Workshop on:

"Implementing Good Laboratory Practices & Quality Control in routine & research laboratories"

28-30 August 2018 – Vientiane (Lao PDR)

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Dr Christian Hartamnn

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.**

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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 corrctly, to have good food that everybody like it and enjoy.





Introduction:

When you do chemical analysis, it is the same:

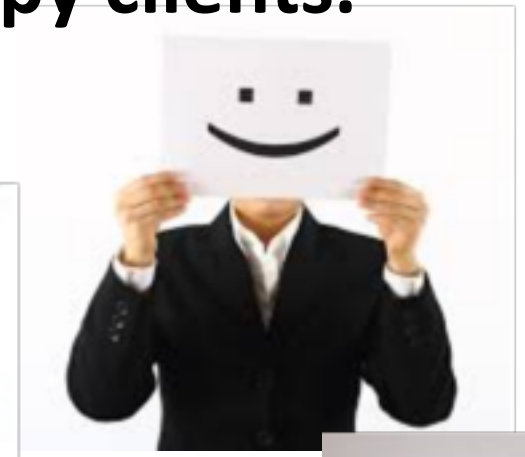


Introduction:

When you do chemical analysis, it is the same:
you want good results & happy clients.









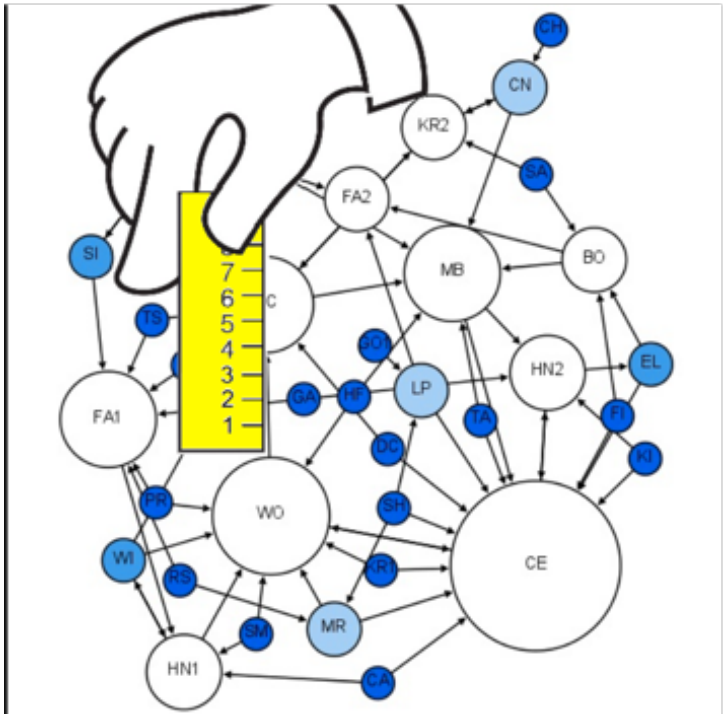
How can you get good analytical results?

How can you get good analytical results?

Chemical analysis

=

MEASURE what is inside your sample.

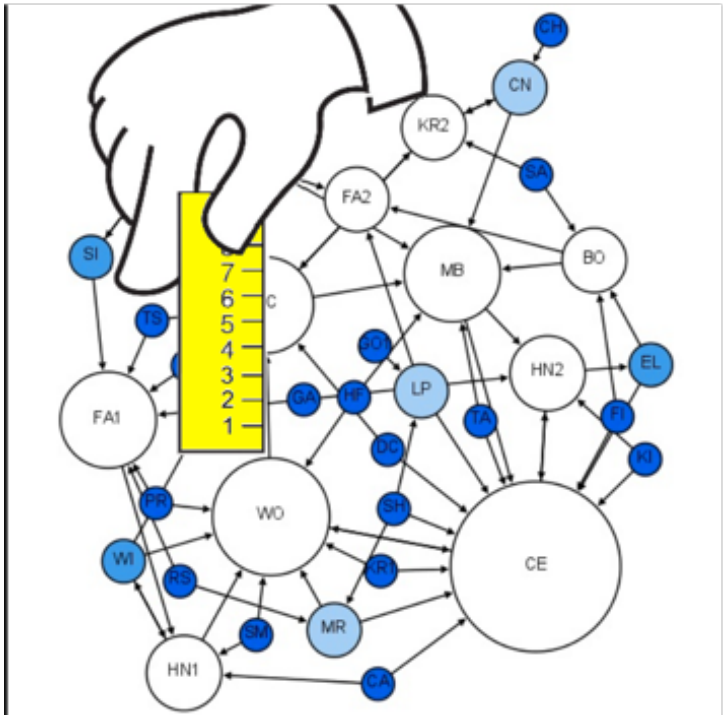


How can you get good analytical results?

Chemical analysis

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MEASURE what is inside your sample.

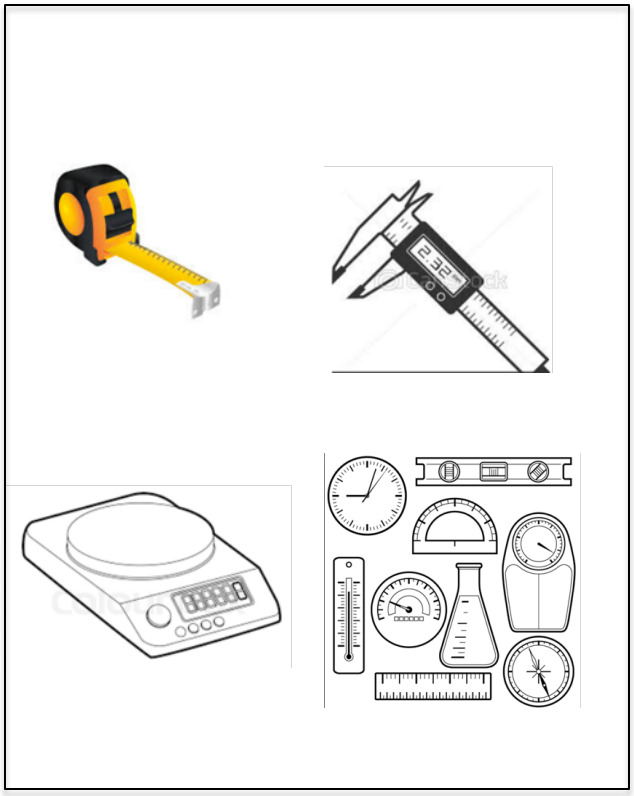


you need firstly to do good MEASUREMENT !

MEASUREMENT:

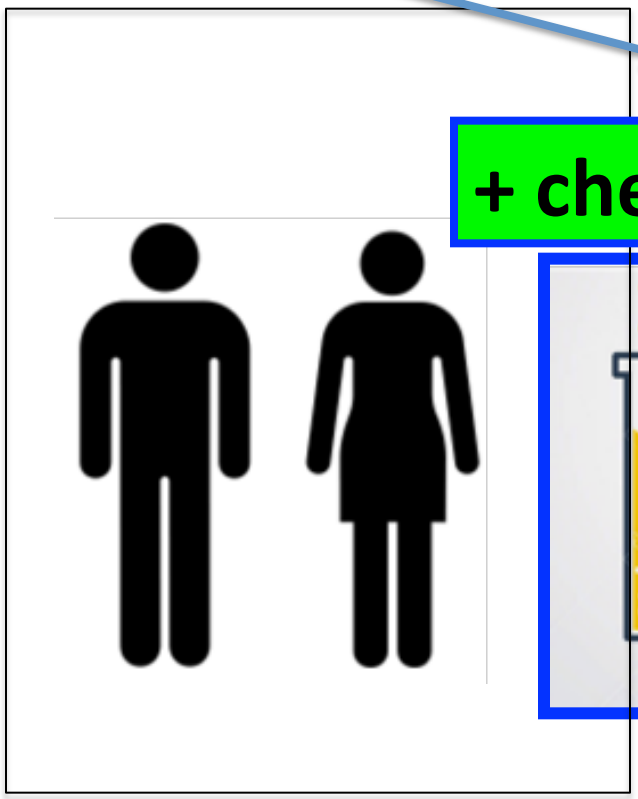
People → **using** → **Instruments**





ANALYSIS:

People



doing

+ chemical reactions

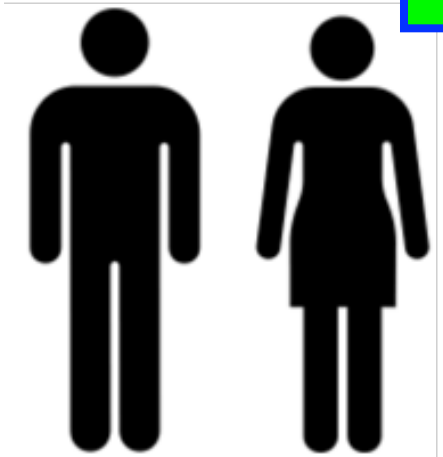


ANALYSIS:

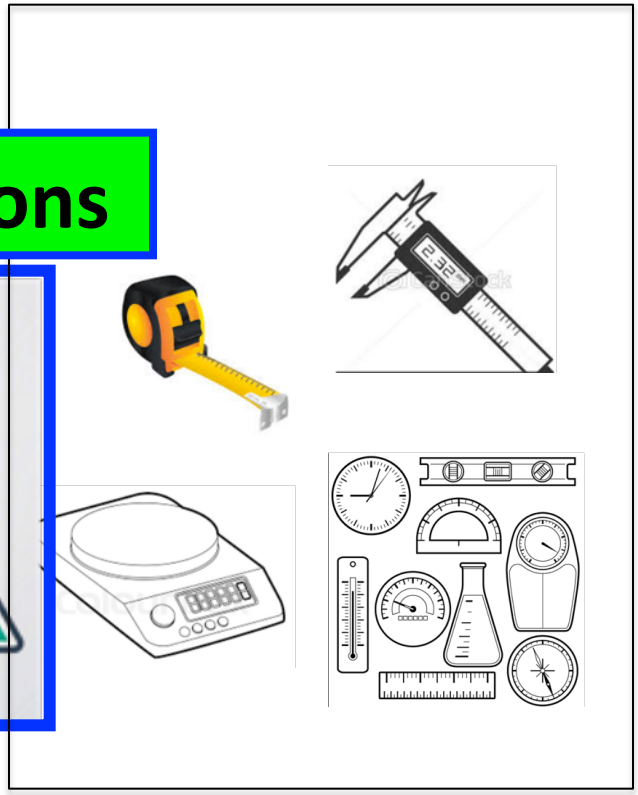
People → using → Instruments

doing

+ chemical reactions



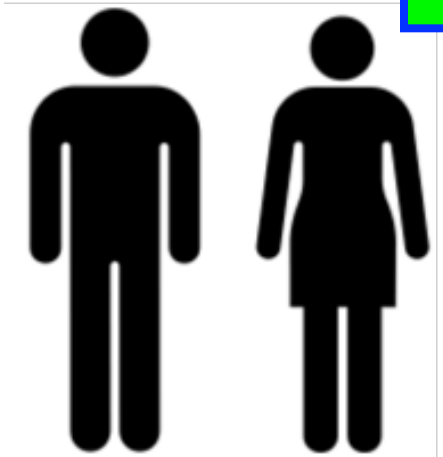




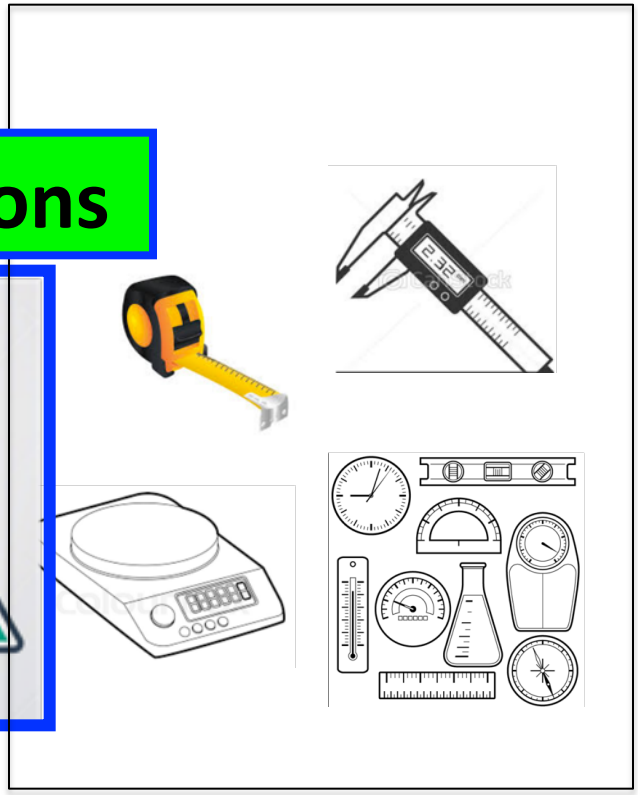
ANALYSIS:

People → doing → using → 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 itit 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

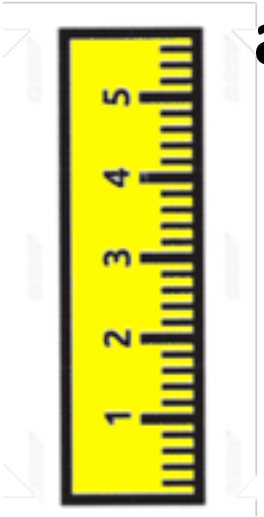
To demonstrate that it is not easy to make professional measure

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…



and measure the egg:




