



Setting standards  
in analytical science



## The Importance of Quality Assurance



valid analytical measurement

# Outline



- Reasons for analysis
- What is quality?
  - consequences of getting the wrong result
- Quality control vs quality assurance
- Quality standards
- The Valid Analytical Measurement (VAM) Programme



Chemical analysis is used for many reasons and affects all aspects of our lives.

The slide shows examples of some of the analyses that are carried out at LGC. *For further information about LGC visit [www.lgc.co.uk](http://www.lgc.co.uk).*

**Veterinary drug residues:** The Veterinary Medicines Directorate runs a national surveillance programme to comply with EU legislation aimed at protecting consumers from harmful residues of veterinary drugs. Animal organs and tissues and animal feedstuffs are analysed for a range of drugs such as antibacterials, steroids and hormones.

**Foodstuffs:** Foodstuffs are analysed for nutrients (e.g. carbohydrates, fats, vitamins) and contaminants and also to check authenticity (e.g. detection of non-durum wheat in pasta).

**Environmental samples:** Soil and water samples are analysed for a range of inorganic and organic contaminants.

**Bioanalysis and toxicology:** Blood samples are analysed to check for the presence of drugs of abuse and to determine the level of alcohol present in drink driving cases.

**Consumer safety:** This involves the testing of consumer products such as cosmetics, toys and childcare articles to ensure their chemical safety. Analytes include metals, plasticisers, colourants and flame retardants.

**Pesticide residues:** The levels of pesticides in a range of foodstuffs, animal feeds and human and animal tissues are determined on behalf of the Pesticides Safety Directorate. The results are used to check compliance with legislation which aims to protect consumers from harmful residue levels. 'Organic' produce is also tested to ensure there are no pesticides present.

## Reasons for analysis (1)



- Comparison with a regulatory limit
  - possible legal action
    - e.g. amount of cadmium released from ceramic ware
- Comparison with manufacturing control limits
  - rejection of unsatisfactory batches
    - e.g. amount of active ingredient in a tablet
- Forensic case
  - conviction
    - e.g. blood alcohol level

Measurements are always made for a reason. When an analyst carries out tests on a sample they are trying to answer a question for the customer. It is important that the analyst understands why they are carrying out a particular analysis and what the results will be used for. The reason for the analysis will, amongst other things, influence the choice of test method used. The method performance requirements for an analysis which may lead to legal action are likely to be different from those for a quick screening test which is used to decide whether more rigorous additional analysis is required.

The following slide gives some further examples of when chemical analysis is required. The customers of analytical laboratories are many and varied. They include government departments and organisations (e.g. DEFRA, Food Standards Agency, Environment Agency), local authorities, Customs and Excise, police forces, pharmaceutical companies, food manufacturers, chemical manufacturers and water companies.

## Reasons for analysis (2)



- Part of a survey
  - to determine if legislation is required to control a problem
    - e.g. plasticizer release from PVC teethingers
- Long term monitoring
  - legislation or changes in practices required
    - e.g. levels of metals in foodstuffs
- Screening test to decide if further analysis is required
  - more sophisticated analysis used to confirm 'positives'
    - e.g. drugs of abuse in urine

## What is quality?



- “Conformance with requirements”
- “Fitness for purpose”
- Producing results that meet the requirements of the customer

The analyst working in a laboratory needs to ensure that the results they produce meet the requirements of the customer (the person who will use the results to make a decision). If the analyst produces results that are incorrect or inappropriate, there could be serious consequences (see following slide).

‘Quality’ is all about ensuring that the results produced by a laboratory are fit for the purpose for which they will be used. This involves making sure that results produced are sufficiently accurate so as to be of use to the customer. It is also essential that the correct parameter is measured. For example, an analyst is asked to investigate the amount of cadmium in the paint on a wooden toy. The analyst could measure the total amount of cadmium present in a sample of the paint, or they could measure the amount of cadmium released when flakes of the paint are extracted with a stomach acid simulant. The two experiments will give very different results. It is important that the analyst knows which parameter the customer is interested in - total cadmium or ‘released’ cadmium. Results for total cadmium will be of little use if the customer is interested in the amount of cadmium that may be released into stomach acid, and vice versa.

This lecture describes the activities that laboratories should carry out to ensure that they produce quality results.

## Need for quality

### Consequences of getting it wrong



- Forensic science - wrongful conviction
- Trade - substandard goods
- Health - drinking water contamination
- Environment - homes built on contaminated land
- New materials go undiscovered
- Impurities go unnoticed

When discussing examples of where analytical chemistry is used, it is also useful to think about the consequences of a laboratory producing unreliable results. This helps to get across the importance of taking steps to ensure the quality of analytical results.

