Quality control and assurance in FMD laboratory testing

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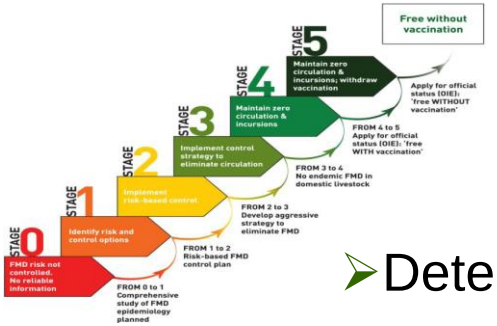
National Reference Laboratory for FMD



Control of Foot-and-Mouth Disease

- Detect and confirm outbreaks
- Investigate outbreaks (source, spread, serotype..)
- Estimate incidence of the disease
- Estimate vaccination coverage and efficiency
- Surveillance within the country and imports

LABORATORY DIAGNOSIS OF GOOD QUALITY

Role of laboratory diagnosis

- Supports the surveillance program
- Confirms clinical diagnosis
- Supports but does not replace the need for accurate clinical diagnosis
- Requires full epidemiological information on samples submitted for rational interpretation
- The quality of the laboratory diagnosis depends on the selection and quality of the samples

Consequences of a laboratory diagnosis of poor quality

- Inappropriate action
  - Over-investigation
  - Over-treatment
  - Mistreatment
- Inappropriate inaction
  - Lack of investigation
  - No treatment
- Delayed action
- Loss of credibility of laboratory

Laboratory diagnosis of good quality ?

= provide the right result that is accurate, timely and properly interpreted

CONFIDENCE

???