1
2
3
4
5
351 × 430 - sunnyqueen.com.au

Results…

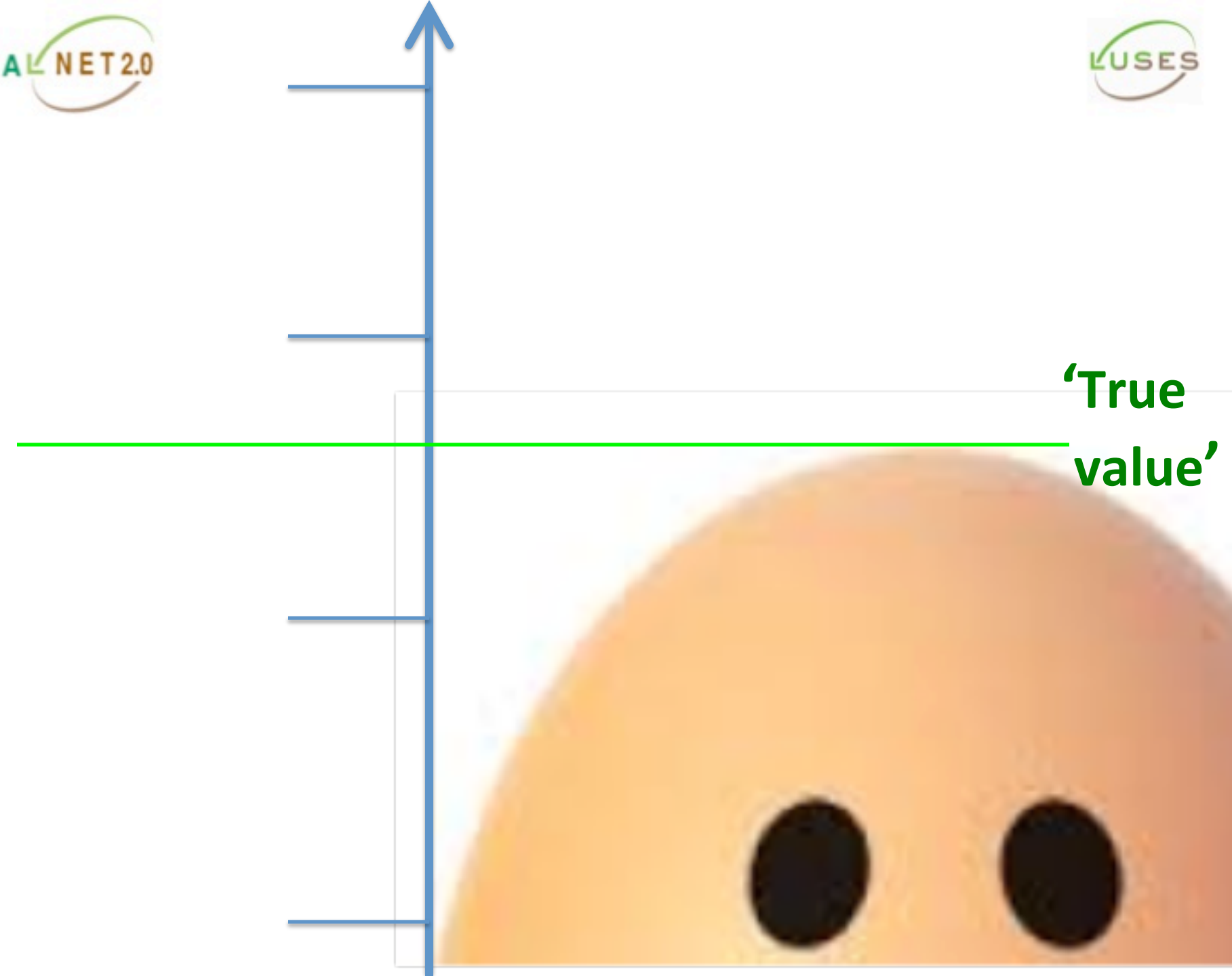


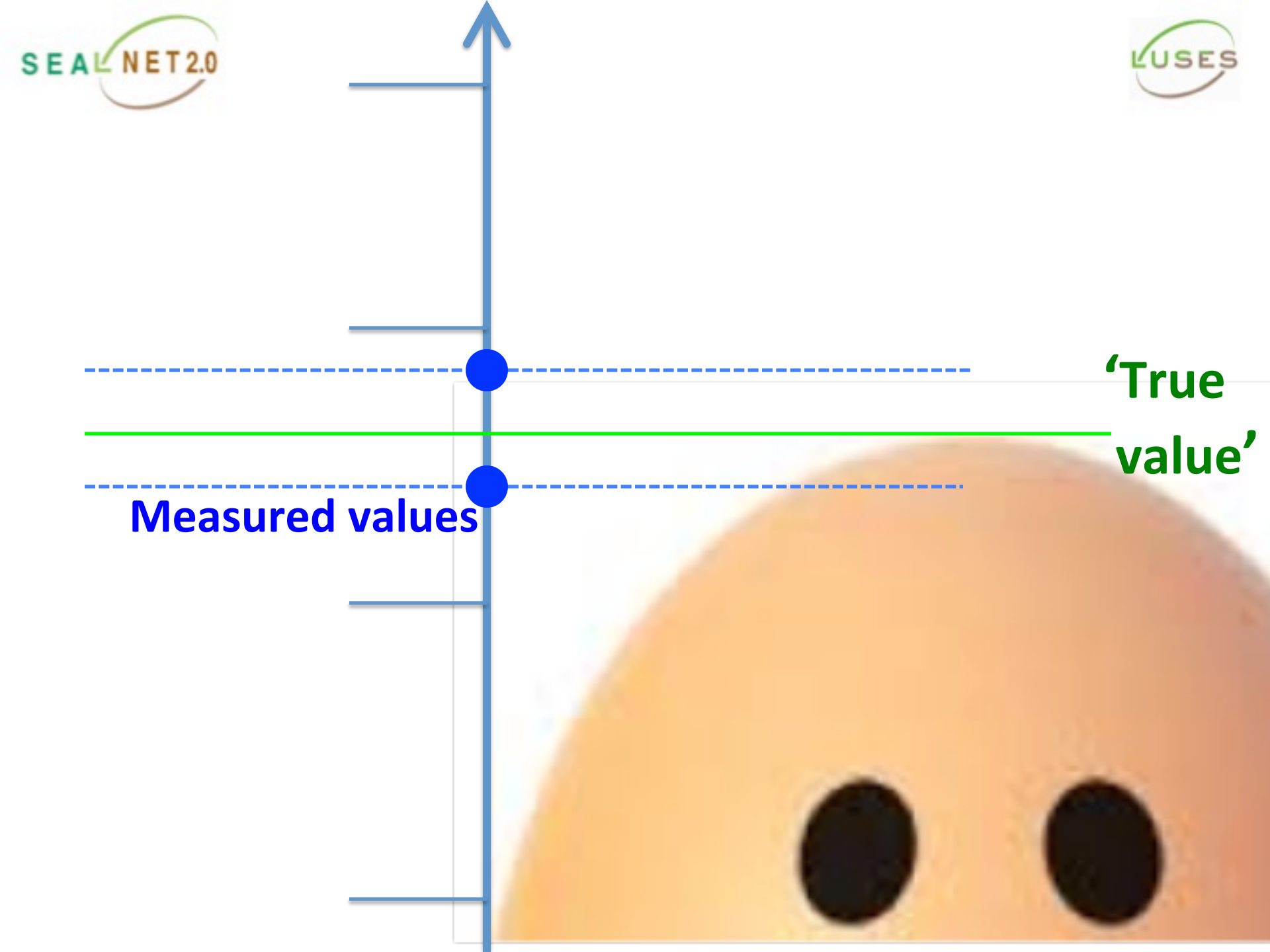
for one egg, one ruler,
but different people==> different measures.

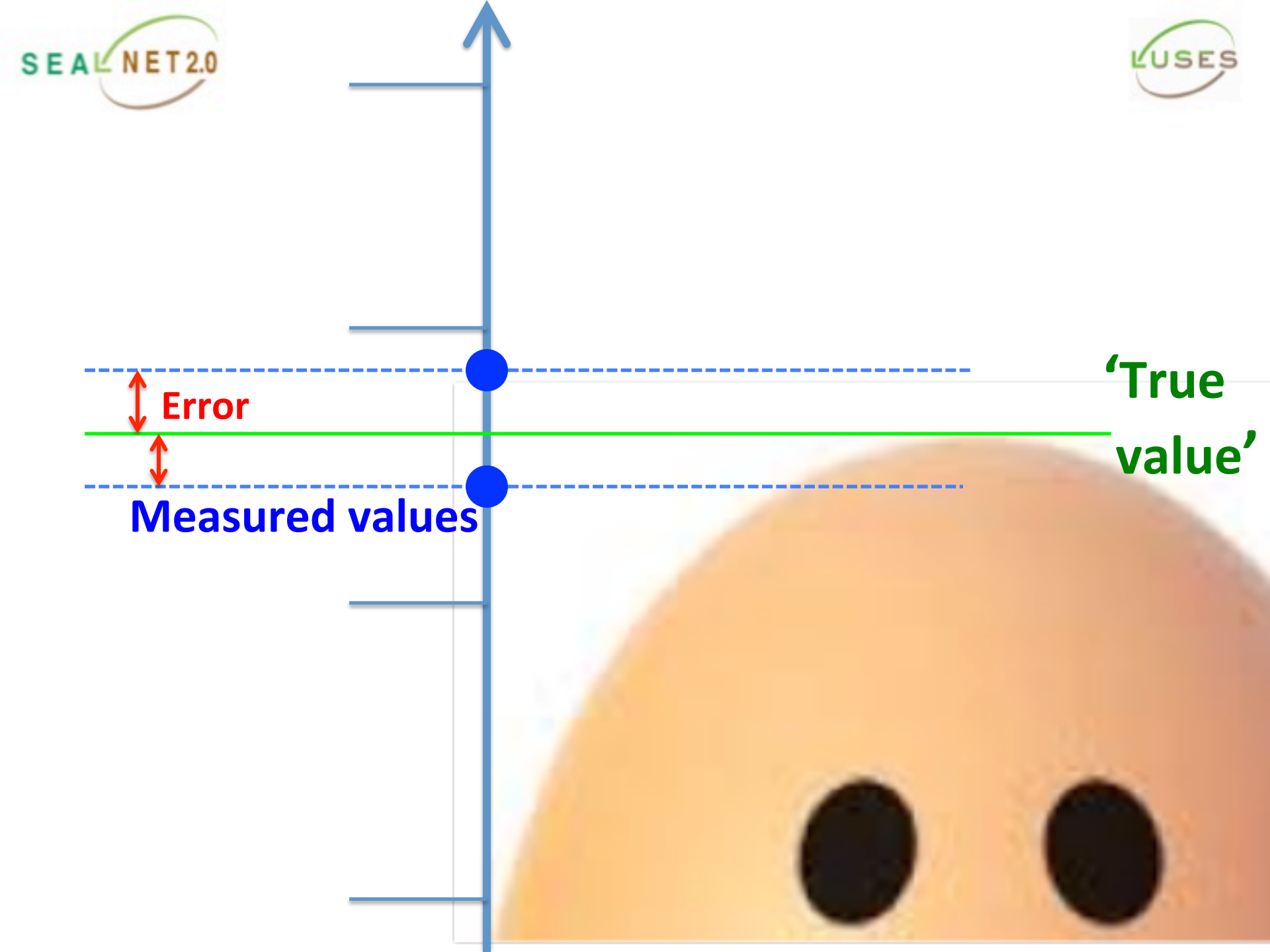
What happened?

Ruler

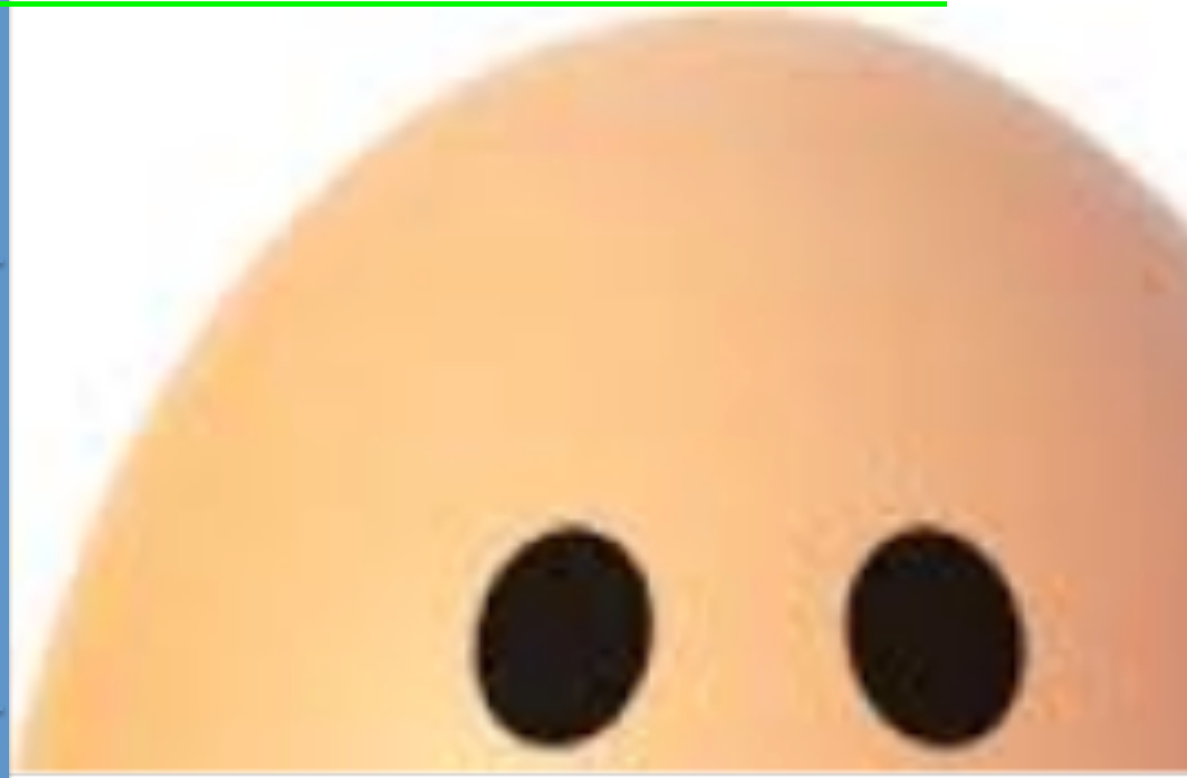



'True value'


'True value'
Measured values

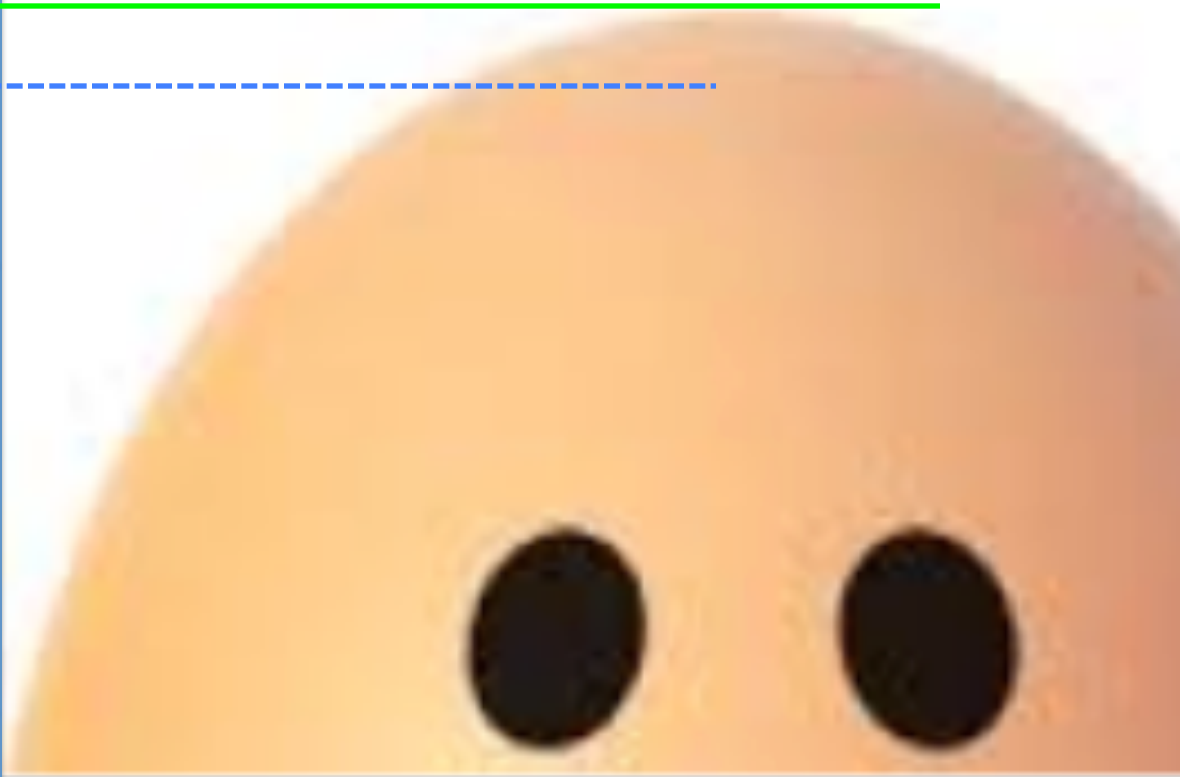

Error
'True value'
Measured values

cannot know ‘true value’



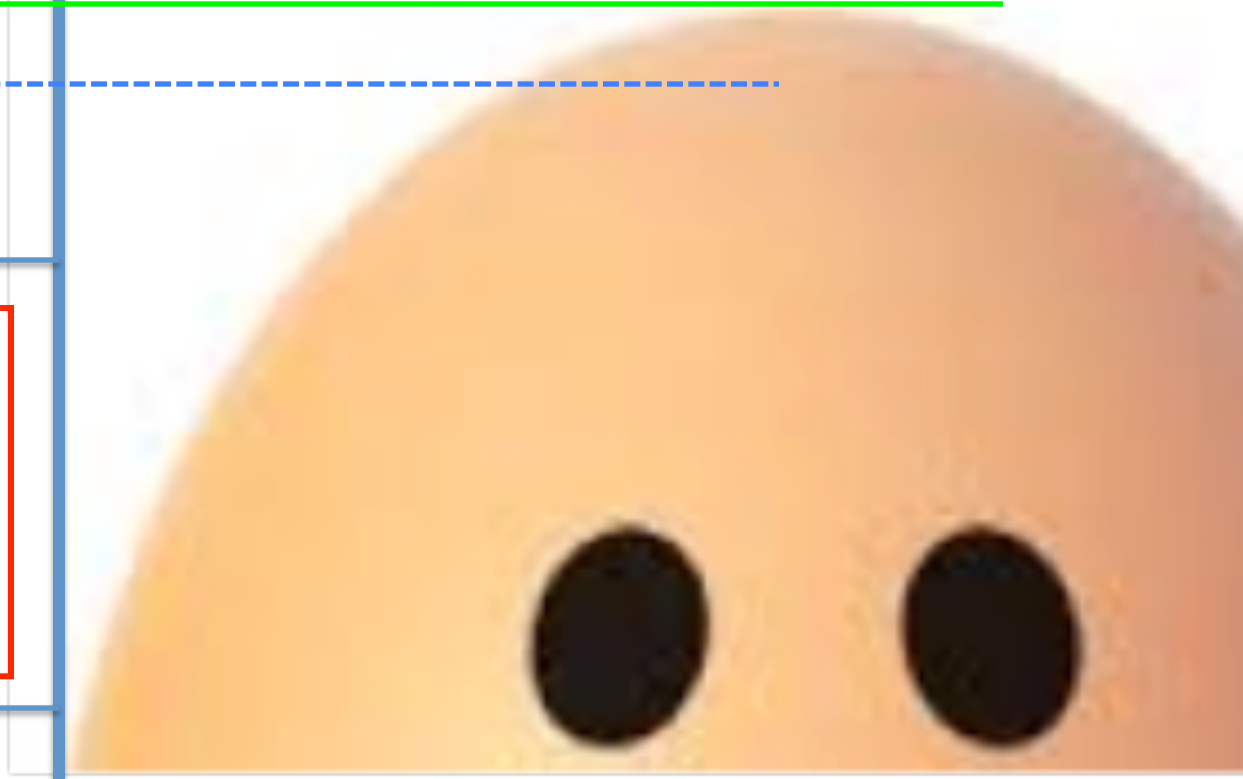
cannot know error

cannot know ‘true value’

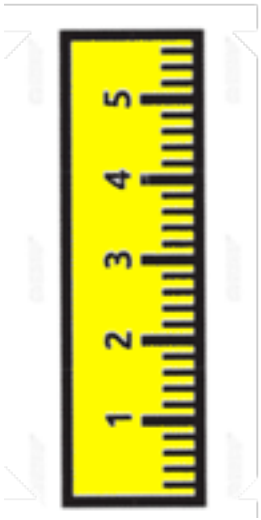


cannot know error

cannot know ‘true value’



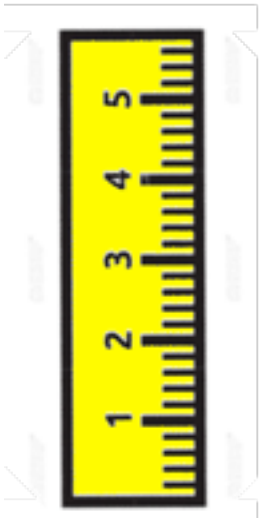
can only minimise the errors…





the egg has one size but….

