LGC

Setting standards
in analytical science

The Importance of Quality Assurance

VAM
valid analytical measurement

Outline

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- 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

measurement of veterinary drug residues in animal tissues and foods

nutrients and contaminants in foods

analysis of soils and water samples for organic and inorganic contaminants

drugs of abuse and alcohol levels in blood

chemical safety of consumer products

pesticide residues in foods and animal feeds

Reasons for analysis (1)

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- 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

Reasons for analysis (2)

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- Part of a survey
  - to determine if legislation is required to control a problem
    - e.g. plasticizer release from PVC teethers
- 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?

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- “Conformance with requirements”
- “Fitness for purpose”

- Producing results that meet the requirements of the customer

Need for quality
Consequences of getting it wrong

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

Cost of poor quality data

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

The cost of getting it wrong
Cyanide in imported grapes

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- 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

Poor quality results
Which laboratories can we trust?

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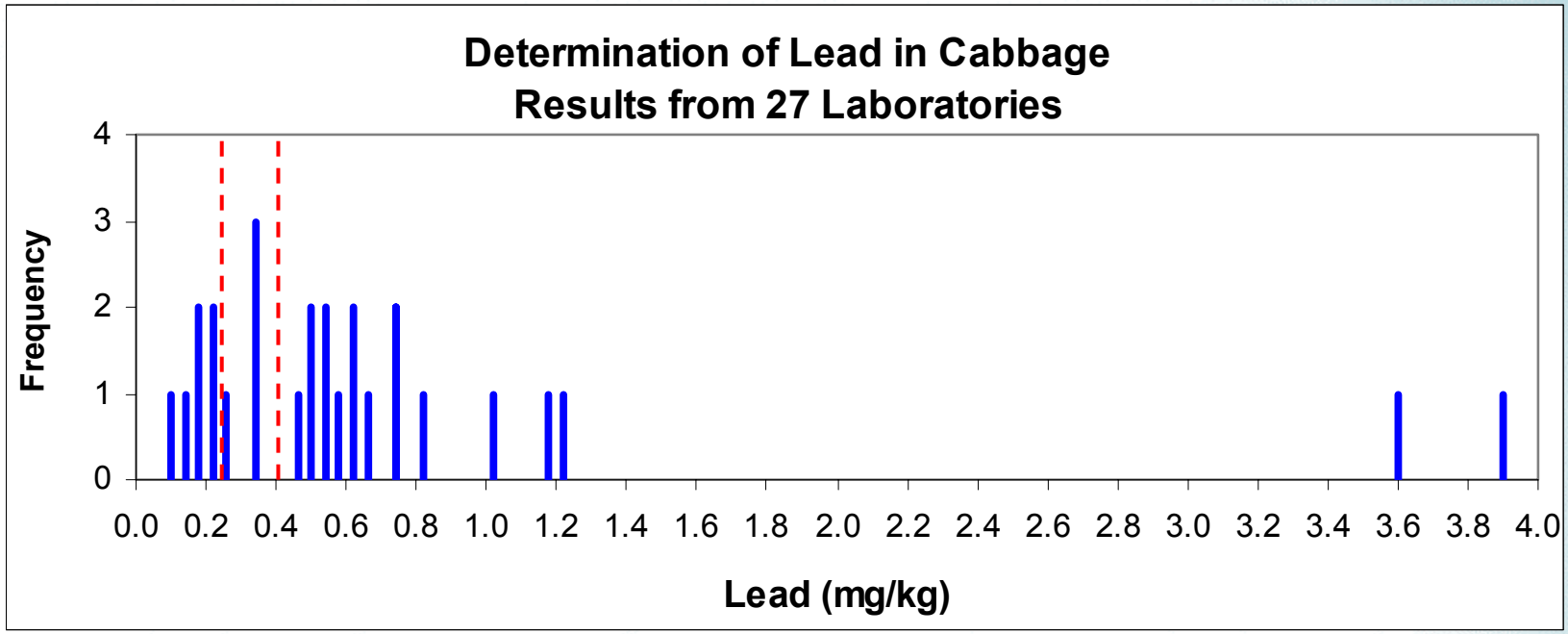

- Acceptable range 0.23 - 0.41 mg/kg
- 4 laboratories within acceptable range

Quality control vs quality assurance

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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

Quality control procedures

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

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- 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