Receipt of sample

Processing of sample

Conducting analyzes

Interpretation of results

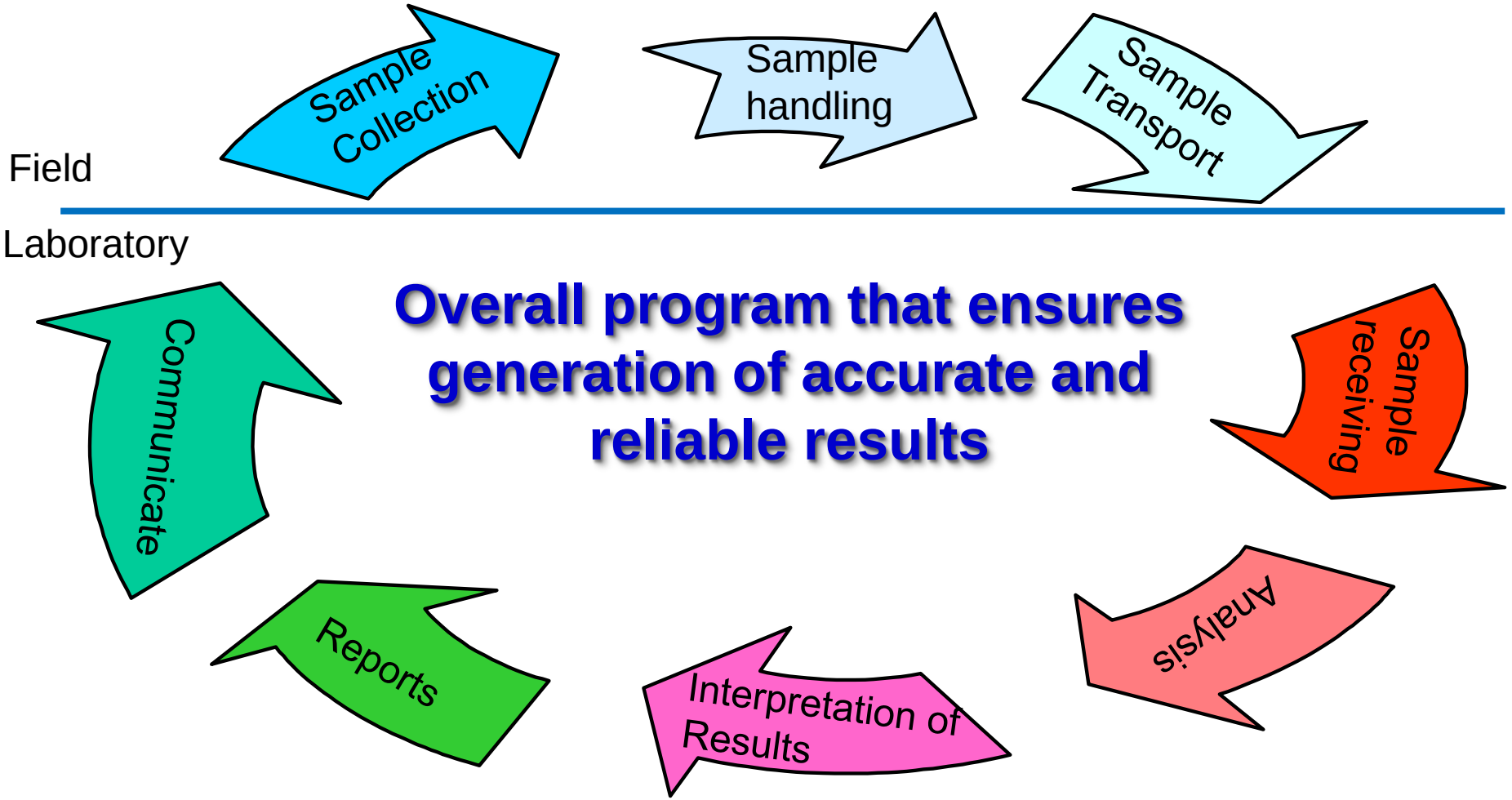
Reporting of results

Quality assurance

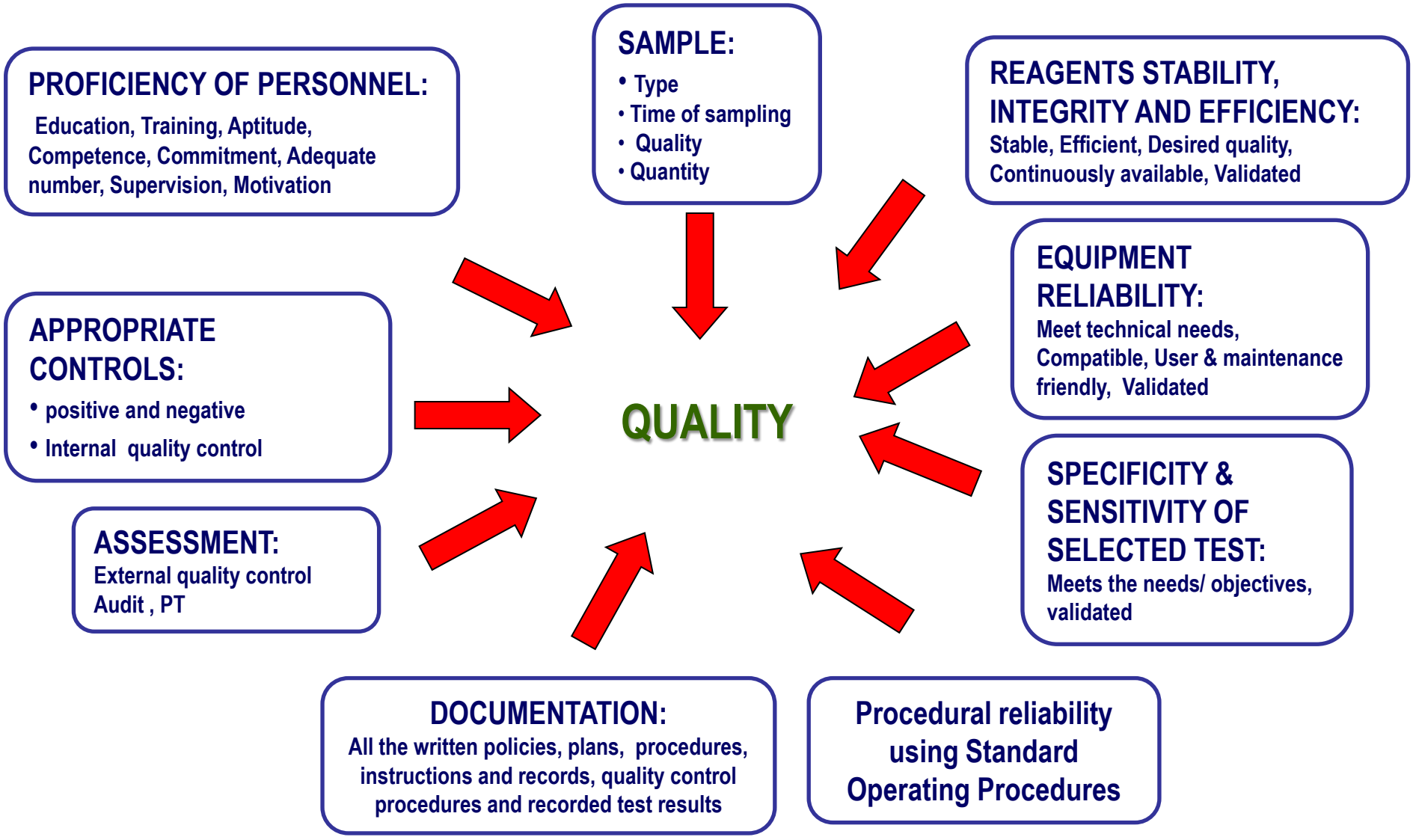
ISO 17025

ACCREDITED LABORATORY

Quality assurance



Variables that affect the quality of results



Components of Quality assurance of test

1) Internal quality control 2) External quality assessment

ISO/IEC 17025:2005(E)

Saga Web pour ANSES le 4/12/2010 21:08 *NF EN ISO/CEI 17025:2005-09*

5.9 Assuring the quality of test and calibration results

5.9.1 The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

a) regular use of certified reference materials and/or internal quality control using secondary reference materials;

b) participation in interlaboratory comparison or proficiency-testing programmes;