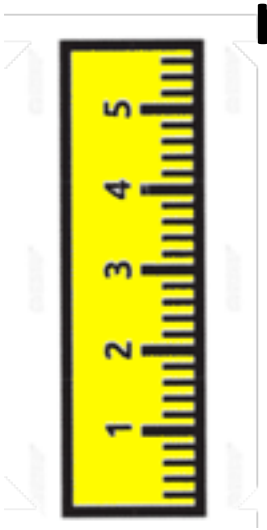
we have different measures!





METROLOGY teach us that all measures contain errors.

measure the egg….

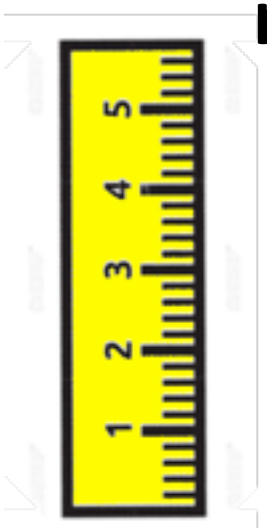




METROLOGY teach us that
all measures contain errors:

measure = true value +/- error

measure the egg….

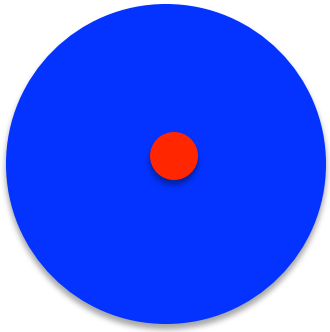




METROLOGY teach us that
all measures contain errors:

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?

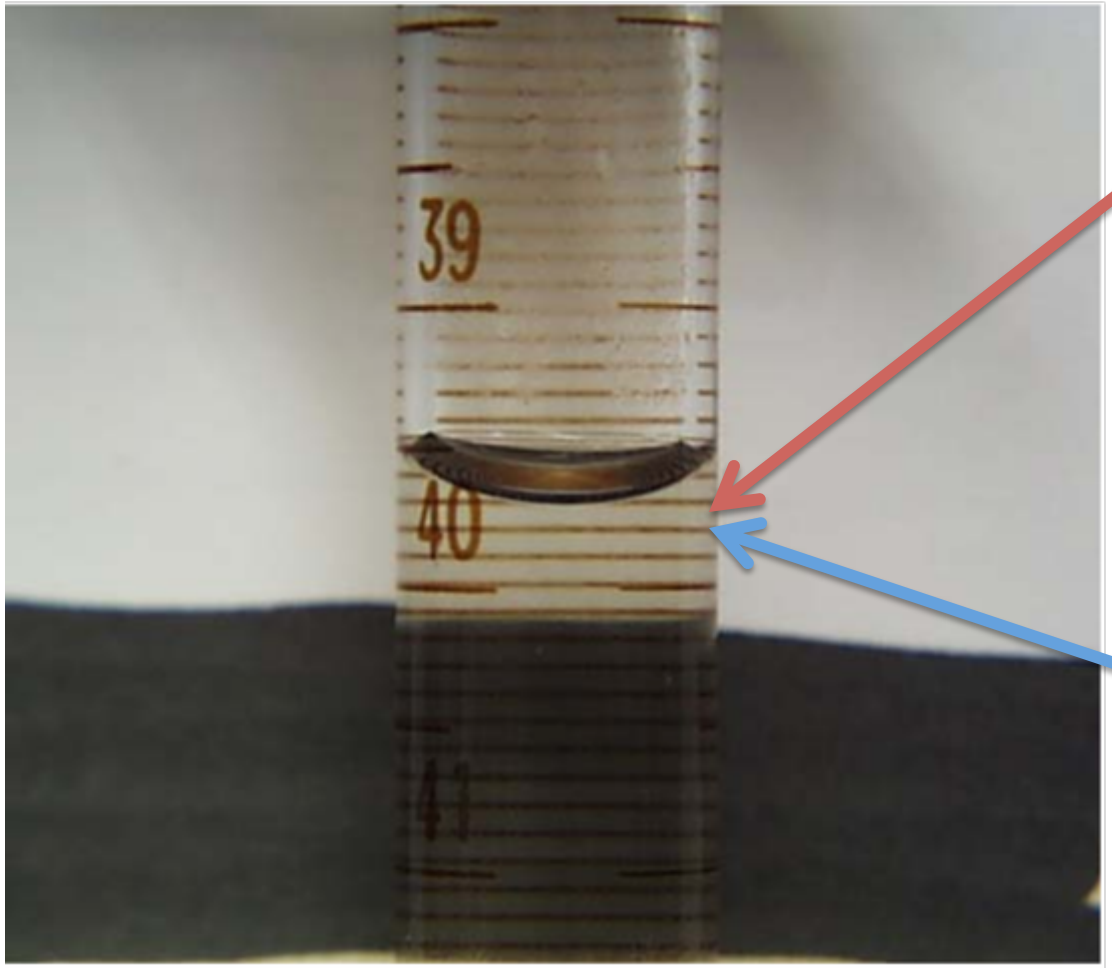


Figure 20: Liquid in a Burette

≠ 39.7

≠ 39.8

Error:

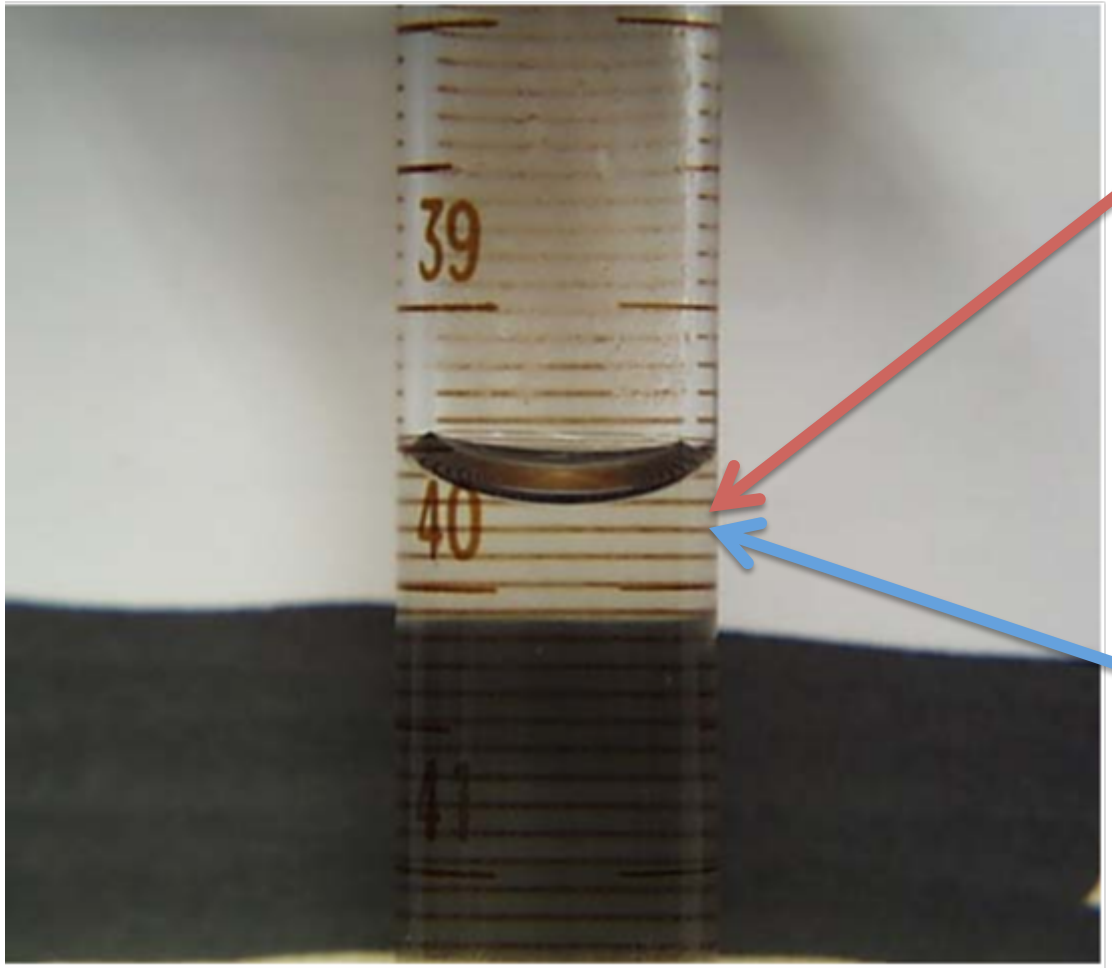


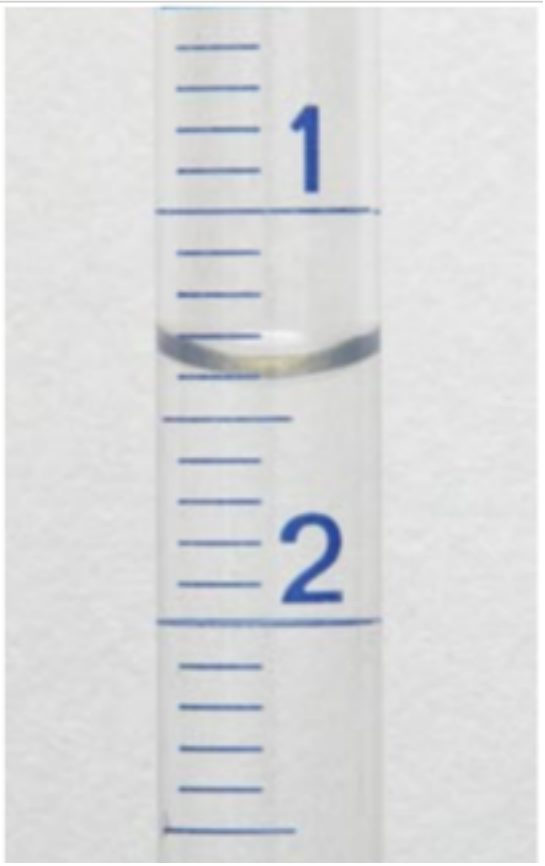
Figure 20: Liquid in a Burette

39.71?

≠ 39. 72?

anyway my result will contain an error

Another example:

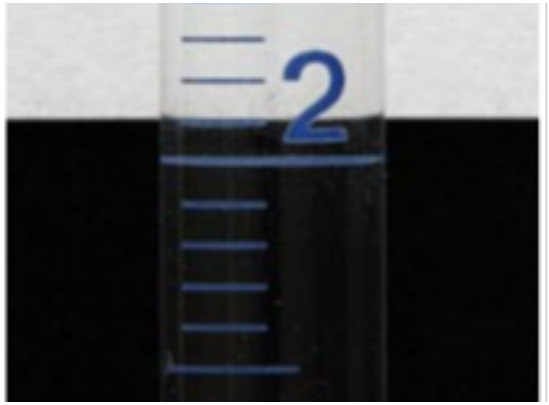



1.40
1
2

Error:

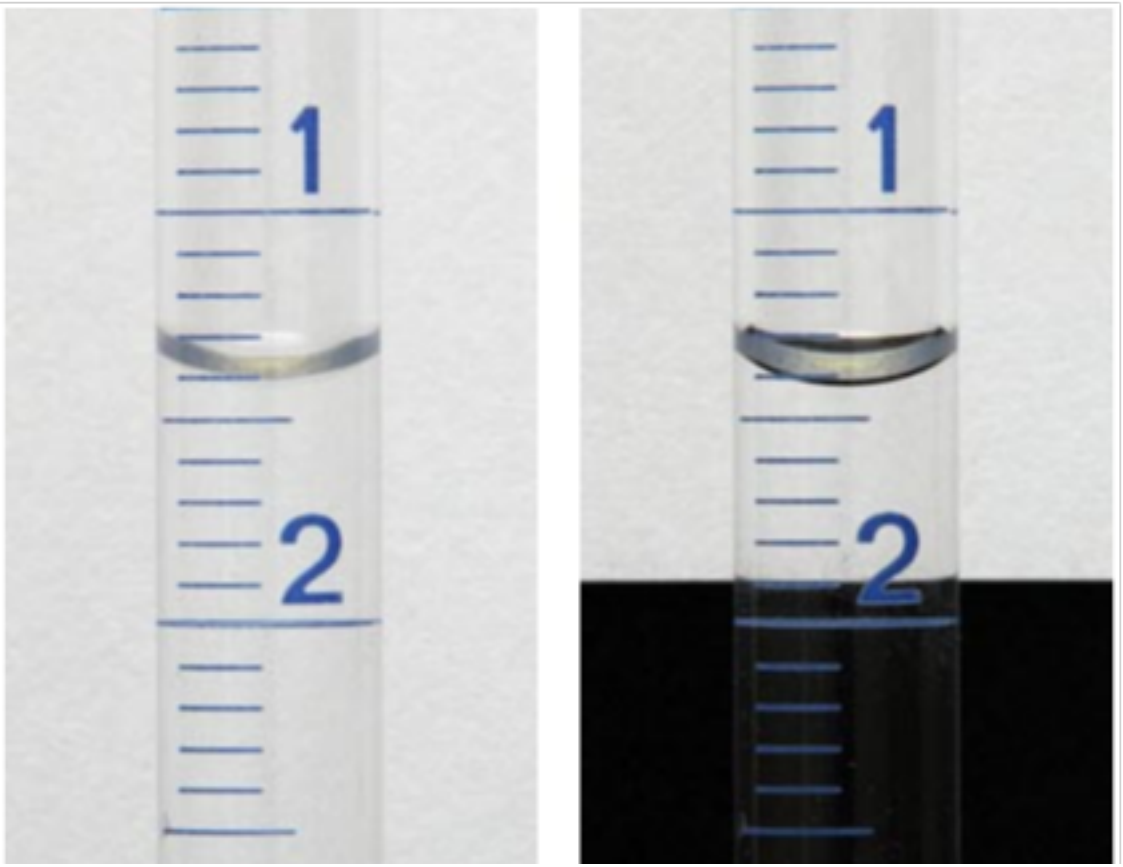
1.40





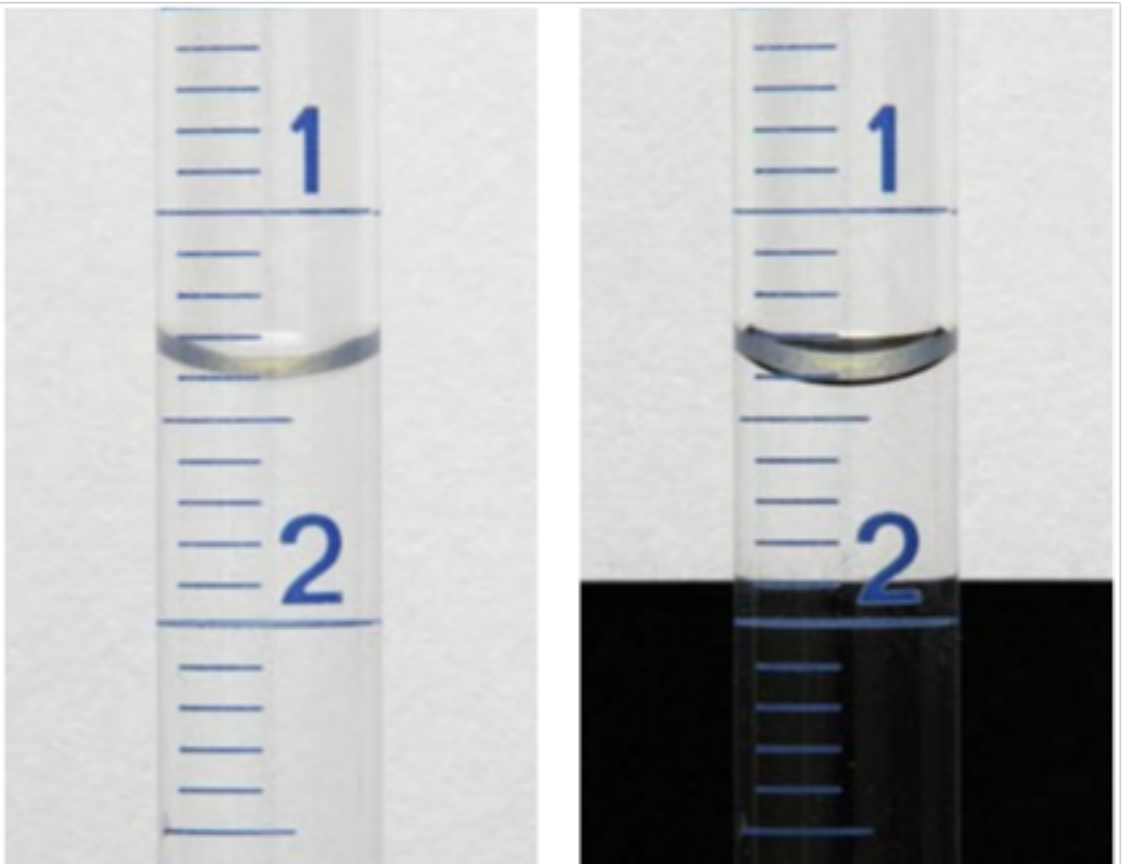
Error:

1.40



Error:

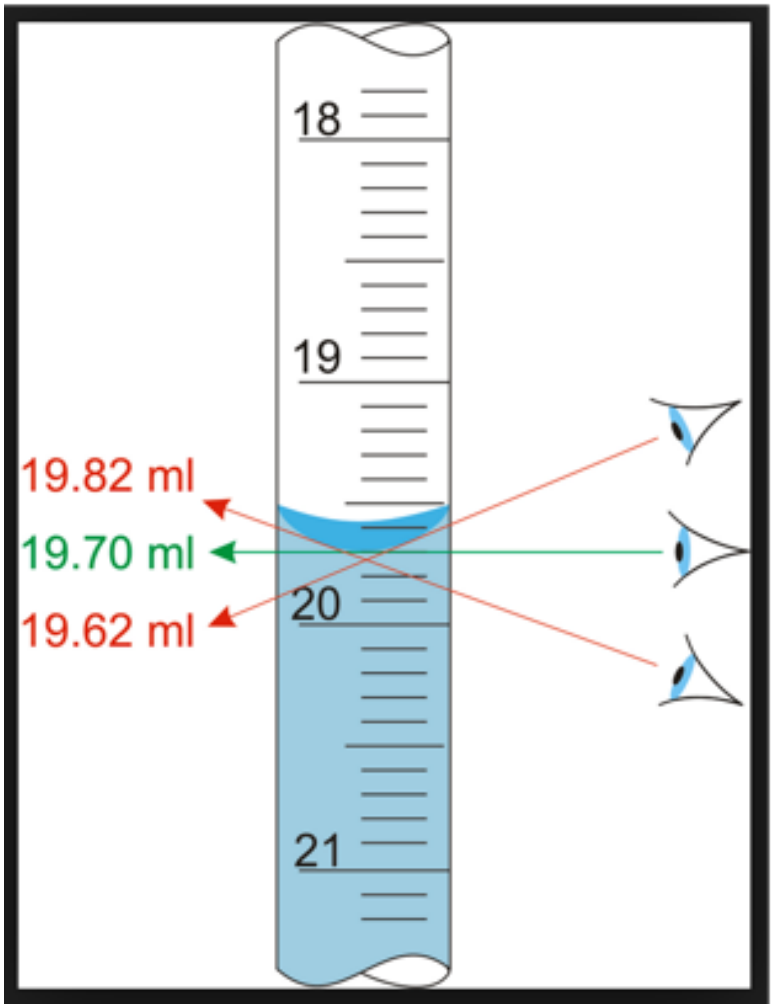
1.40



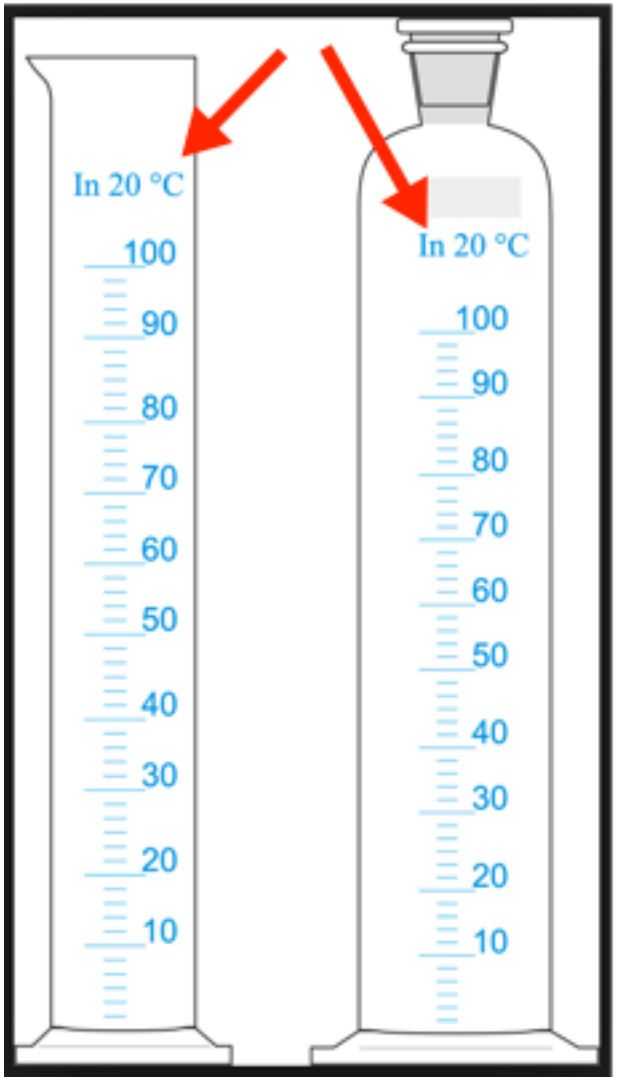
≠ 1.40

😟

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…

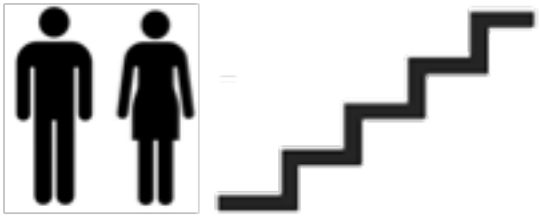
True value = middle of the target..



If you are a beginner:



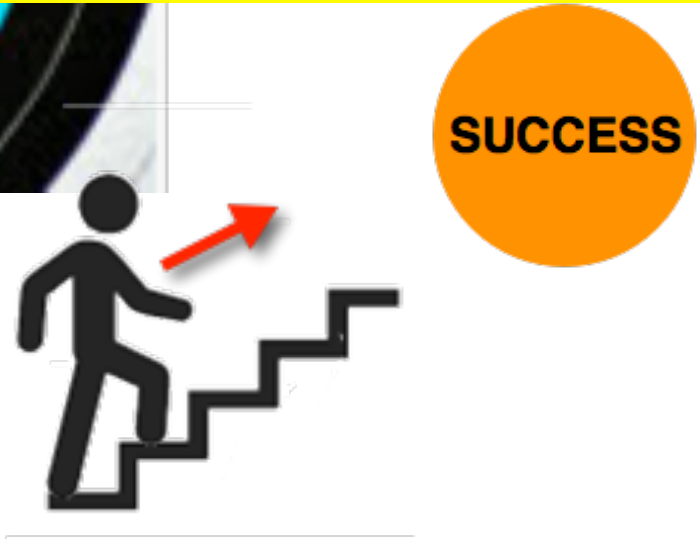




If you are a beginner:



you have to improve!



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!



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



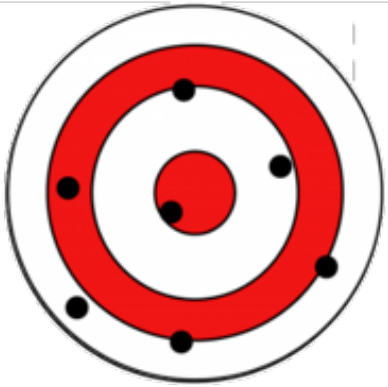
low

Precision: high low

Accuracy:

high





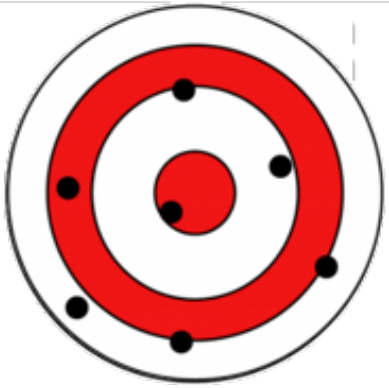
low

Precision: high low

Accuracy:

high





low

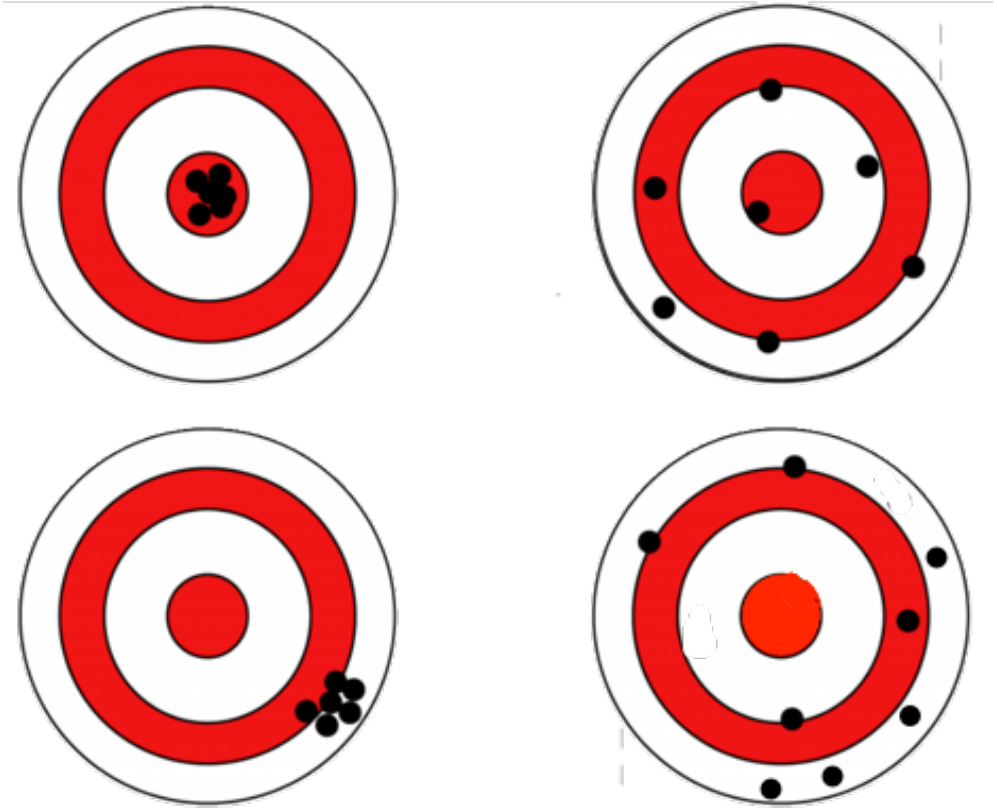


Precision: high low

Accuracy:

high

low



Accuracy and precision in every day life…

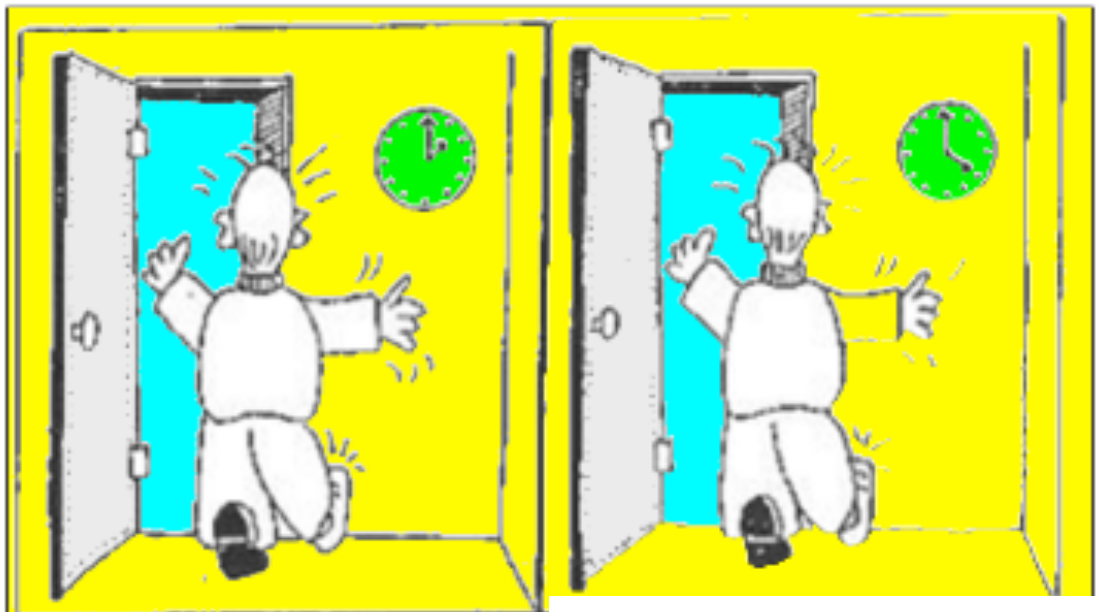
Accuracy and precision in every day life…

going threw a door with:
high precision
but low accuracy

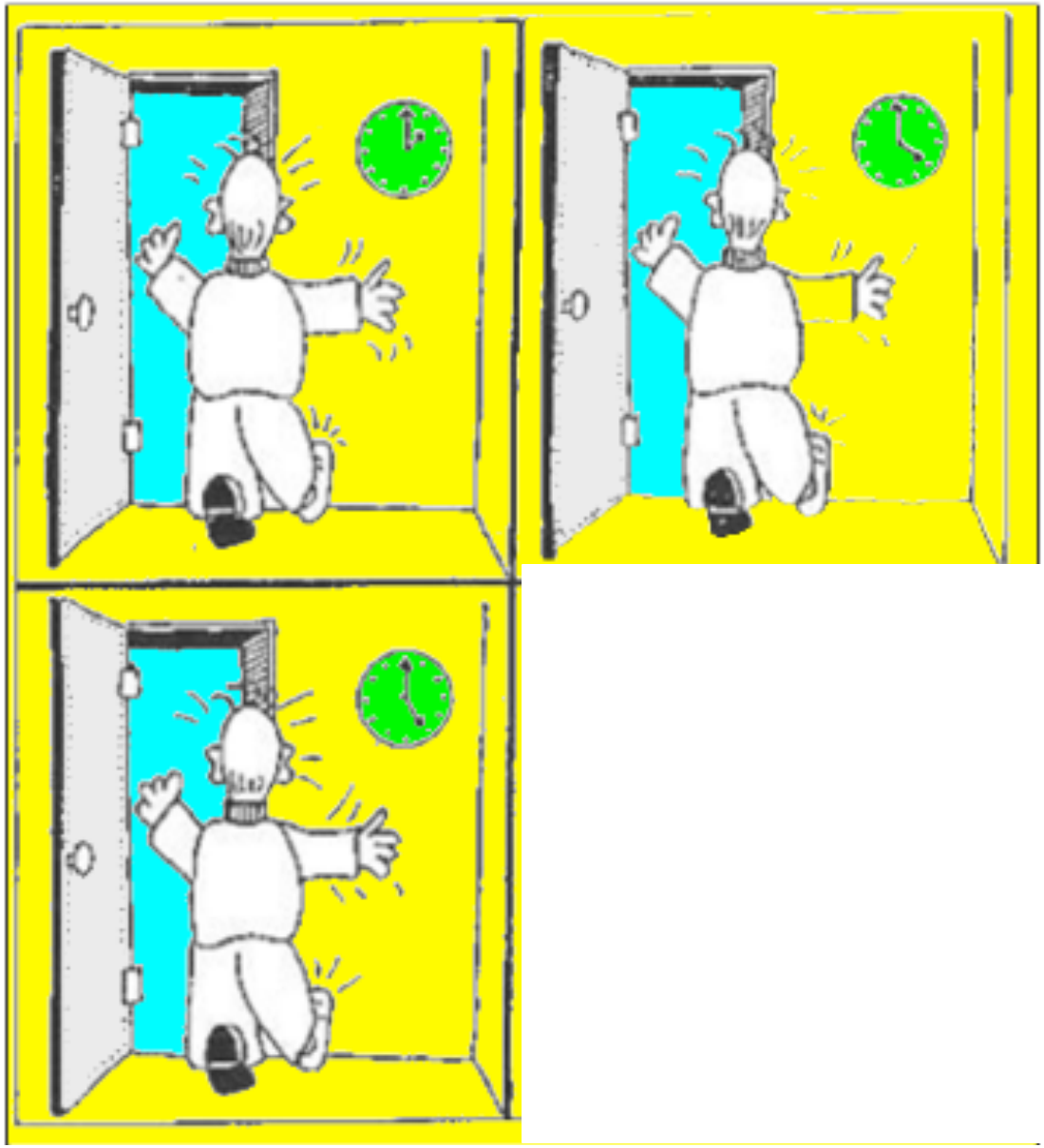
Accuracy and precision in every day life…



