produced for a particular process, between analysts, between laboratories, and over time intervals. Thus an SOP should contain whatever level of information is necessary to avoid ambiguity. A well written SOP also helps auditors to follow the course of the work done and so assess the validity of the data. In an R&D environment it is expected that as the science improves, so SOPs can be reviewed and changed to reflect the improvements (e.g. in speed, in material and money savings, in waste production, *etc.*) as long as the results are convincingly demonstrated to be comparable or better than those obtained with existing versions. Changes must be authorised, prior to use, in line with document control policy.
- 6.3.3 Where SOPs do not already exist or are inappropriate, contemporaneous notes should be made



STANDARD OPERATING PROCEDURES

SOP: 1844
PAGE: 1 of 6
REV: 0.0
DATE: 11/08/02

SOIL pH DETERMINATION

CONTENTS

- 1.0 SCOPE AND APPLICATION
- 2.0 METHOD SUMMARY
- 3.0 SAMPLE PRESERVATION, CONTAINERS, HANDLING AND STORAGE
- 4.0 INTERFERENCES AND POTENTIAL PROBLEMS
- 5.0 EQUIPMENT/APPARATUS
- 6.0 REAGENTS
- 7.0 PROCEDURES
 - 7.1 pH Calibration Procedure
 - 7.2 pH Meter Operation
 - 7.3 Temperature Compensation
 - 7.4 Sample Preparation with Reagent Water
 - 7.5 Sample Preparation with Calcium Chloride Solution
 - 7.6 Sample Measurement
 - 7.7 Battery Replacement
 - 7.8 Cleaning the Probe
- 8.0 CALCULATIONS
- 9.0 QUALITY ASSURANCE/QUALITY CONTROL
- 10.0 DATA VALIDATION
- 11.0 HEALTH AND SAFETY
- 12.0 REFERENCES
- 13.0 APPENDICES

The laboratory structure: nested activities.

Technical elements

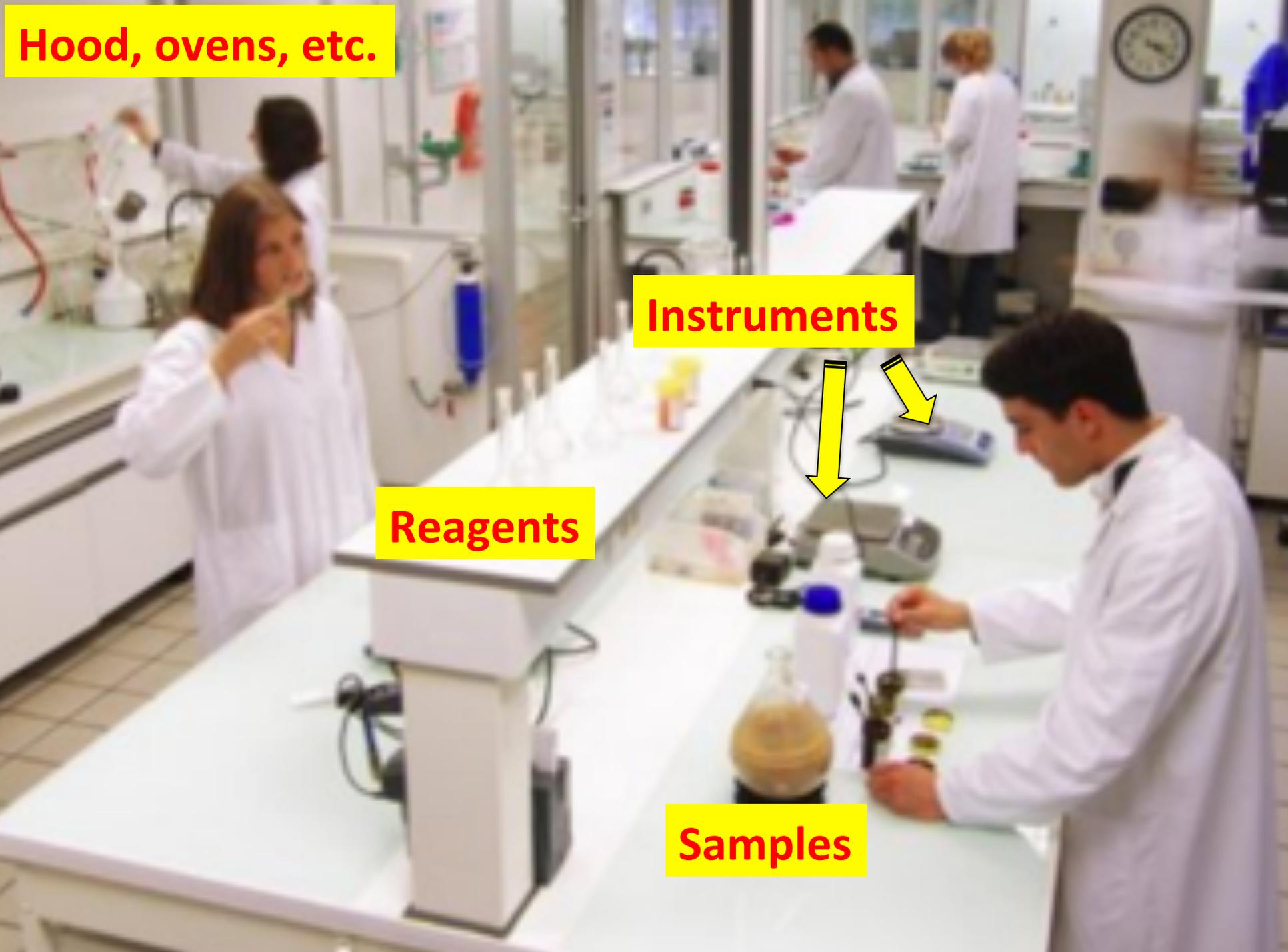
Reagents, instruments, etc..