c) replicate tests or calibrations using the same or different methods;

d) retesting or recalibration of retained items;

e) correlation of results for different characteristics of an item.

NOTE The selected methods should be appropriate for the type and volume of the work undertaken.

5.9.2 Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.

1) Internal quality control

= sample(s) that must be included during each assay run

➢ to verify that the test is working properly and the results generated are correct

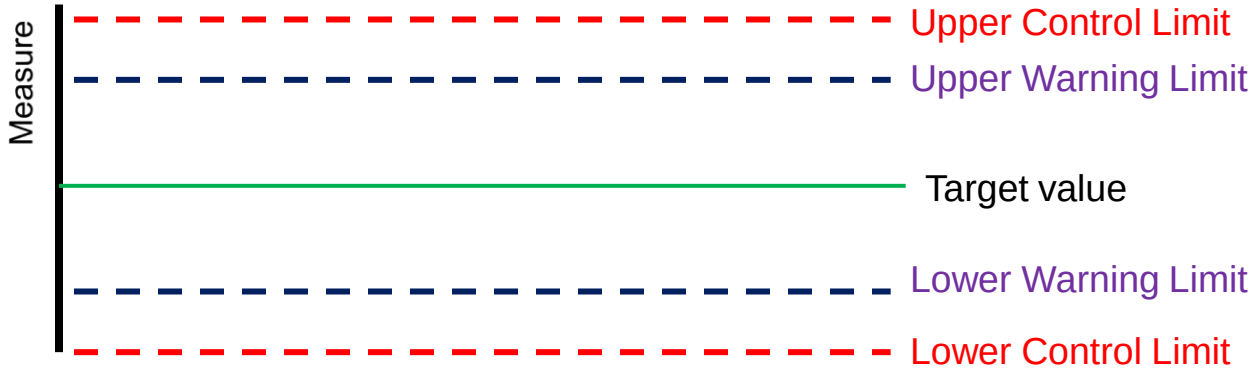
➢ (unavoidable) **errors** made are quantified to enable a decision whether they are of an acceptable magnitude and that unacceptable errors are discovered so that corrective action can be taken and erroneous data are not released.