Shewhart QC chart

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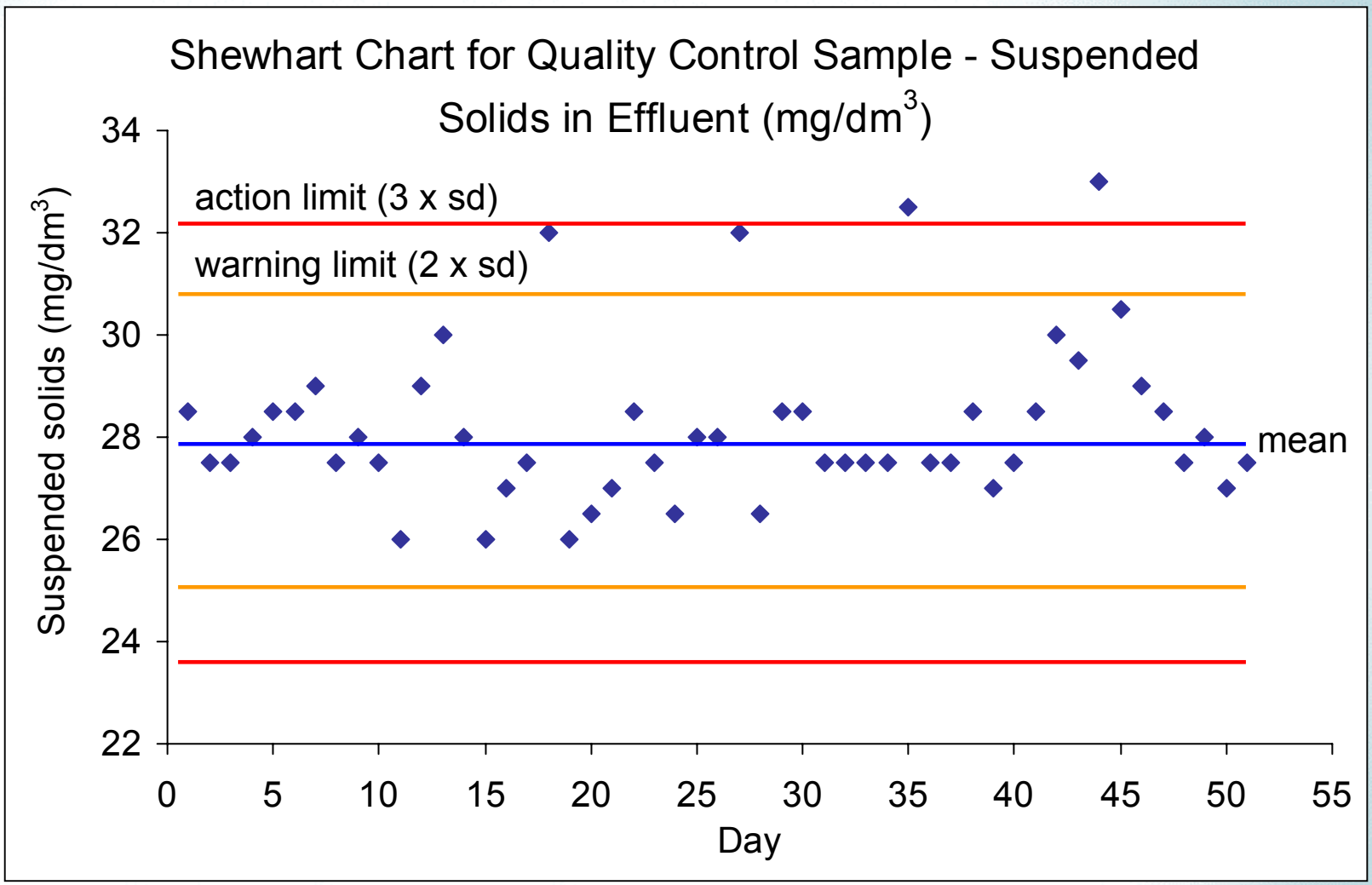

Key aspects of quality assurance (1)

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- 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

Key aspects of quality assurance (2)

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- 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