The slide shows some of the possible consequences of analytical results that are not fit for purpose.

## Cost of poor quality data



- Repeat analyses
- Loss of production batches
- Legal disputes/actions
- Public health
- Bad publicity
- Loss of customer confidence

There is always a cost associated with poor quality analytical data. If the problem is spotted, the laboratory will have to repeat the analyses. It is costly for laboratories to have to repeat a large number of tests. It is therefore in the laboratory's interest to ensure that it gets results 'right first time'.

In a manufacturing company, erroneous data could lead to the unnecessary destruction of batches of product (or the release of sub-standard product to the market).

Unreliable data can lead to costly legal disputes, particularly if different laboratories can't agree on the answer for a particular sample.

A laboratory that produces data that do not satisfy its customers is bound to attract bad publicity which is likely to result in lost customers.



## The cost of getting it wrong Cyanide in imported grapes

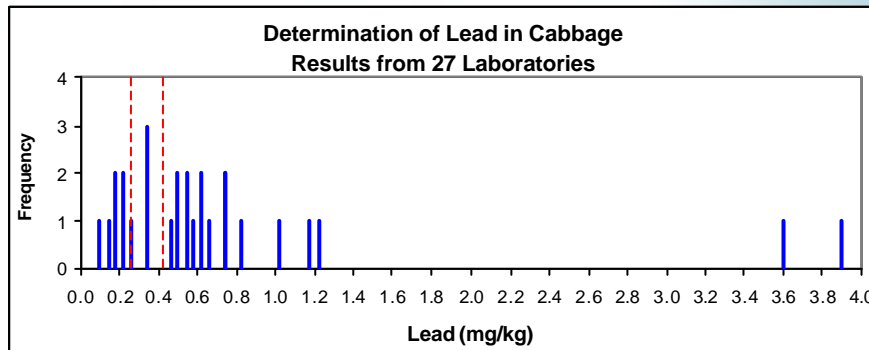


- US FDA detected cyanide at low levels in grapes imported from Chile
- Imports banned for 5 days
- Subsequent studies cast doubt on findings
- Chilean fruit growers file law suit against US government
  - cost to Chilean farmers estimated as at least \$400 million

There are a number of examples that illustrate the problems associated with poor quality data.

In 1989 the US government received a phone tip-off that consignments of fruit from Chile had been deliberately contaminated with cyanide. The Food and Drug Administration (FDA) detected low levels of cyanide in two grapes in a box imported from Chile. As a result, the US banned all fruit imports from Chile for five days. However, subsequent studies cast doubts on the results of the FDA analysis. This resulted in Chilean fruit growers filing a legal claim against the US government claiming that mistakes in the FDA's analysis had cost them at least \$400 million.

## Poor quality results Which laboratories can we trust?



- Acceptable range 0.23 - 0.41 mg/kg
- 4 laboratories within acceptable range

During the 1980s an interlaboratory study was undertaken to evaluate the reliability of analytical results for the determination of lead and cadmium in foodstuffs. Laboratories were asked to analyse a number of different samples, including a sample of cabbage. 27 UK laboratories returned results. All the laboratories had experience of carrying out this type of analysis. The results for lead in cabbage are shown in the slide. This shows that there were significant differences in the results reported by the laboratories - even though they had all analysed portions of the same cabbage sample. Only 4 laboratories obtained results within the target range of 0.23 to 0.41 mg/kg.

The results from the other food samples studied in the exercise showed similar variability. The study highlighted the need for laboratories to change their operating procedures and implement tighter controls to ensure the quality of their data.

Reference: J. C. Sherlock, W. H. Evans et al., Chemistry in Britain, November 1985

## Quality control vs quality assurance



### Quality Control

- A planned system of activities to provide a quality product
  - what you do on a day to day basis

### Quality Assurance

- A planned system of activities designed to ensure that the quality control system is effective
  - how you do it and prove that it has been done

Laboratories can improve their performance and ensure the reliability of their results by implementing quality control and quality assurance procedures.

### Quality Control

Quality Control is the day-to-day activities which are carried out to provide a series of checks on the analytical results produced by a laboratory. These activities are planned in the quality assurance system.

### Quality Assurance

Quality assurance is a planned set of documented activities which are designed to ensure that the quality control programme is carried out effectively, and can demonstrate that this is so. It is the over-arching system which plans and documents the processes involved in ensuring quality.