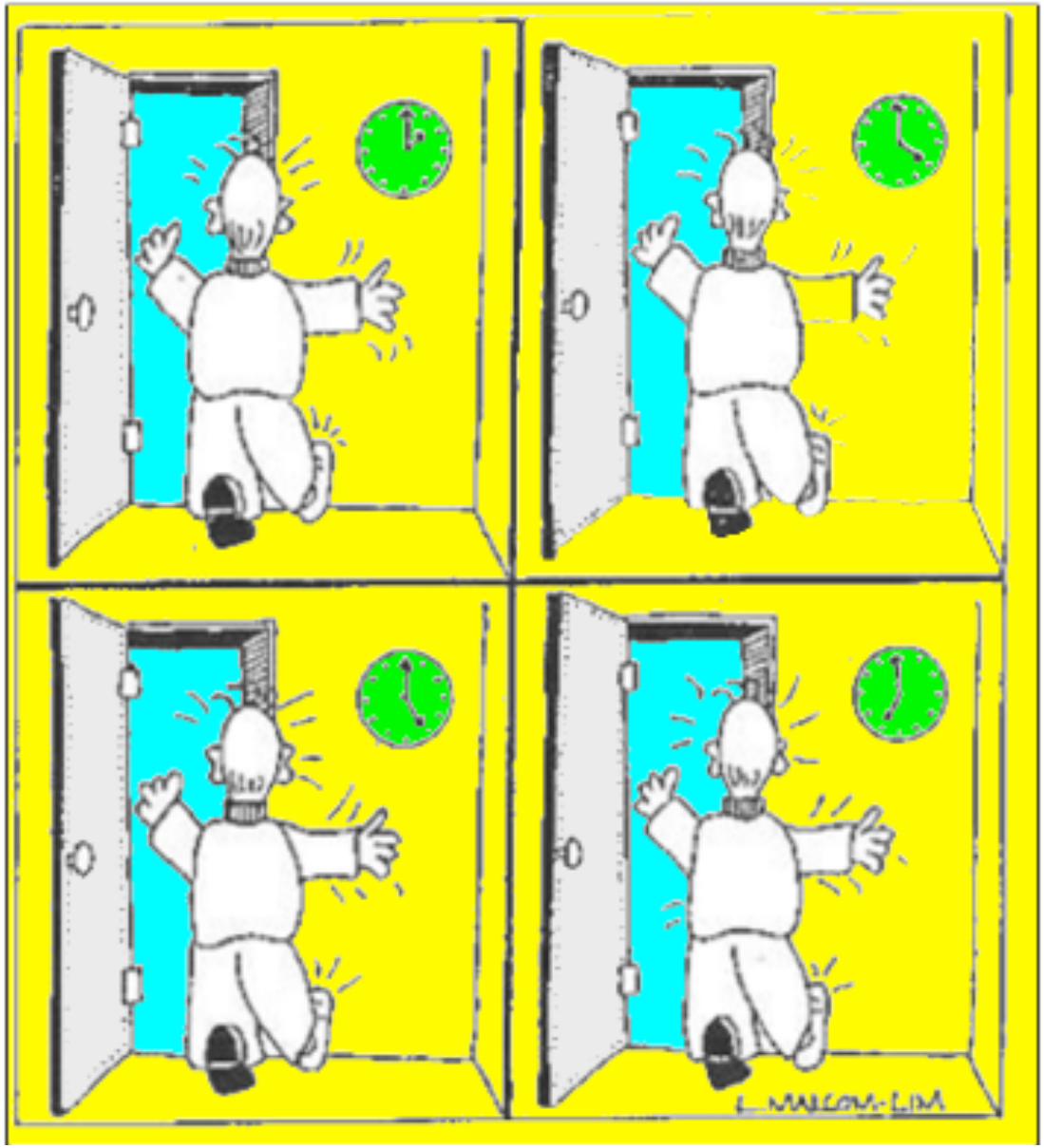
Accuracy and precision in every day life…



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….







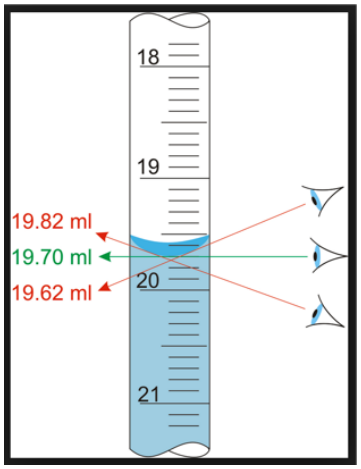
Error:

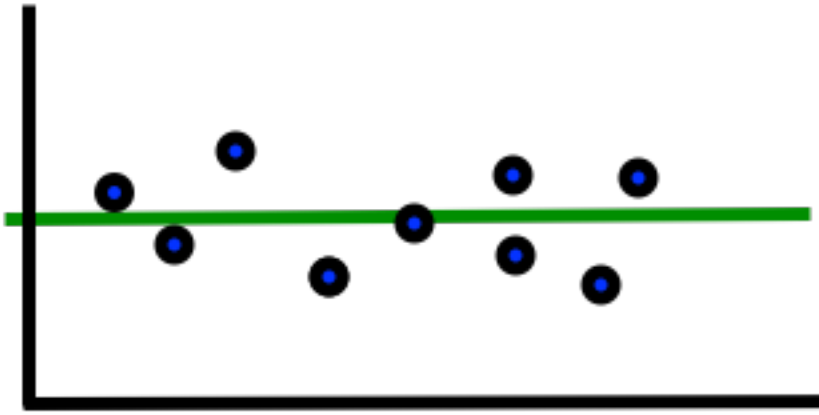
the difference between your result and the "true" value.

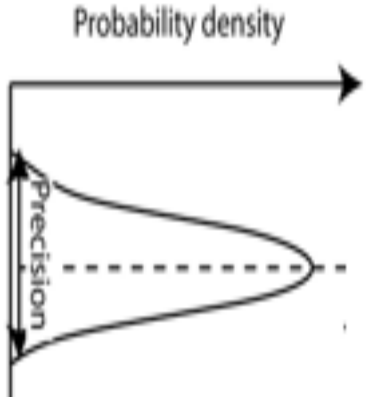
Analytical errors can be of 2 categories:

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1. Random or 'unpredictable' deviations between replicates

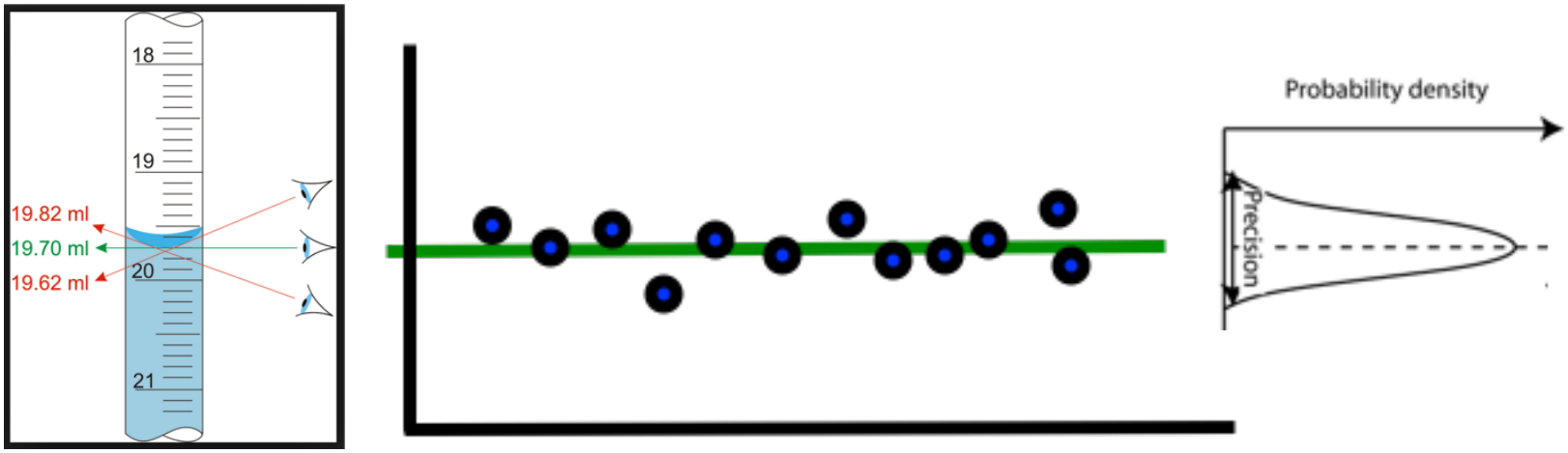






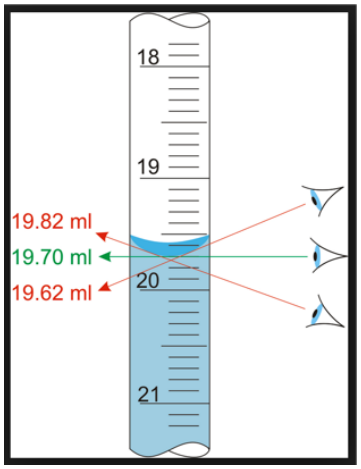
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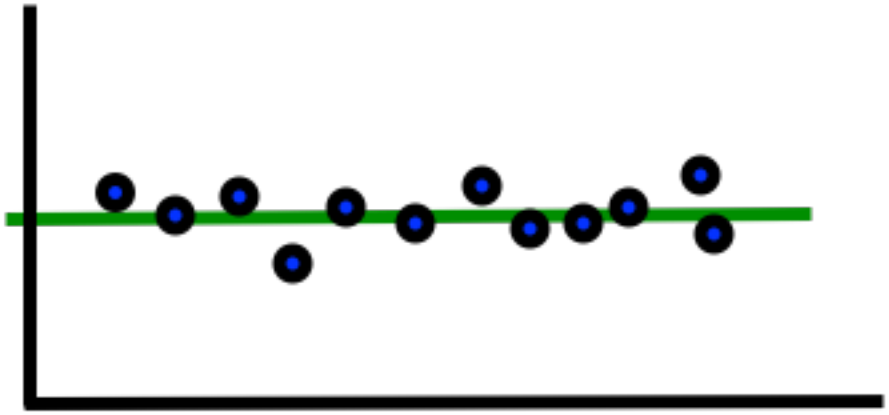
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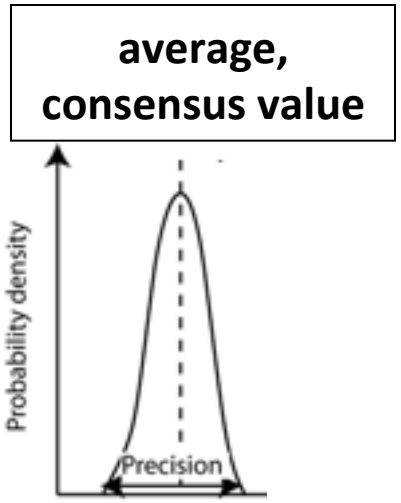


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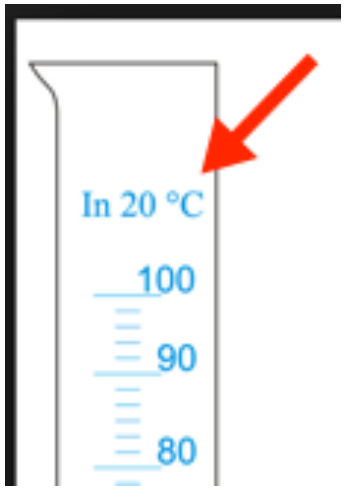






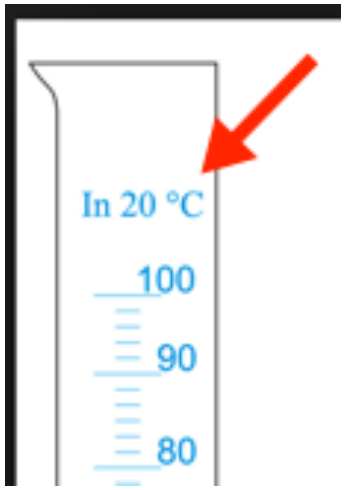
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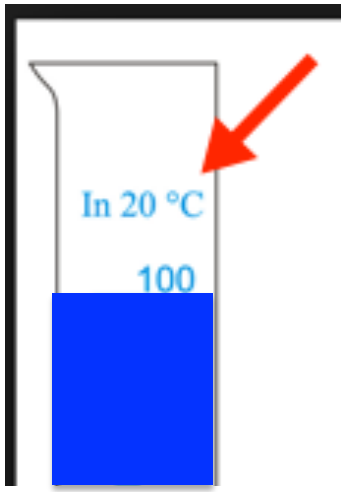
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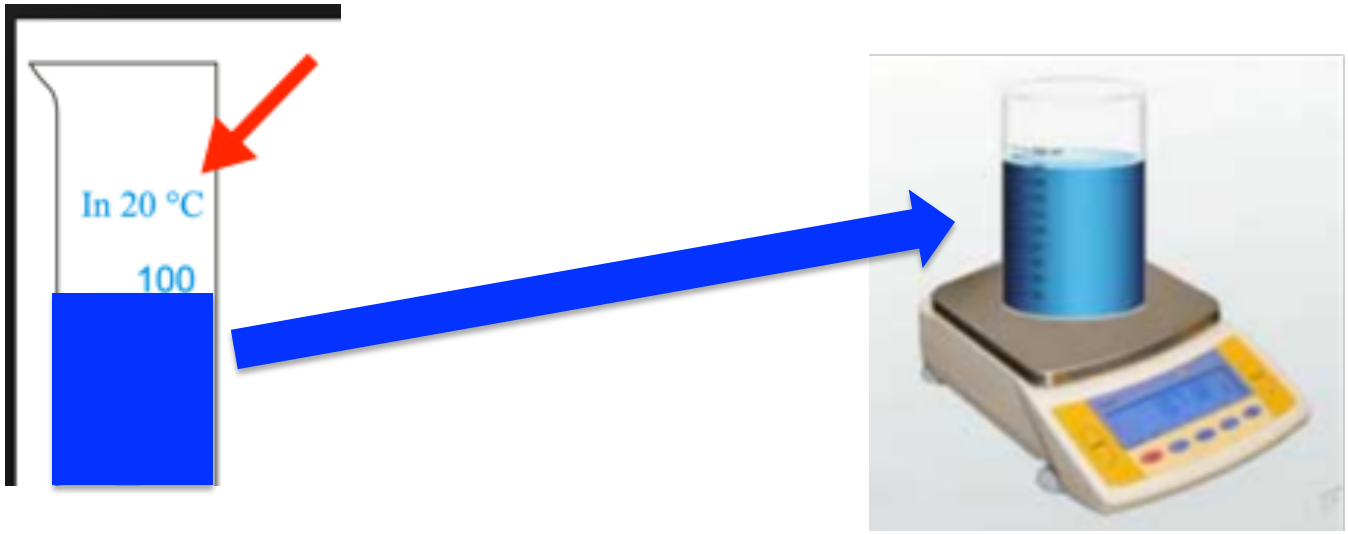
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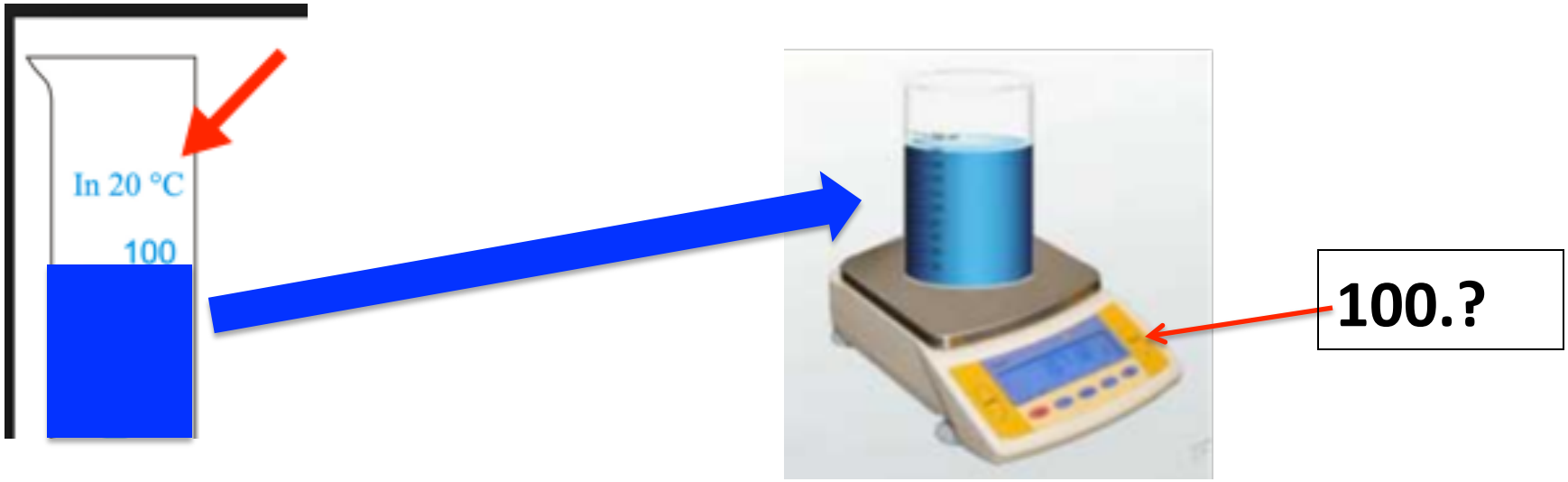
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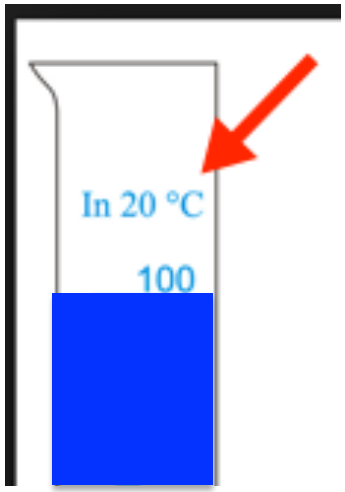
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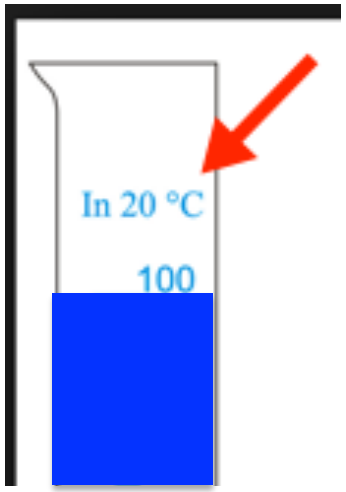