Instrument calibration

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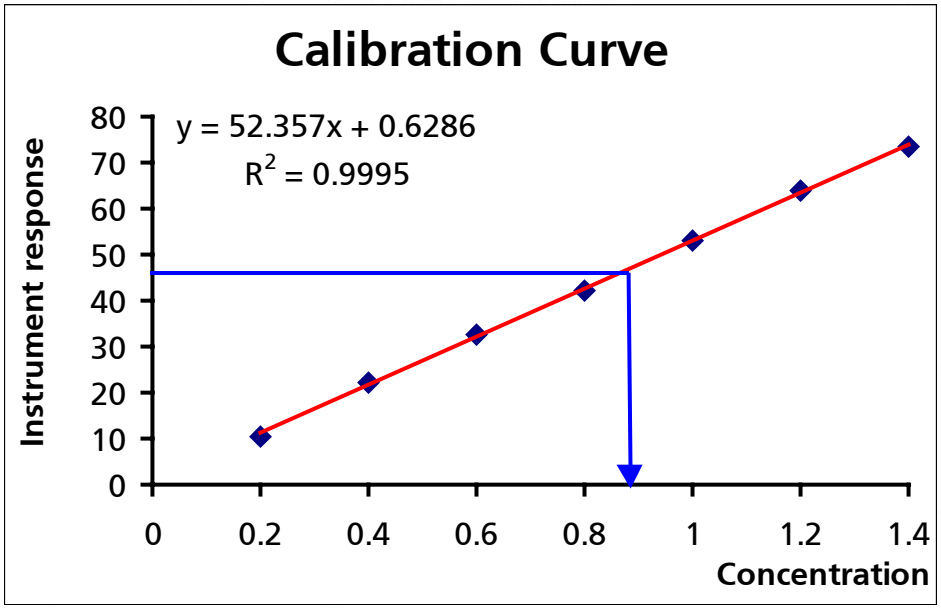
- Establish a relationship between instrument response and amount of analyte



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

Sample handling and documentation

Chain of evidence and custody

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- 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)

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- 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 (2)

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- 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

Accuracy, bias and precision

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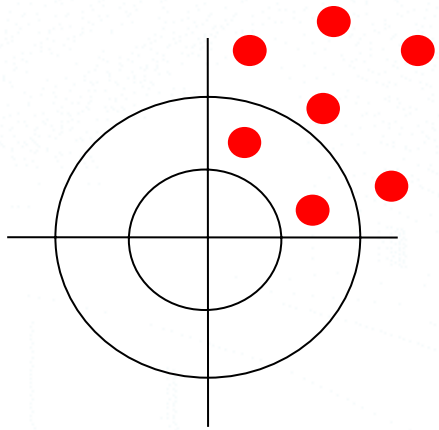
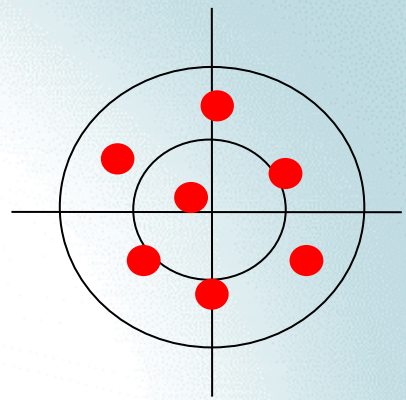
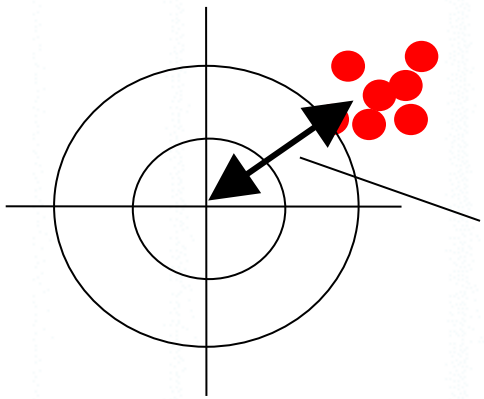
a) imprecise, biased