## Quality control procedures

*It costs less to prevent a problem than it does to correct it!*



- Analysis of blanks
  - check for contamination or interferences
- Analysis of standards and reference materials
  - calibration of instruments
- Analysis of QC samples
  - check the method is working consistently
  - plot QC results on control charts
- Replicate analysis of samples
  - gives greater confidence in the result we report

Laboratories employ quality control (QC) procedures to monitor the quality of the measurements they are making, and to ensure that the systems and procedures used stay within some predefined limits. QC procedures should be carried out on a frequent basis. The frequency depends on the criticality of the results (i.e. the consequences of reporting an incorrect result).

The slide lists some examples of common QC procedures:

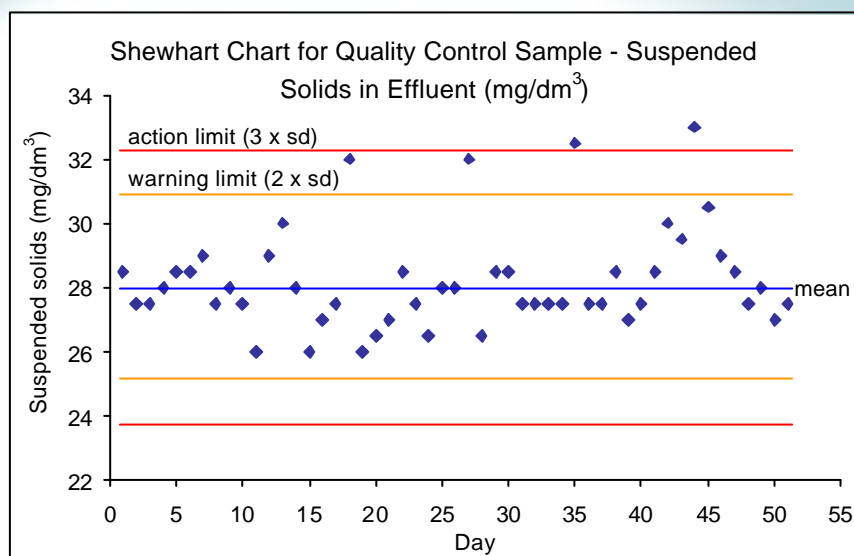
Analysis of blanks: A blank sample is a sample which does not contain any of the analyte of interest. It should be treated in the same way as test samples. In addition, it is often useful to run a reagent blank. A reagent blank is a solution obtained by carrying out all the steps of the analytical method without any sample present. Blanks are used to look for interferences or contaminants which could affect the result of the measurement.

Analysis of standards and reference materials: These are used to calibrate equipment and ensure that the equipment and the method as a whole are working satisfactorily.

Analysis of QC samples: QC samples should be representative of test samples in terms of matrix and the level of analyte present. The QC samples are analysed regularly alongside test samples (e.g. within every batch of analyses). The results from the QC samples are used to check that the method is working consistently. The results can be plotted on a control chart (for example a Shewhart chart) to look for drift or other trends and problems.

Replicate analysis of samples: Analysing a test sample more than once will give greater confidence in the result reported to the customer. It also allows the analysts to estimate how much results vary from one analysis to the next.

## Shewhart QC chart



QC samples are analysed to monitor the performance of a method. The most effective way of doing this is to plot the QC results on a control chart. There are a number of different types of control charts. The slide shows one of the commonly used types of chart - the Shewhart chart. This particular control chart is for a method for the determination of suspended solids in effluents. A QC sample (kaolin suspended in water) is analysed with each batch of samples. The result from the analysis of the QC sample is plotted against day of analysis.

To help the analyst interpret the results and identify when the method is 'out of control' (i.e. no longer operating as expected), control limits are added to the chart. The middle line represents the target value for the QC sample. This is typically the mean of the results from around 20 analyses of the QC sample.

The results from the QC sample should be scattered randomly around the target value. However, some results may appear to be a considerable distance away from the target value. To help determine whether deviations from the target value are significant, warning and action limits are added to the chart. These are based on the expected variability of the results, when the method is operating correctly. The expected variation in the results is estimated by calculating the standard deviation of the results used to estimate the target value. The warning limit is set at 2 times the standard deviation. Based on knowledge of the Normal distribution of data, we would expect around 95% of results to fall within the warning limits. The action limits are set at 3 times the standard deviation. We would expect 99.7% of results to fall within the action limits. Therefore, a QC result outside the action limit is unlikely to occur by chance. This indicates that there was probably something wrong with that batch of analyses. The analyst should disregard the results from the batch that contained the suspect QC result and investigate the cause of the problem. If the QC result is outside the warning limit but within the action limit then the normal procedure is to repeat the analysis of the QC sample. There is a 5% probability that a result could be outside the warning limit by chance, i.e. when there isn't actually a problem with the result. If the repeat analysis is also outside the warning limit the analysts should stop and investigate the cause as it is unlikely that this would happen by chance.