Tools for ICQ

The most important tool is the Shewhart control chart.

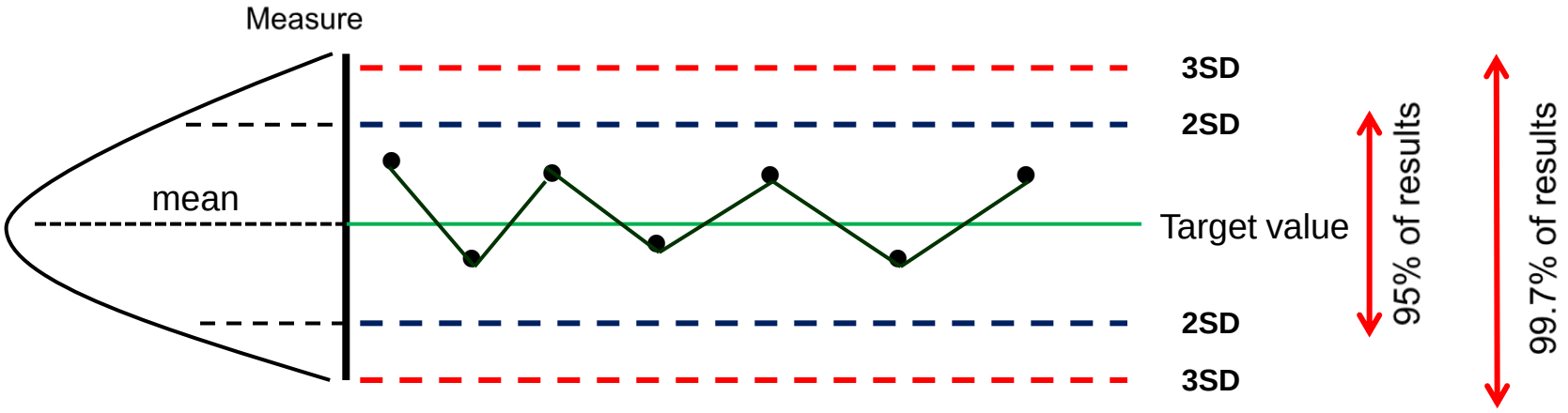
Walter Shewhart

- The laboratory runs control samples together with the routine samples.
- The control values are plotted in a control chart.



- The control limits can be set based on method performance (statistical control limits) or according to the requirement on within-laboratory reproducibility (target control limits).
- The central line in the control chart can be the calculated mean value of the control values or a reference value for the control sample.

Distribution of IQC sample results



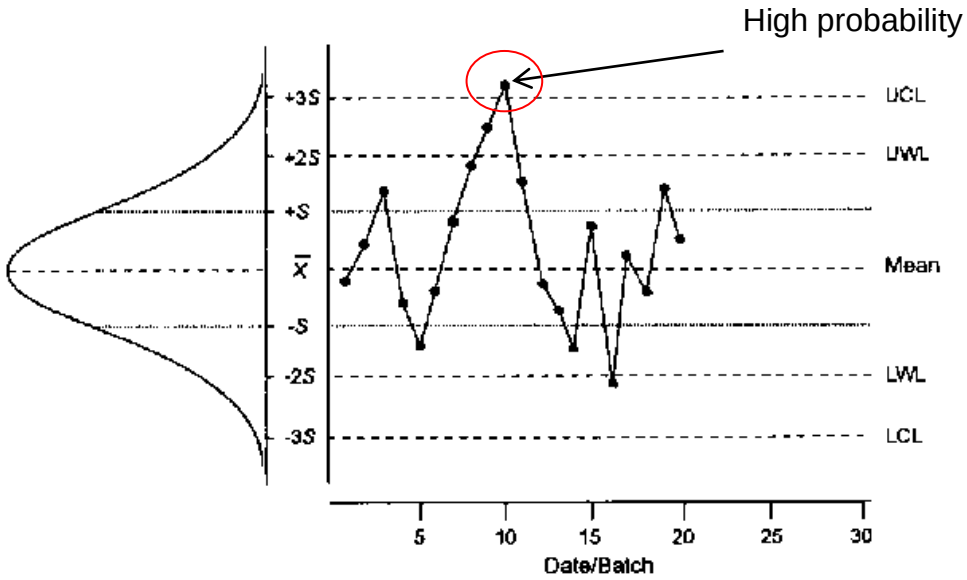
If there are no errors, the values of the IQC follow a normal distribution