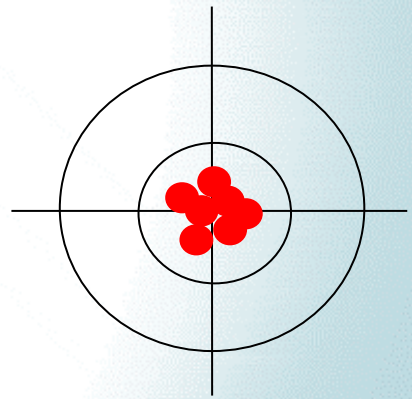
c) imprecise, unbiased



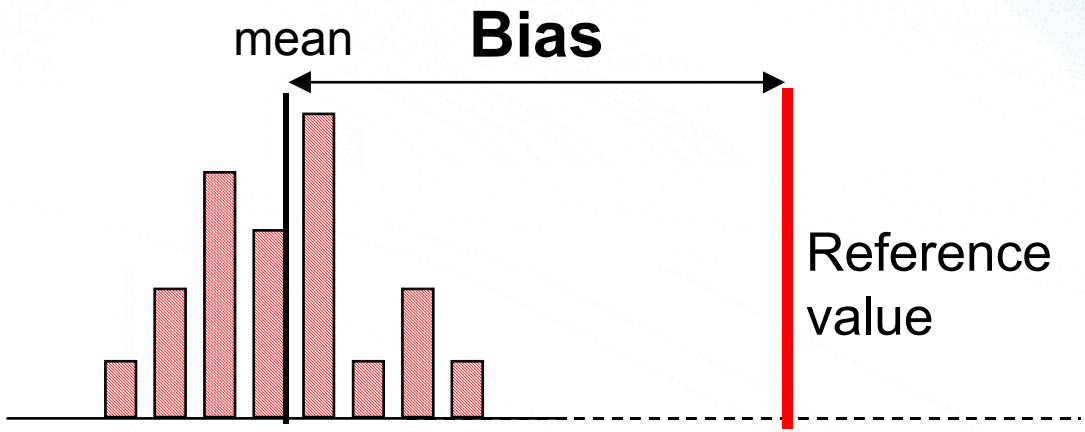
b) precise, biased



d) precise, unbiased, accurate



Bias



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

Precision

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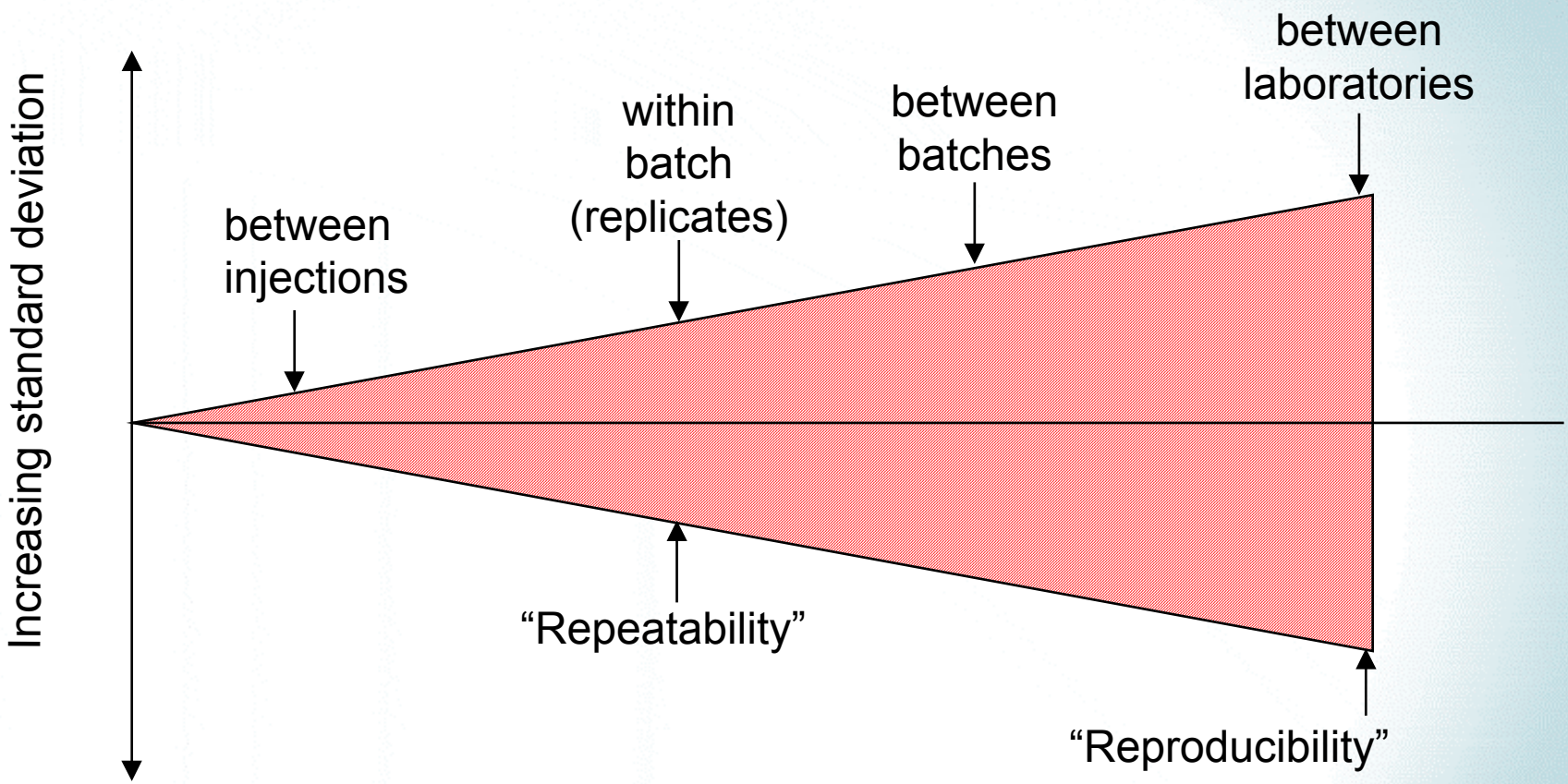