## Key aspects of quality assurance (1)



- Work in a suitable environment
- Make sure staff are trained and competent
  - document training procedures and competency assessment
- Have procedures for sample handling and documentation
- Use documented and validated methods
- Use suitable equipment that is properly maintained
- Calibrate equipment correctly (traceable to National/International Standards)
- Use certified reference materials

Quality assurance contains a number of activities which, taken together, build up into a comprehensive system. Key aspects of quality assurance are shown in this and the next slide.

It is important to ensure that the laboratory environment will not adversely affect the analytical results. Depending on the type of analysis being carried out, control of laboratory temperature and humidity may be required, or it may be necessary to take special precautions to guard against accidental contamination of test samples.

Staff must be trained to carry out the method of analysis and their competence demonstrated and recorded.

All stages of the analytical procedure, from sample handling to calculating and reporting the final result should be clearly documented.

Equipment such as balances and pipettes, as well as more sophisticated pieces of equipment such as spectrophotometers and gas chromatographs, should be properly calibrated. The calibration should be checked on a regular basis.

Certified reference materials (CRMs) are well characterised materials, accompanied by a certificate, which can be used for calibration of equipment and to check that a method of analysis is performing adequately.

## Key aspects of quality assurance (2)



- Use suitable reagents
- Have procedures for checking and reporting results
- Record keeping (work books, equipment logs etc)
- Set up complaints procedure
  - learn from past mistakes
- Regularly audit and review quality procedures
- Get independent assessment of laboratory performance
  - participate in proficiency testing schemes
- Have regular external assessment of quality procedures

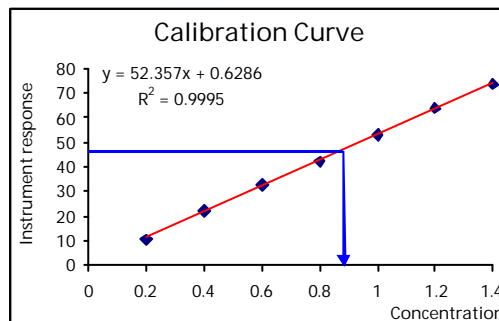
Laboratories should regularly audit and review their quality procedures to ensure that they are fit for purpose.

Independent assessment of laboratory performance is best achieved through participation in proficiency testing schemes (discussed later).

Regular external assessment of quality procedures can be achieved through obtaining formal accreditation to an internationally recognised quality standard such as ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories.

## Instrument calibration

- Establish a relationship between instrument response and amount of analyte



- Use relationship to predict the amount of analyte in test samples

Calibration is an essential part of most measurement procedures. It is a set of operations that establish the relationship between the output of the measurement system (e.g. the response of an instrument) and the accepted values of the calibration standards (e.g. the amount of analyte present).

The calibration procedure results in a calibration function, for example the equation for a straight line in the case of linear calibration. This function is used to transform measurements made on test samples into estimates of the amount of substance present.

The analyst must take care when carrying out the calibration step in a method. Problems at this stage will lead to unreliable results. Calibration frequently involves the preparation of standard solutions. This involves weighing out material and using volumetric glassware such as pipettes and volumetric flasks. The analyst therefore needs to be skilled in these basic laboratory operations. No matter how sophisticated the instrument the analyst still has to prepare the calibration standards accurately.



# Sample handling and documentation

## Chain of evidence and custody



- Procedures must be in place to ensure that
  - test samples can be tracked through the system
    - receipt → analysis → reporting → retention → disposal
  - all staff involved in dealing with samples are clearly identified
  - records of sample handling are kept
    - who received sample? when? what was done to it? where did it go next?
- Essential for any legal or forensic work

## Method validation (1)



- Providing evidence that the method produces results that are fit for purpose
- Essential information
  - applicability (scope) of method - will it work for the samples I need to test?
  - precision - how close are the results of replicate measurements made on the same sample?
  - bias - how close are my results to the 'right' answer?
  - specificity - are there any interferences that might lead to wrong results?

Method validation is a key aspect of ensuring the quality of analytical results. Before any method is used to analyse test samples it should have been evaluated to demonstrate that it is capable of producing results that are fit for purpose.

The formal definition of method validation is: “**Confirmation**, through the provision of **objective evidence**, that the requirements for a **specific intended use or application** have been fulfilled” (ISO 9001:2000).

Validation has three important parts. When applied to method validation, these translate as:

- 1 the specific intended use or application, is the analytical requirement which derives from the problem that the analysis is intended to solve
- 2 the objective evidence is usually in the form of data from planned experiments, from which the appropriate method performance parameters are calculated;
- 3 the confirmation is taken as a satisfactory comparison of the performance data with what is required, i.e. the method is fit for purpose.