Errors in measurement

Error = the discrepancy between the result of a measurement and the true (or accepted true) value.

➢ **Random Error**

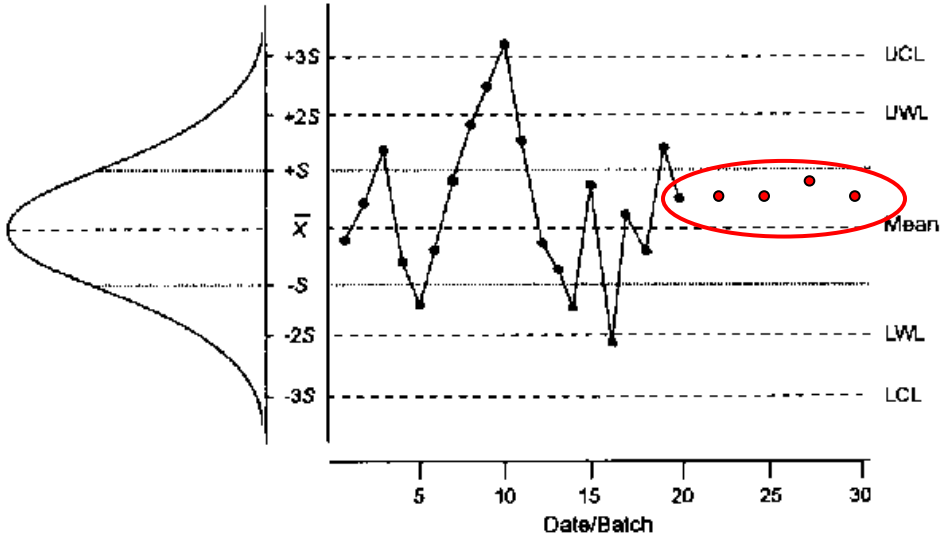
- Varies in an unpredictable manner, in magnitude and sign, when a large number of measurements of the same quantity are made under effectively identical conditions.
- Creates a characteristic spread of results and cannot be accounted for by applying corrections



Example: errors in pipetting and changes in incubation period.

➢Systematic Error

- An error which remains constant when measurements are made under the same conditions, or varies according to a definite law when conditions change.
- Create a characteristic bias in the test results and can be accounted for by applying a correction



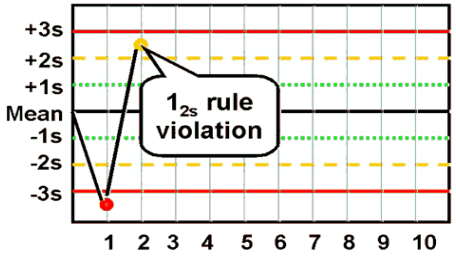
May be induced by factors such as variations in incubation temperature, blockage of plate washer, change in the reagent batch or modifications in testing method

How to interpret the control chart ?

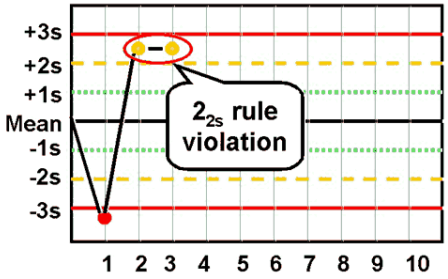
Westgard rules are based on statistical methods to analyze data in Shewhart control charts.