Proficiency testing (PT) schemes

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- 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

Example of PT results

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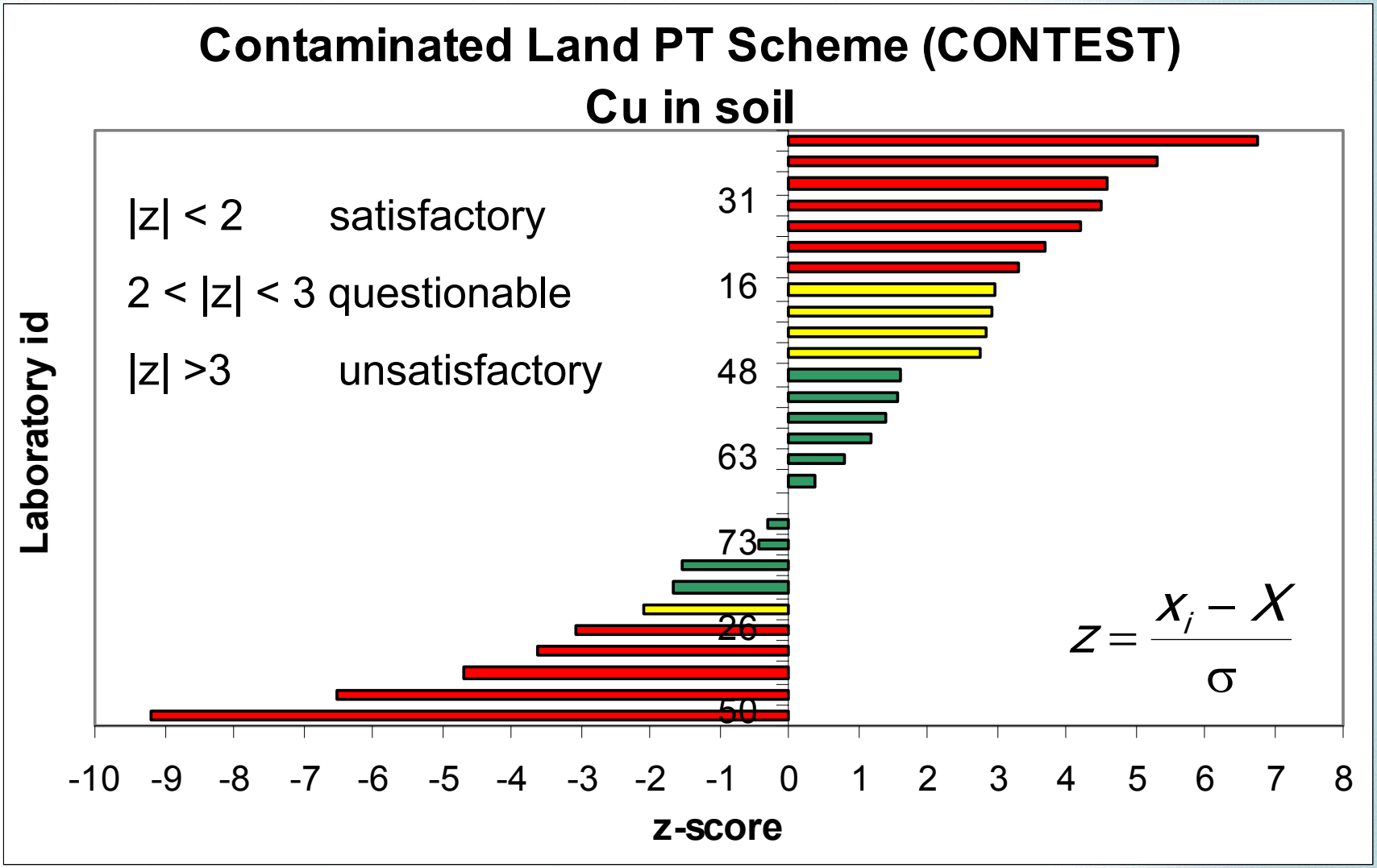

Quality standards

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- 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)

Accreditation and certification

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- 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

Aims of the Valid Analytical Measurement (VAM) programme

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- 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

VAM
valid analytical measurement

The VAM principles

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- 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

Summary

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- 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

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