Analytical tasks

For this also your staff need to be trained...

Lab is a job: even if you have a good mechanic, he will not be a good lab staff because she does not have **laboratory training and skills.**

**Even for the staff, it is important to get trained on a regular basis.
Because when everyday we do the same things,
we can easily forget other things and even basic knowledge...**



Hood, ovens, etc.

Instruments

Reagents

Samples

- 1. Primary measuring equipment,**
- 2. Analytical instruments,**
- 3. Miscellaneous equipment,**
- 4. Reagents,**
- 5. Soil samples.**

1. Primary measuring equipment,

= pipettes, diluters, burettes, thermometers, balance, sieves, crushers, etc.

They do not provide analytical results, but are necessary to prepare your samples, reagents, solutions, etc.

They must be clean and calibrated.

They must be used correctly.

2. Analytical instruments

= pHmeter, spectrophotometers, etc.

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- For all instruments, you must have:**
- an *'Operation Instruction Manual'*,
 - a *'Maintenance Logbook'*.

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= pHmeter, spectrophotometers, etc.

For all instruments, you must have:

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- a *'Maintenance Logbook'*.

Instruments should be:

1. suitably located and adequate capacity,
2. periodically inspected, cleaned, maintained, and calibrated according to SOP.

3. Various equipment & materials

= ovens, fridges, pumps, stills, glassware, etc.

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- For all apparatus, you must have:**
- an *'Operation Instruction Manual'*,
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Apparatus should be:

1. suitably for the job,
2. properly organized, well cared for.

4. Reagents

4. Reagents

One of the most important sources of the errors is: using wrongly prepared or old reagents.

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Reagents have to be :

- prepared very carefully,
- well labelled with: preparation date, expiry dates, operator's name.

Record preparations in a **Reagents Book**.

5. Soil samples

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Need of proper packaging, labelling and management of samples before going to the laboratory.

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Need of proper packaging, labelling and management of samples before going to the laboratory.

Avoid

- samples being accidentally interchanged,
- being contaminated (broken bags),
- losing their identity (i.e. their label or number)
- or getting lost.

The laboratory structure: nested activities.

Management

Technical elements

Analytical tasks

III – INTERNAL QUALITY CONTROL (QC).

You do not analyse only one sample, but large batches...



...with many samples at the same time.



**Quality control in the soil laboratory:
a statistical process
to monitor and evaluate
the analytical process & results' quality.**

Thanks for your attention