In France: 20°C

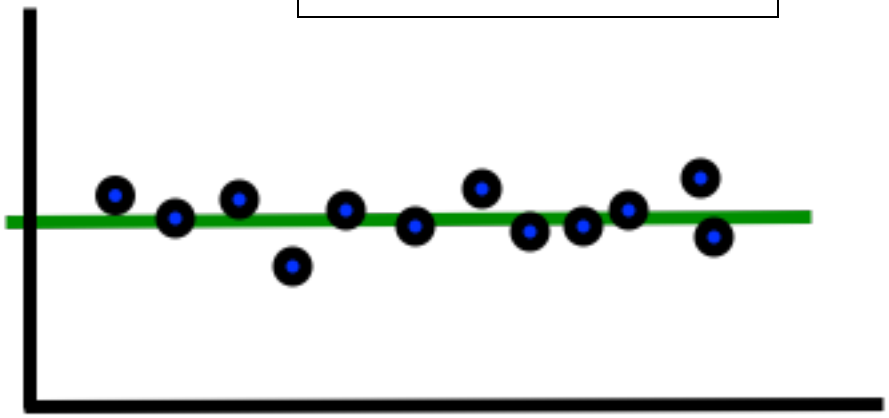
100 mL

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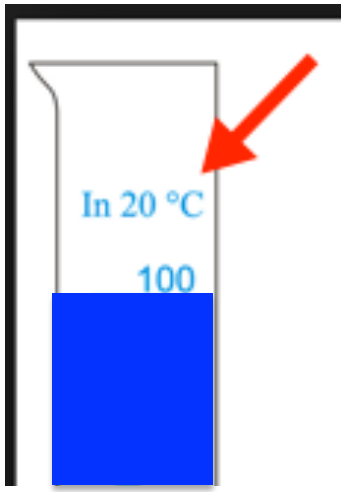


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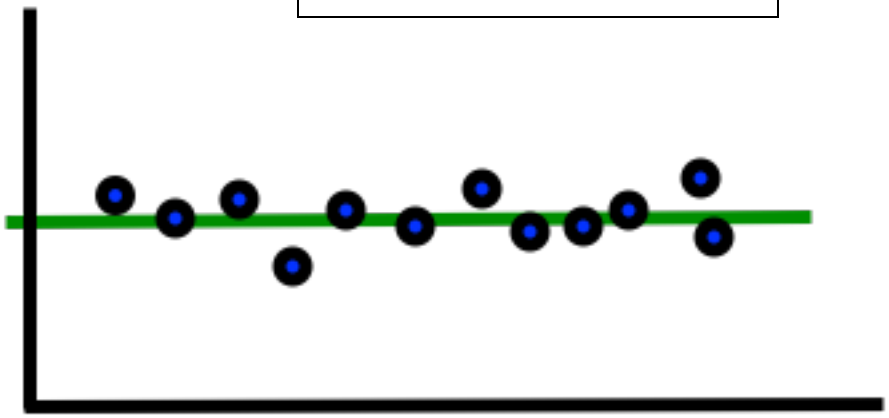


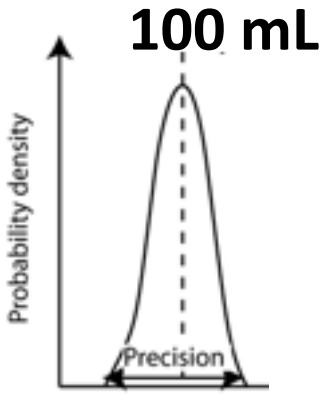
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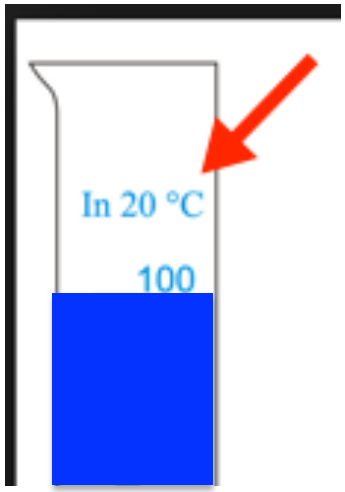




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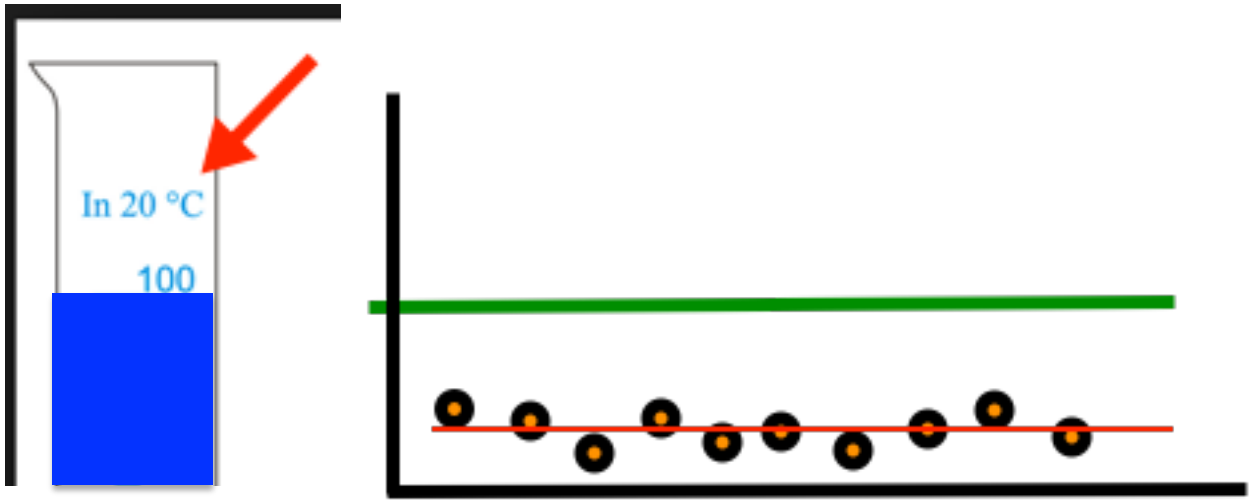


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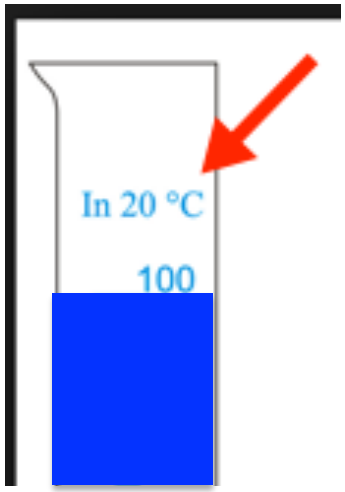
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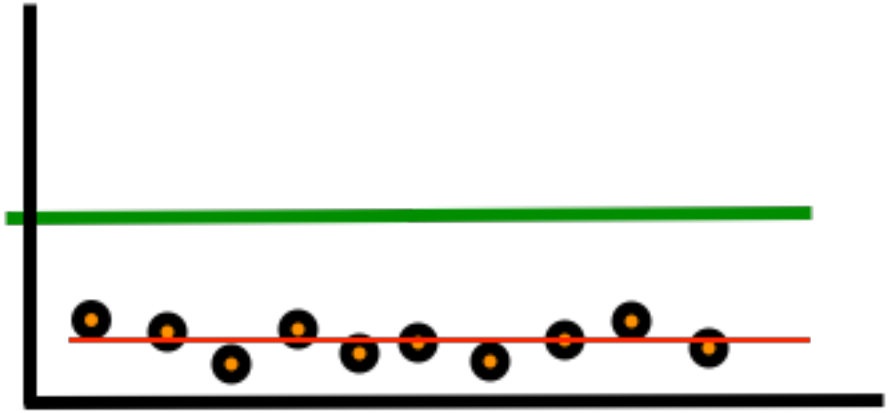


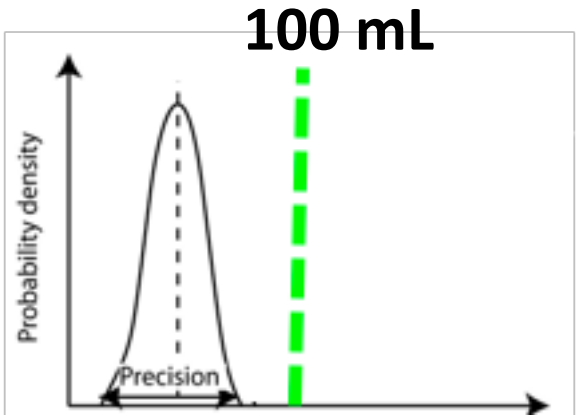
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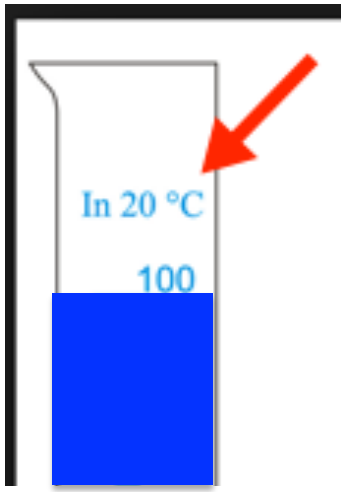


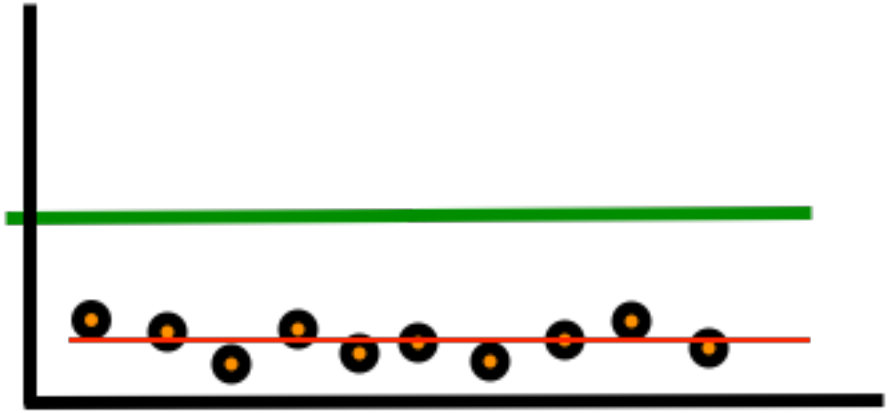


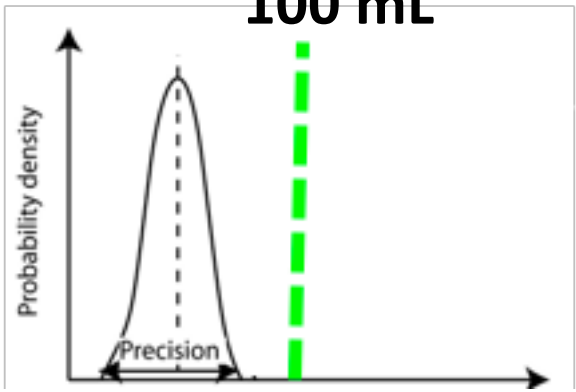
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In Lao PDR: 35°C	(glass expansion)



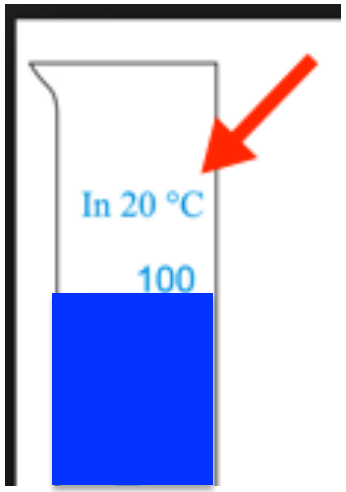


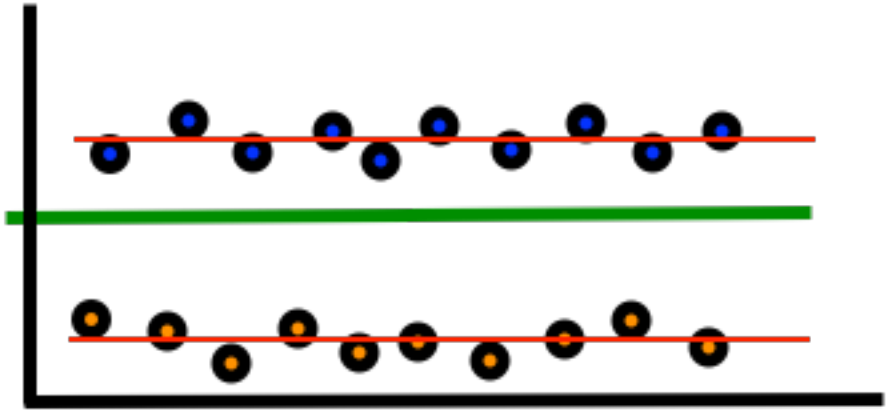


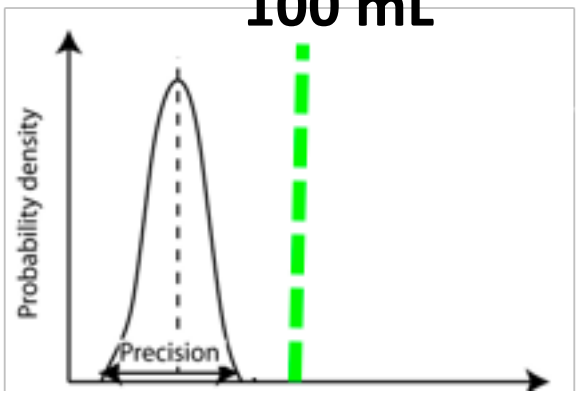
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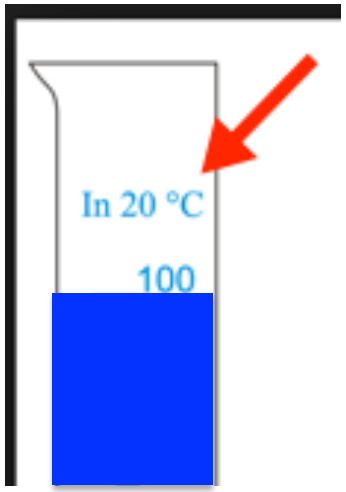


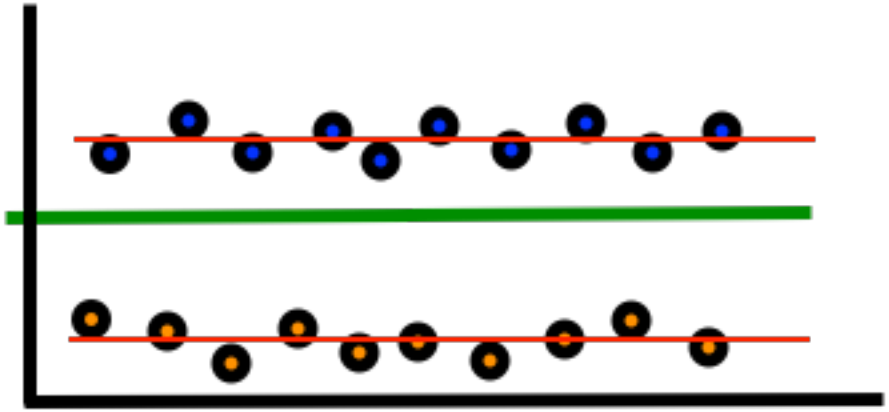


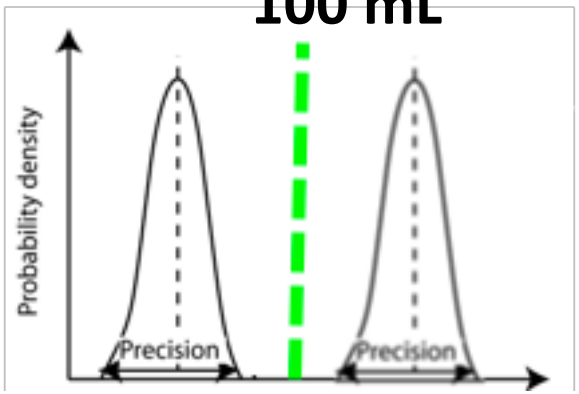
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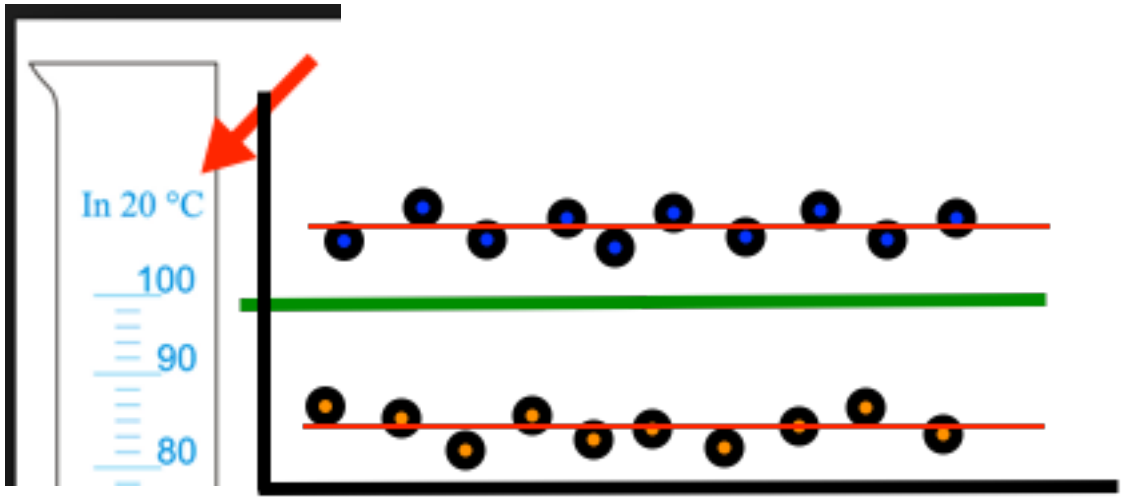