There are a number of aspects of method performance that the analyst will need to consider. These include the precision, bias and specificity of the method.

Reference: ISO 9001:2000, Quality management systems - Requirements

## Method validation (2)



- Sources of analytical methods
    - (Inter)national standards
      - ISO, BSi
    - Regulations
      - Fertilisers (Sampling and Analysis) Regulations
    - Scientific literature
    - Developed by laboratory 'in-house'
  - All methods need validating before use
    - need to show that the method works satisfactorily in your laboratory
- Don't assume that a published method will be fit for purpose*

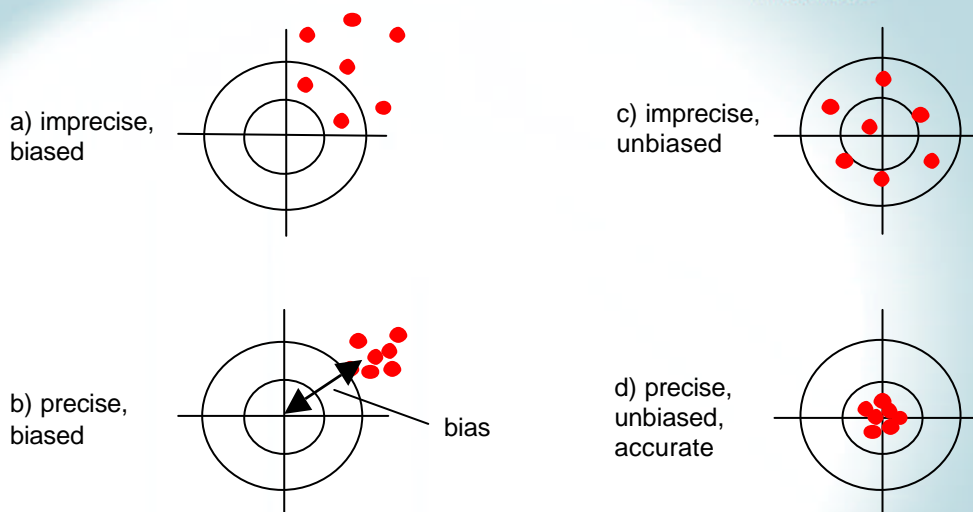
When faced with a particular analytical problem, one of the first tasks for the analyst is choosing a suitable method. In some cases the method may be specified by national regulations. For example there are standard methods for the analysis of fertilisers and feeding stuffs and for the determination of heavy metal release from paint on toys. In other cases, the customer may request that a particular method of analysis is used.

If the method of analysis is not specified by regulations or by the customer then the analyst will have to identify a suitable method. There may be a suitable method published in the literature. It may be that there is no suitable method currently available. The analyst may therefore have to adapt an existing method or develop a method from scratch (a method developed 'in-house').

Regardless of the source of the method, it should always be tested by the laboratory before it is used on test samples. It is not safe to assume that standard methods or methods published in the scientific literature will be fit for purpose when used in a particular laboratory.

The analyst needs to be sure that the method will work for their particular samples in their laboratory conditions.

## Accuracy, bias and precision



Precision and bias are two terms which are commonly used to describe the performance of an analytical method.

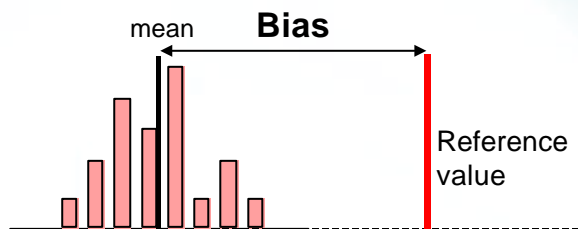
**Precision** is a measure of the spread of results. It is estimated by making repeated measurements. Methods that give results that are close together are said to be **precise**. The size of **random errors** will determine the precision of a method. Precision is estimated by calculating the standard deviation of the results obtained from a set of replicate measurements.

**Bias** is a measure of the difference between the average of repeated measurements and the true value (the 'right' answer). Methods which give results that are very close to the true value are said to be unbiased. **Systematic errors** cause results to be **biased**.

**Accuracy** is a property of a *single result*. It is defined as the closeness of agreement between the true value and the result of a measurement. Measurement results which are precise and unbiased are said to be **accurate**.