James WESTGARD

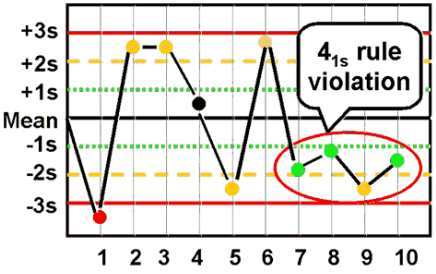
Warning 1_{2SD}



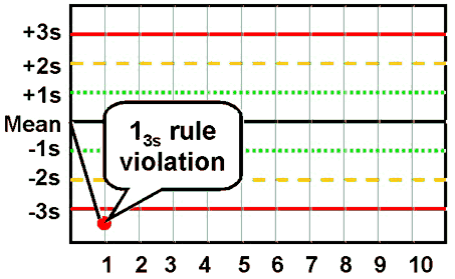
Warning 2_{2SD}



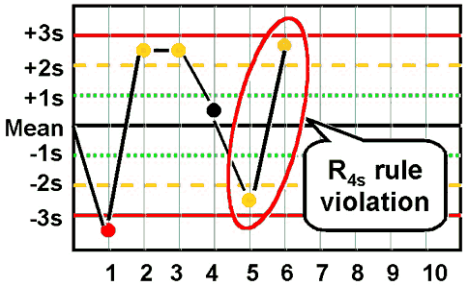
Warning 4_{1SD}



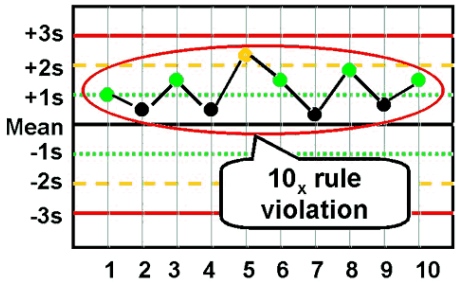
Mandatory 1_{3SD}



Mandatory R_{4SD}



Mandatory 10x



2) External quality assessment

3 types :

- External Quality Control (EQC): organizer provides surveys in which the same or similar material will be tested by all participating laboratories (PT) (ISO/CEI 17043)
- Rechecking (RC): Participating laboratories send specimens to EQC organizer for rechecking
- On-site visits: physical assessment by experts (Audit)

Objectives of EQC for laboratories

1. Identify possible deficiencies in laboratory practice, and guiding participants in any corrective actions to be taken for improvement;
2. Identify the reliability characteristics of particular methods, materials and equipment under routine conditions and suggest corrective actions as appropriate;
3. View how your laboratory performance compares to other laboratories
4. Assess and monitor the impact of training; help for the preparation of future trainings

Rechecking (RC)

1. Participating laboratories send specimen to be rechecked on a regular basis to the EQC organizer
2. Targeted specimens and/or randomized specimens
3. Usually blind, can be single or multiple

On-site visits

1. For laboratory assessment (regular audit)
2. For laboratory accreditation
3. After repeated problems (corrective action)
4. After training session (practical implementation of the training)

CONCLUSION (1/2)

- The fight against FMD requires accurate and reliable laboratory diagnosis that is one of the key elements.
- Diagnosis of poor quality may have serious consequences such as the spread of disease and may lead to a situation difficult to control.
- Diagnosis of good quality can be ensured by establishing and maintaining quality assurance in laboratory.
- The establishment of internal quality control helps in the detection of errors and avoids release of erroneous data.
- External quality assessment for laboratories aim to provide the laboratory management with an insight into the quality of the work of their laboratories.

CONCLUSION (2/2)

Don’t forget that:

- ✓The quality of laboratory results depends on several factors that start in the field and end by reporting.
- ✓Laboratory diagnosis supports but does not replace the need for accurate clinical diagnosis and surveillance.

Thank you