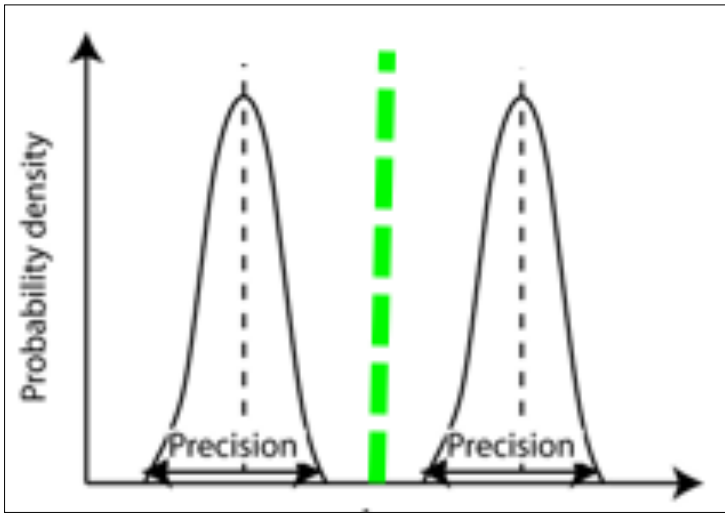




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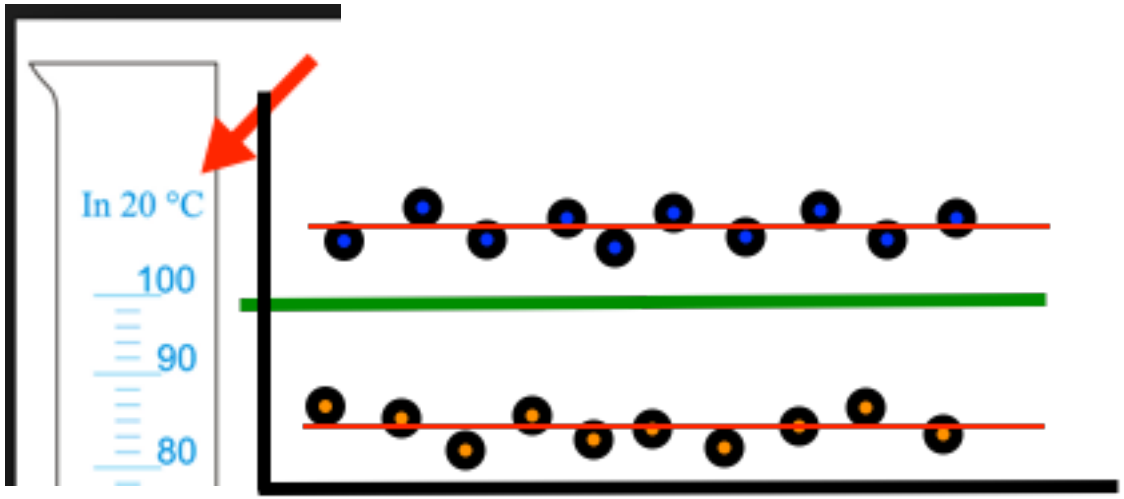
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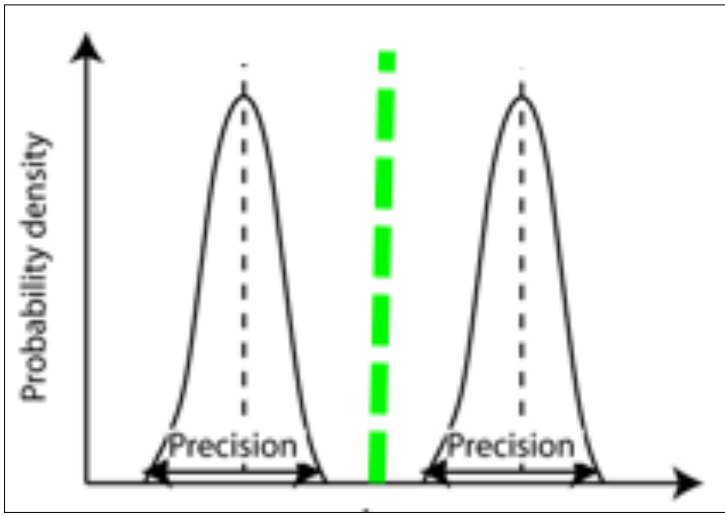




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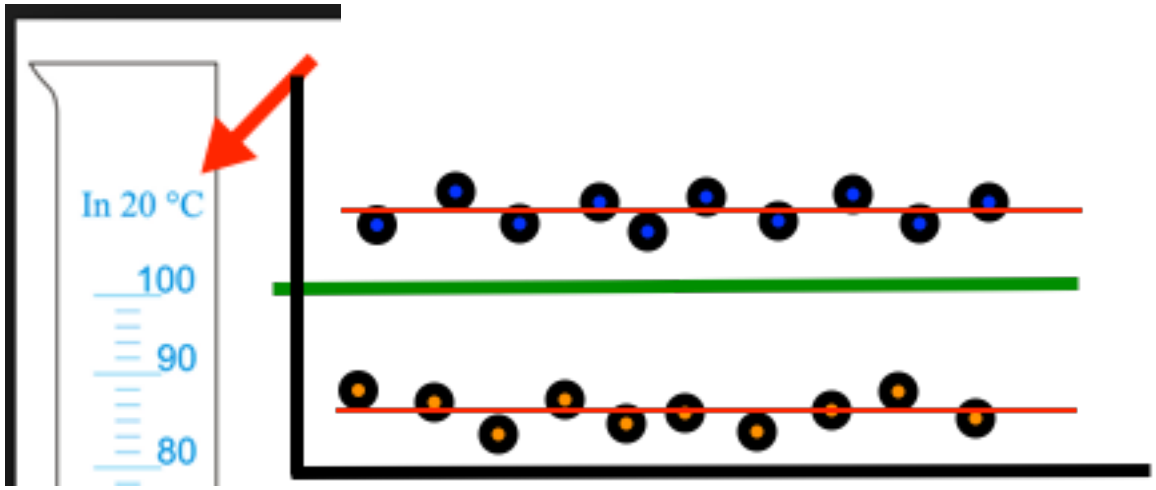
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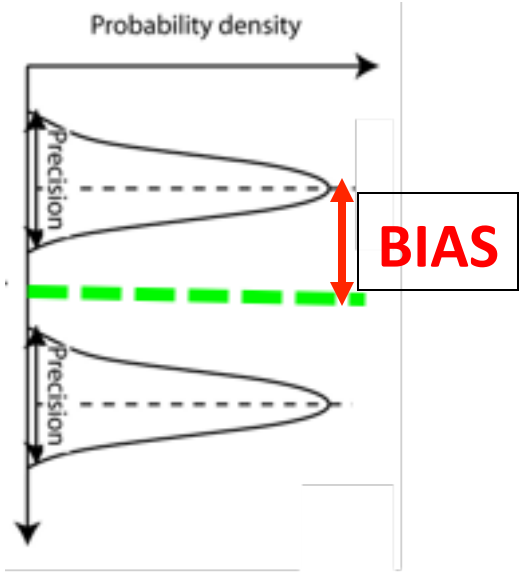


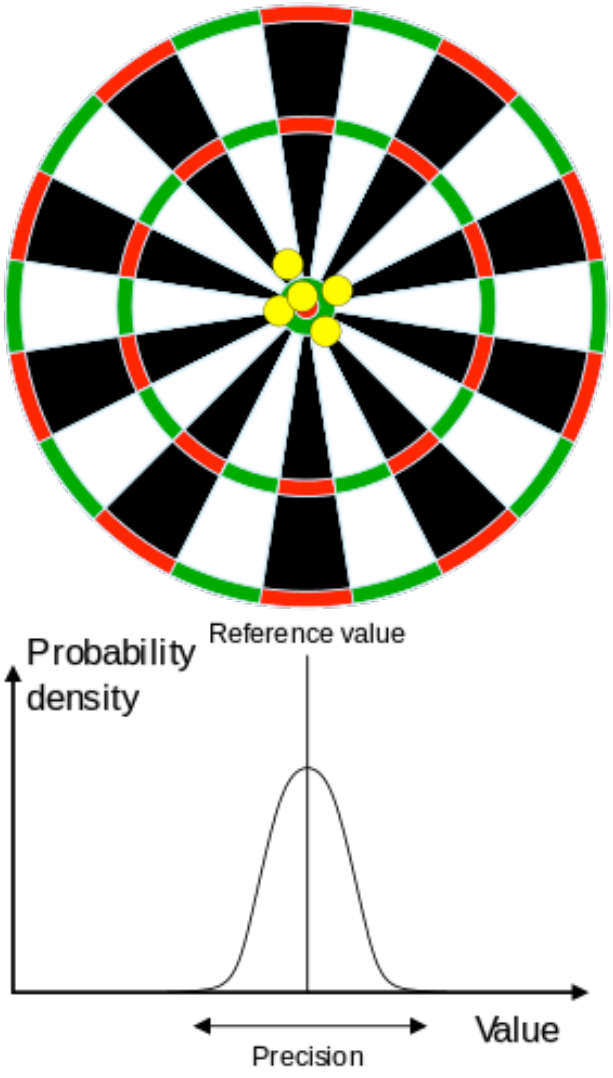
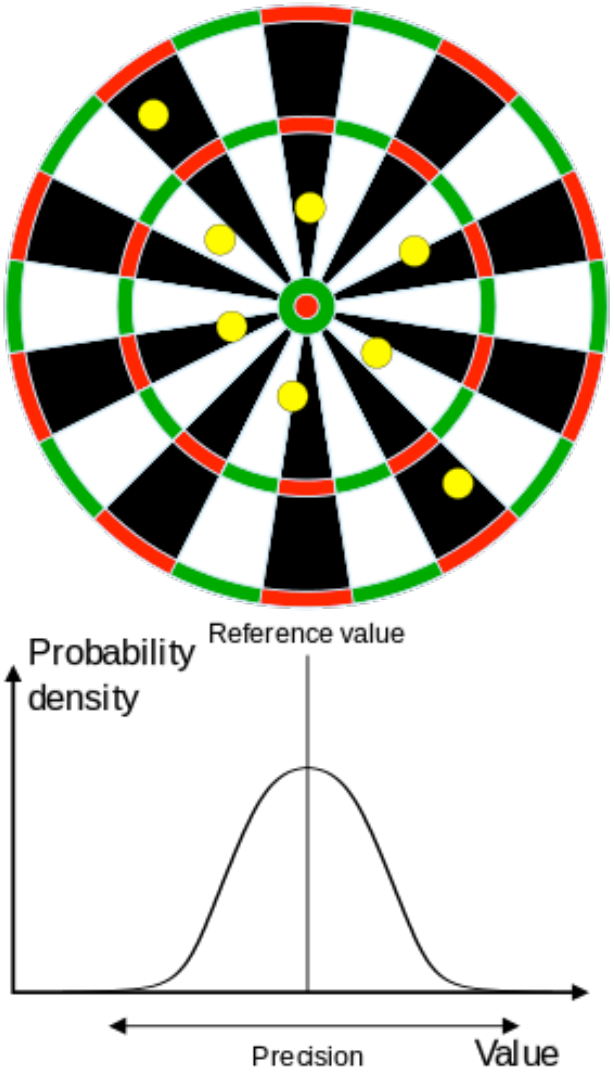


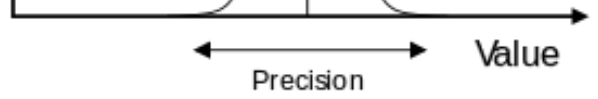
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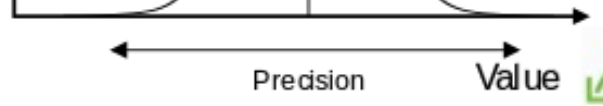
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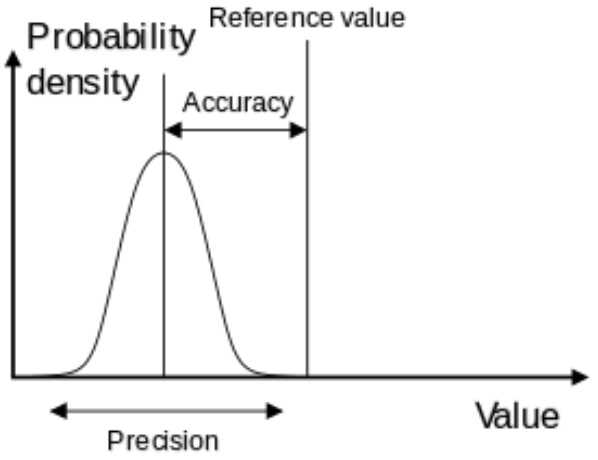
	Yes	No
Yes	Reference value Probability density Precision Value	Reference value Probability density Precision Value
		

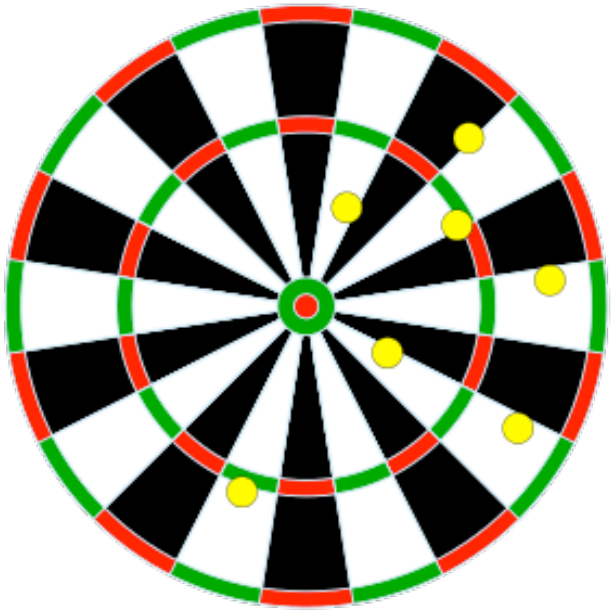

Precision
Value

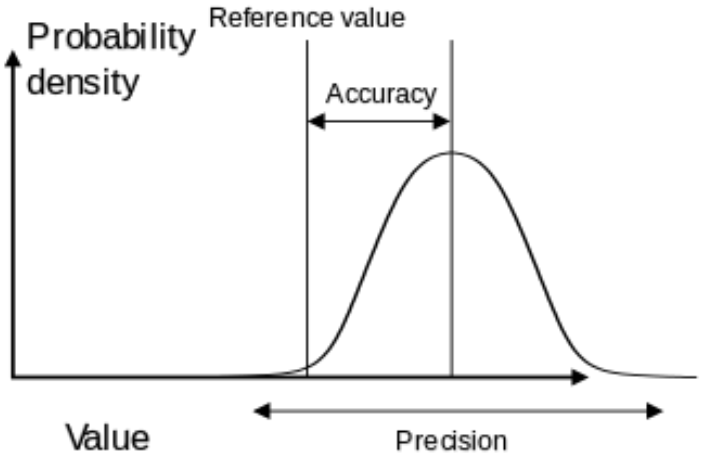

Precision
Value

No




Reference value
Probability density
Accuracy
Precision
Value




Reference value
Probability density
Accuracy
Value
Precision

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 <u>always</u> keep in mind:

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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 <u>not</u> 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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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*)

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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..