Consider an archer practising shooting at a target. The aim is to get all the arrows close together near the centre of the target. The results are shown on the slide. Attempt a): the shots are quite widely scattered and some have not even hit the target. The shots show poor precision as they are quite widely scattered. There is also a bias in where the shots have landed – they are grouped in the top right-hand corner, not near the centre of the target. Attempt b): the precision has improved as the shots are now more closely grouped. However, there is still a bias, as the group of shots is offset from the centre of the target. Attempt c): the archer has managed to reduce the bias – all the shots are now on the target and scattered round the centre. Unfortunately the precision is poor as the shots are quite widely scattered. Attempt d): The shots are precise and unbiased - they are all grouped close together in the centre of the target.

# Bias



- Replicate analyses of reference material
- Bias = difference between mean value of observed results and reference value

## Random and systematic error

It is easy to observe the effects of random error. If replicate measurements are made, there will always be some variability in the results. However, systematic errors will also affect experimental results. Systematic effects are associated with the property of *trueness* of a measurement, and lead to *biased* results. For method validation to be complete, both precision and bias should be considered.

## Trueness

The ISO 3534 definition of trueness reads:

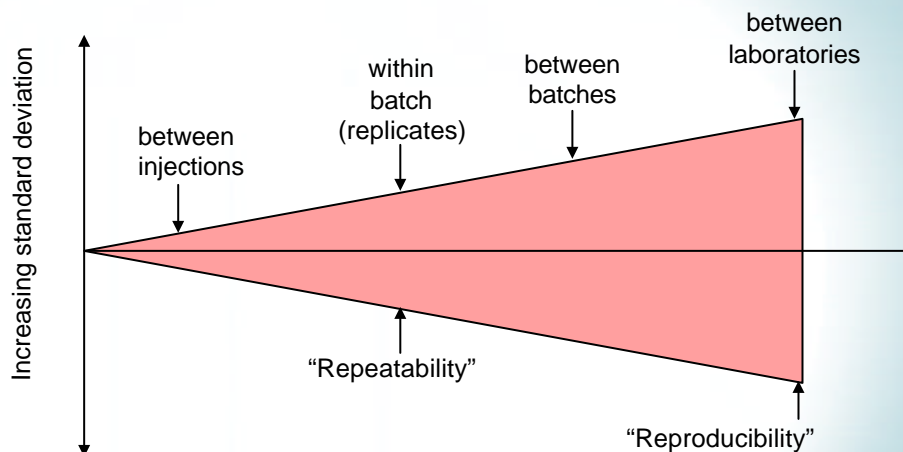
“The closeness of agreement between the average value obtained from a large set of test results and an accepted reference value”

with a note that:

“The measure of trueness is normally expressed in terms of **bias**.”

Reference: ISO 3534-1:1993, Statistics - Vocabulary and symbols -Part 1: Probability and general statistical terms

# Precision



Precision is defined in ISO 3534 as:

“The closeness of agreement between independent test results obtained under stipulated conditions.”

It is important to know the conditions under which a precision experiment was carried out. The examples shown in the slide will all give a measure of ‘precision’, however a much larger spread of results (represented by the standard deviation) would be expected if the measurements were made in different laboratories compared to measurements made in a single laboratory over a short time scale.

**Repeatability** is the precision estimate obtained when repeated measurements are made, over a short period of time, by a single analyst, working in the same laboratory, using the same apparatus.

**Reproducibility** is the precision estimate obtained when measurements are made on identical samples, over an extended time period, by different analysts, working in different laboratories, using different apparatus.

Sometimes the terms ‘in-house reproducibility’ or ‘intermediate precision’ are used to describe the precision estimate obtained when measurements are made in a single laboratory over an extended period of time. The results may be generated by different analysts. The precision estimate obtained would be expected to lie somewhere between repeatability and reproducibility.

## Proficiency testing (PT) schemes



- Homogeneous samples distributed simultaneously
  - representative of routine test samples
- Results statistically analysed
  - performance of each laboratory evaluated
- Results reported to participants
- Technical advice available from scheme co-ordinator
- Confidentiality maintained

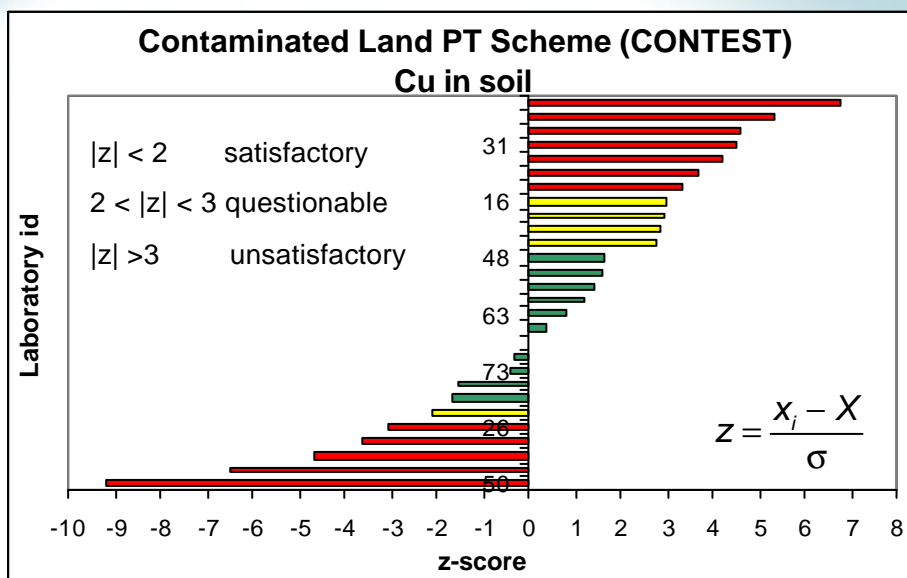
*Independent assessment of laboratory performance*

One activity which has an important role in quality assurance is participation in proficiency testing (PT) schemes. This allows laboratories to obtain an independent check on how they are performing.

There are many PT schemes available but they generally operate in the same way, as shown in the slide.

Information about the wide range of PT schemes available can be found on the EPTIS website ([www.eptis.bam.de](http://www.eptis.bam.de)) which contains a database of hundreds of PT schemes operated in Europe and the US.

## Example of PT results



Each participant in a PT exercise receives a statistical score which they can use to judge how well they have done. One of the most common scoring systems used is the z-score.

Performance assessment in PT generally involves calculating the difference between a laboratory's result and a target value (also known as the assigned value), and comparing this difference with a target range.

In the equation for 'z' shown on the slide,  $x_i$  is the laboratory result,  $X$  is the target value and  $s$  is the target range. There are a number of different approaches that PT scheme organisers can use to establish the target value and target range. One of the most common approaches is to obtain the values from the data submitted by the participants. The data are usually treated to minimise the effects of any extreme values returned by the laboratories. This can be done by carrying outlier tests to identify extreme values which are then removed before calculation of the target value or range. An alternative approach is the use of robust statistics which reduce the effect of extreme values on the calculated mean and spread.

Laboratories use the z-score to judge their performance. An absolute z-score of less than 2 is considered satisfactory. An absolute score between 2 and 3 is considered questionable. A score greater than 3 indicates an unsatisfactory result. The scores are based on the properties of the Normal distribution of data. For normally distributed data one expects 95% of values to be within 2 standard deviations of the mean. There is a 5% chance that a result may be greater than 2 standard deviations away from the mean but still be a valid result. This is why a score of between 2 and 3 is used to indicate a questionable result. It is not that likely that a valid result would be that far away from the mean, but once in a while, purely by chance, a laboratory will produce a result that is more than 2 standard deviations from the mean. There is only a very small chance (around 0.3%) that a valid result would be more than 3 standard deviations away from the mean. A z-score of 3 therefore indicates an unsatisfactory result.



## Quality standards



- ISO 9001:2000
  - many types of organisation
  - the whole organisation - focuses on continual improvement, planning and objectives
- ISO/IEC 17025:2005
  - calibration and testing facilities
  - applicable to specific methods/matrices/analytes
- GLP
  - specific studies
  - pharmaceuticals, pesticides
  - (formal registration)

Many laboratories choose to formalise their quality management systems by seeking third party accreditation and/or certification. In some cases the customer will require the laboratory to be accredited. Formal accreditation has the advantage that the laboratory gets a regular external assessment of its quality procedures. Accredited laboratories have to set up a quality system that meets the requirements of certain internationally agreed standards.

Three of the most common quality management standards are shown in the slide. An organisation may work to more than one standard, depending on the nature of their work.

ISO/IEC 17025:2005, 'General requirements for the competence of testing and calibration laboratories', is the current international standard for the accreditation of testing and calibration laboratories. Accreditation is given for **specific tests** in terms of the scope of a particular method, i.e. the analyte, the matrix and concentration range. Technical requirements feature strongly, namely, method validation, measurement uncertainty and traceability.

ISO 9001:2000, 'Quality management systems - Requirements', is the quality management standard commonly used by organisations manufacturing or supplying products or services in the UK and across the world. Many analytical laboratories have ISO 9001 certification in addition to accreditation to ISO/IEC 17025 so as to include the broader aspects of their operation.

GLP devised by the OECD (Organisation for Economic Cooperation and Development) is different in that it is a legal requirement for particular studies. It is a set of principles intended to regulate the design, conduct, monitoring, recording and reporting of studies carried out by laboratories where these studies are to be submitted for the purpose of assessment of chemicals, foods and pharmaceuticals in support of regulatory licensing for human, animal or environmental use. The Department of Health Good Laboratory Practice Monitoring Authority (GLPMA) is responsible for administering GLP in the UK.