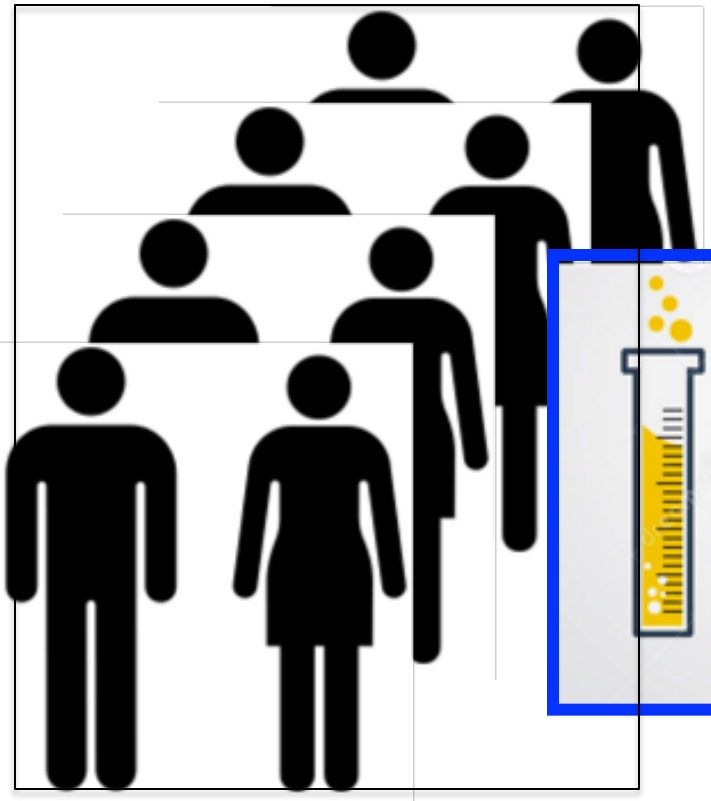


Analytical tasks

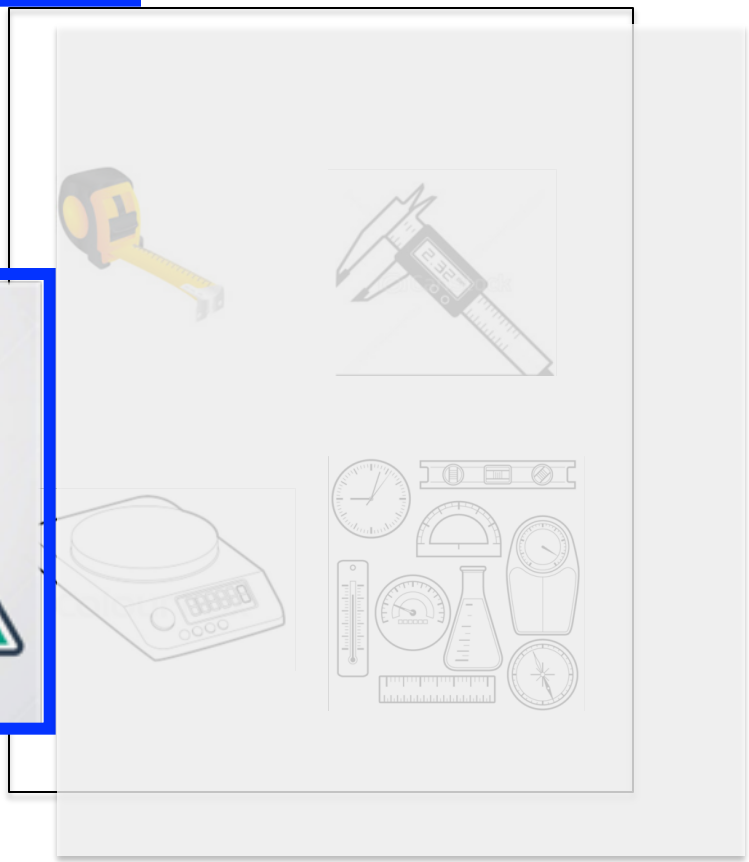
pH, NPK, etc..

ANALYSIS:

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.

with GLP you need:

STANDARD OPERATING PROCEDURES (SOP)

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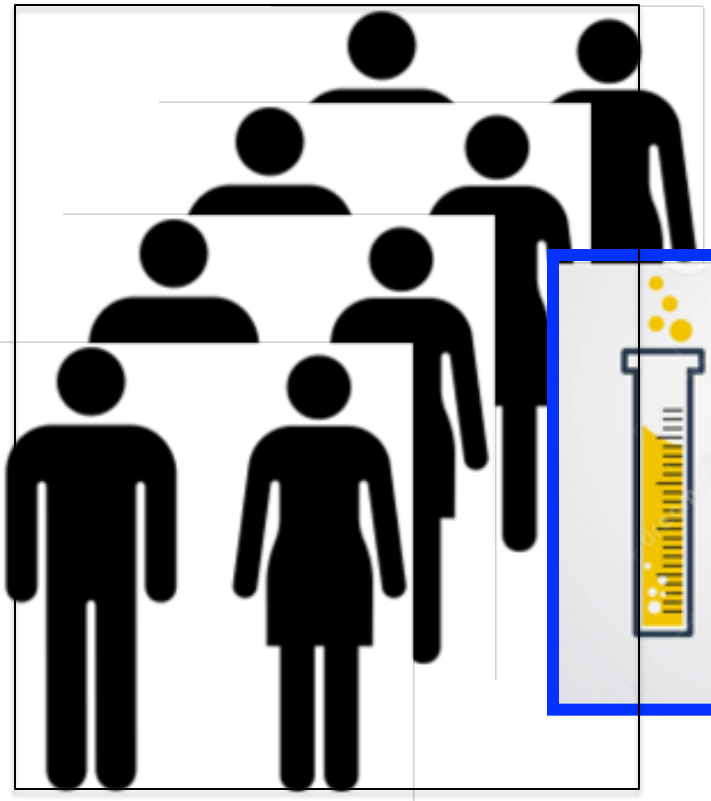
Repeated application of **unchanged processes** and procedures, and **their documentation**.

SOP are mandatory instructions!

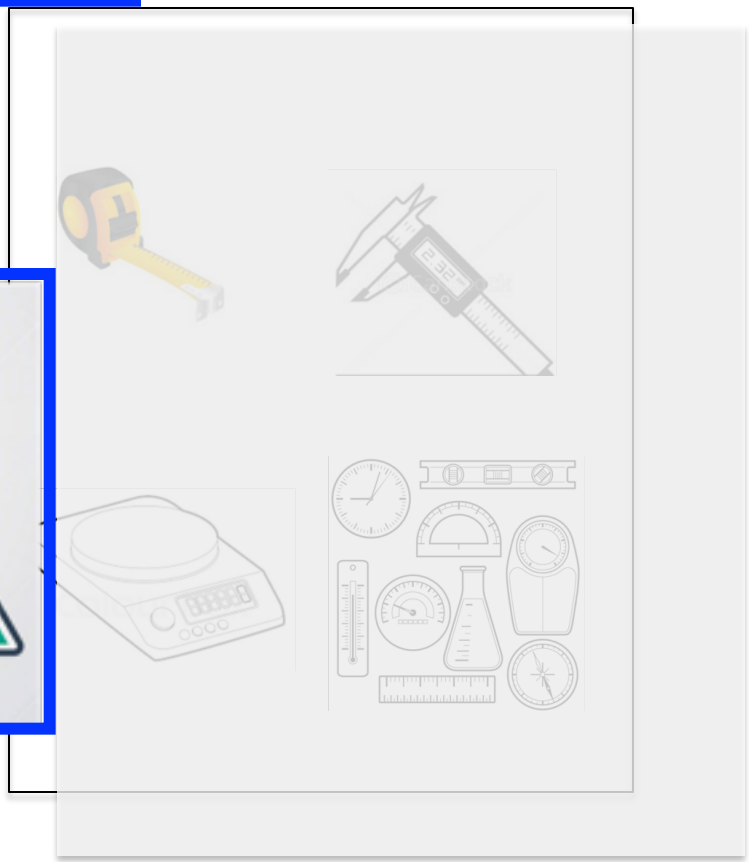
You have to strictly follow a SOP, not to adapt it.

ANALYSIS:

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 follo 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 intrantional accreditaiton and custommer want to know you fit with international rules.
For example Chinese, Thai, australian copany, etc… want to be sure your data fit with whzt they know....

A good exemple is Carbone and ORGANIC MATTER

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

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



SOIL pH DETERMINATION

CONTENTS

1.0 SCOPE AND APPLICATION

2.0 METHOD SUMMARY

3.0 SAMPLE PRESERVATION, CONTAINERS, HANDLING AND STORAGE

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5.0 EQUIPMENT/APPARATUS

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7.0 PROCEDURES

- 7.1 pH Calibration Procedure
- 7.2 pH Meter Operation
- 7.3 Temperature Compensation
- 7.4 Sample Preparation with Reagent Water
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- 7.6 Sample Measurement
- 7.7 Battery Replacement
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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

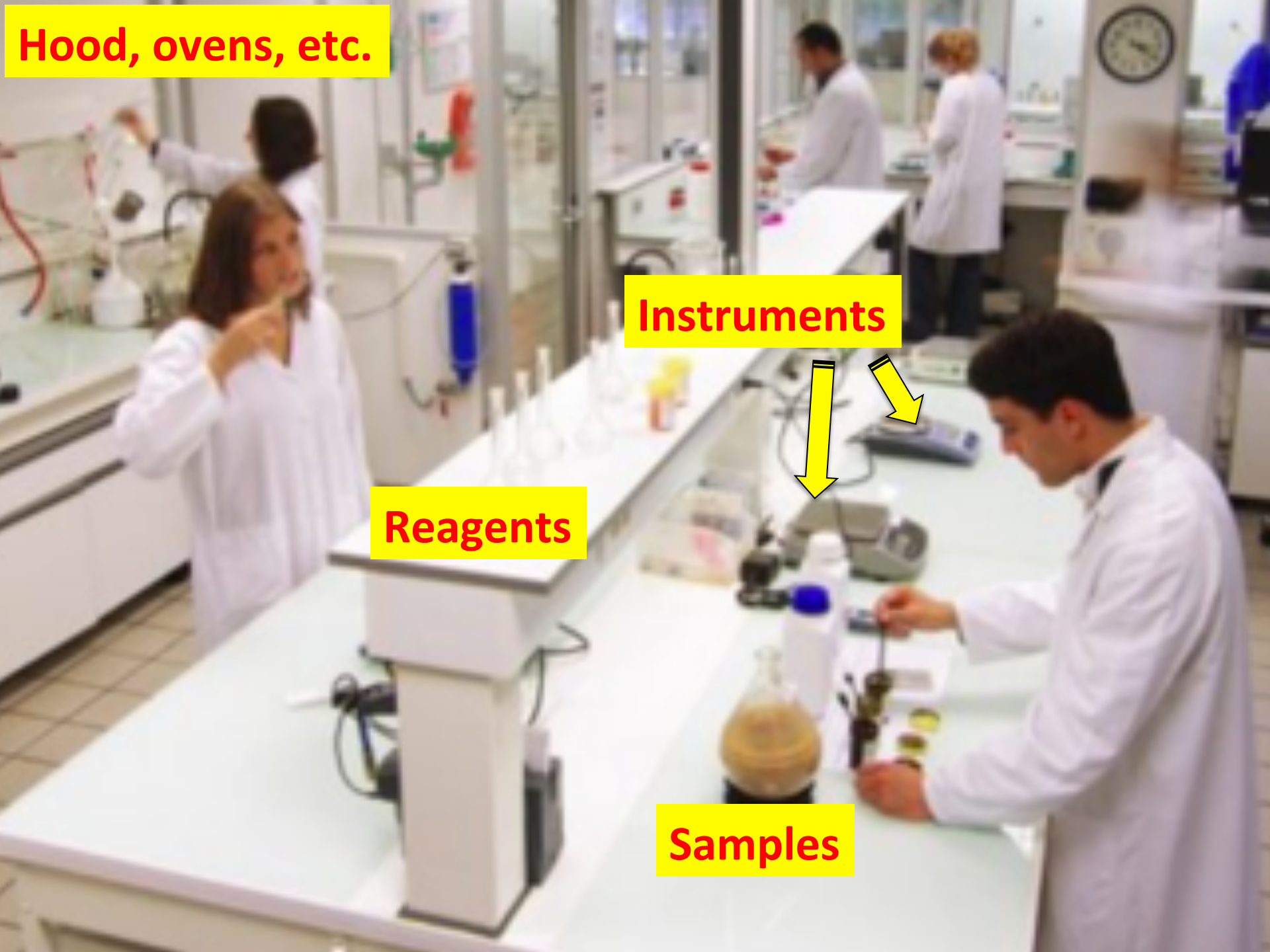
Reagents, instruments, etc..

Analytical tasks

For this also your staff need to be trained…

Lab is a job: even if yoy have a good mechanics, 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 everyyday we do the same things,
we can easily froget other things and even basic knowledge…


Hood, ovens, etc.
Instruments
Reagents
Samples

Technical elements

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

Technical elements

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.

Technical elements

vieux pHmetre pourri

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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- an '*Operation Instruction Manual*',
- a '*Maintenance Logbook*'.

Instruments should be:

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

Technical elements

3. Various equipment & materials

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

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

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

Apparatus should be:

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

Technical elements

4. Reagents

Technical elements

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

Technical elements

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

Reagents have to be :

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

Record preparations in **a Reagents Book**.

Technical elements

5. Soil samples

Technical elements

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

Technical elements

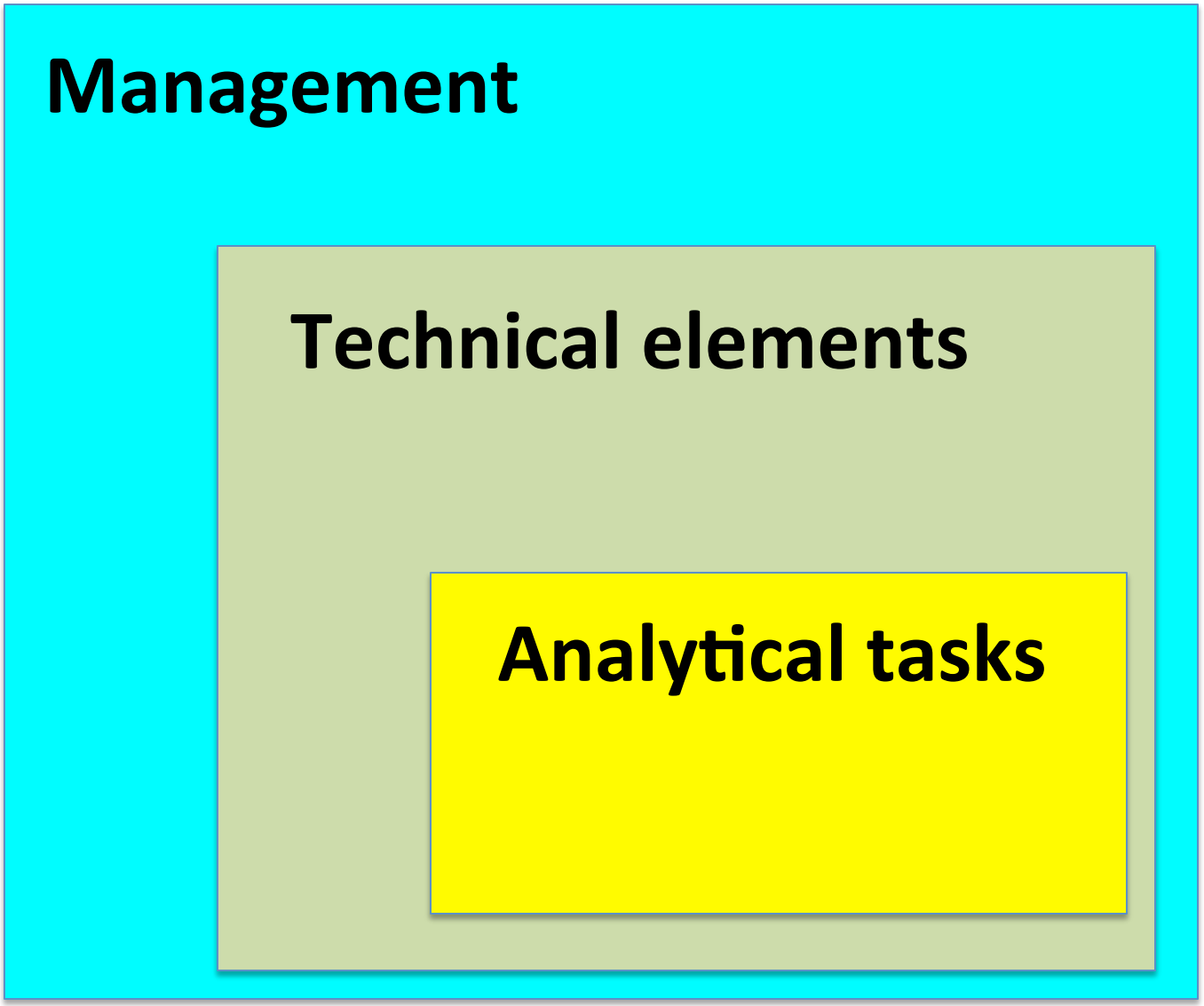
5. Soil samples

Need of proper packaging, labelling and man agement 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.



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