## Accreditation and certification



- Process by which an authoritative body gives formal recognition that a laboratory is competent to carry out specific tests or calibrations
- In UK, testing and calibration laboratories are accredited to ISO/IEC 17025 by UKAS (United Kingdom Accreditation Service)
- In UK, organisations are certified to ISO 9001:2000 by BSi or any other approved institution

Accreditation is the procedure carried out by the relevant authority (usually a national accreditation body) which confers a formal recognition that the laboratory is competent to carry out specific tests or calibrations. Accreditations are usually given for specific combinations of analyte, matrix and method.

Certification is defined as a procedure carried out by a third party against a recognised standard (usually ISO 9001) giving formal assurance that a product, process or service conforms to specified requirements. The technical competence of the organisation is not tested.

## Aims of the Valid Analytical Measurement (VAM) programme



Setting standards  
in analytical science

- A DTI funded programme which aims to:
- Improve the quality of analytical measurements made in the UK
- Facilitate mutual recognition of analytical data across international boundaries
- Develop a robust and transparent infrastructure aimed at achieving international comparability and traceability of chemical and biochemical measurements

*Measured anywhere accepted everywhere*



Evidence of poor analytical results (such as the lead in cabbage study mentioned earlier) led the government to develop a programme aimed at improving the quality of analytical measurements.

The VAM programme is one of a portfolio of programmes supporting the development of the UK's National Measurement System (NMS). The NMS is the technical and organisational infrastructure that ensures a consistent and internationally recognised basis for measurement in the UK. In simple terms, this means enabling organisations in the UK to make valid measurements that are fit for purpose.

The programme covers the field of 'analytical' measurements, which are carried out widely by industry, for example, to assure the composition of manufactured products, in process control, and in research and development.

The VAM programme helps organisations in the UK to carry out analytical measurements competently and accurately. The programme enables the UK to demonstrate the comparability of analytical measurements with those of its trading partners and provides working laboratories with the 'tools' needed to implement best practice and demonstrate the reliability and integrity of their results.

## The VAM principles



- Analytical measurements should be made to satisfy an agreed requirement
- Analytical measurements should be made using methods and equipment which have been tested to ensure they are fit for purpose
- Staff making analytical measurements should be both qualified and competent to undertake the task
- There should be a regular and independent assessment of the technical performance of a laboratory
- Analytical measurements made in one location should be consistent with those made elsewhere
- Organisations making analytical measurements should have well defined QC and QA procedures

The six VAM principles provide a framework to enable organisations to deliver reliable results first time, every time, and achieve bottom line improvements through increased operational efficiency and reduction in risk. Laboratories that adopt the VAM principles provide customers and users of data with increased confidence that results of analytical measurements are valid and fit for purpose.

You will notice that the VAM principles cover all of the quality related activities that have been discussed in this presentation. The principles are a way of encapsulating best practice.

## Summary



- Analysis is done for a reason
  - all results should meet the customer's requirement (fit for purpose)
- Quality control → day-to-day activities to ensure quality results
- Quality assurance → system to ensure QC is effective
  - ideally follow an international standard (ISO/IEC 17025)
- VAM programme aims to improve quality of analytical results in UK
  - [www.vam.org.uk](http://www.vam.org.uk)

## Acknowledgement



- This lecture material was produced by LGC under contract with the Department of Trade and Industry as part of the National Measurement System Valid Analytical Measurement (VAM) programme
- For further information on the VAM programme visit [www.vam.org.uk](http://www.vam.org.uk)



### Additional VAM resources

The following resources, produced under the VAM programme, may also be of interest.

Introduction to Measurement Terminology, E. Prichard, LGC, 2004, ISBN 0 948926 21 X

Introducing Measurement Uncertainty, V. Barwick, E. Prichard, LGC, 2003, ISBN 0 948926 19 8

Preparation of calibration curves: A guide to best practice, V. Barwick, LGC/VAM/2003/032

In-house method validation: A guide for chemical laboratories, LGC, 2003, ISBN 0 948926 18 X

Analytical Measurement Terminology, E. Prichard, RSC, 2001, ISBN: 0 85404 443 4

VAMSTAT II: Statistics training for valid analytical measurements, LGC, 2001

[help@postgrad\\_studies.ok](mailto:help@postgrad_studies.ok), E. Prichard, LGC/VAM/2000/098

QA training resources web area,  
[http://www.vam.org.uk/training/training\\_qaofmeasurement.asp](http://www.vam.org.uk/training/training_qaofmeasurement.asp)

*For further information, visit the 'Publications' area of the VAM website.*