

# Laboratory Management

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# EPA Licence conditions

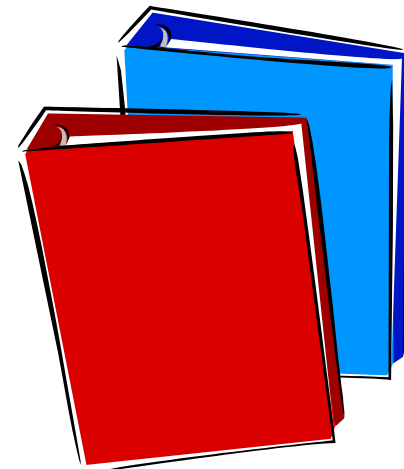
- Analysis shall be undertaken by competent staff in accordance with documented operating procedures;
- Such procedures shall be assessed for their suitability for the test matrix and performance characteristics determined;
- Such procedures shall be subject to a programme of Analytical Quality Control using control standards with evaluation of test responses;
- Where analysis is sub-contracted it shall be to a competent laboratory.
- Monitoring and analysis equipment shall be operated and maintained as necessary so that monitoring accurately reflects the emission or discharge.

# Laboratory Management

- Policy
- Staff
- Facilities
- Equipment
- Procedures
- Documentation
- Records
- Quality Control
- Review

# Policy

- Commitment
- Documented policy
  - endorsed by senior management
- Documented Quality Manual
  - based on ISO17025?
- Evidence of Review of System



# Laboratory Audit

Is a documented quality manual in place?

Is the quality manual based on the requirements of ISO 17025?

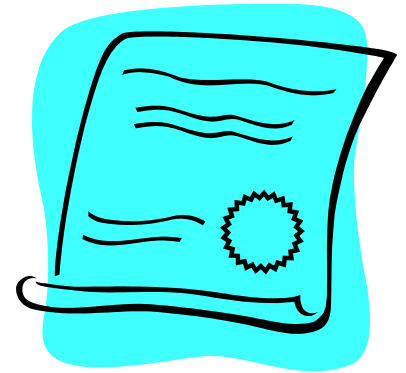
Does the quality manager conduct audits to assess compliance with systems and methods?

Licence Condition:

**Analysis shall be undertaken by  
competent staff**

## ■ Management

- Documented Commitment
- Qualified and Experienced
- Nominated Deputy
- Organisation structure for laboratory



# Laboratory audit

## **LABORATORY MANAGEMENT:**

Is there a nominated manager & deputy who are suitably qualified and experienced?

Is there a suitably qualified quality control manager responsible for all quality control activities in the laboratory?



# Staff

## ■ Staff

- Adequate number
- Criteria for selection – qualifications/experience
- Training procedures – assessment of competence
- Training Records – up to date, retraining if necessary
- Review of training



# Training Procedure - example

Policy : It is the policy of the Laboratory that staff shall be required to demonstrate competency in both general procedures and specific test methods before undertaking reporting of analytical data.

Procedure :

1. Preparation - Familiarize themselves with laboratory procedures, test method and instructions on the use of test equipment.
2. Observation - observe the test being undertaken by a competent person, the trainer.
3. Supervision - undertake the test on samples / standards under the guidance of the trainer.

# Training Procedure - example

4. Comparative Performance Test – Asses performance by having both trainer and trainee undertake the analyses of real samples together with relevant AQC's for the test method.
5. Competence Assessment - For trainee competence to have been demonstrated the difference between comparable measurements should be within the precision criteria set out within the test method.
6. Registration – Training record signed/approved
7. On-going competence – External QC's
8. Retraining – if necessary

# Laboratory audit

## STAFF COMPETENCY:

- Is the laboratory manager supported by an adequate number of qualified staff, trained in the principles and practice of relevant areas of analysis;
- Is a training procedure in place for laboratory staff? *(This procedures should cover both analytical procedures and the relevant principles and practice of analysis, including calibration and internal and external analytical quality control)*
- Do the training procedures set criteria and method of assessment of the competence of staff to conduct analysis?
- Are staff training records in place and kept up to date? *(a training record should set out clearly those procedures and practices in which staff have been trained, the dates and results (competency) of that training, the dates and results of audits of training and any re-training and the results of any annual review)*

# Documented Operating Procedures

## Licence conditions:

Analysis shall be undertaken in accordance with documented operating procedures

Sampling and analysis of all pollutants ....as well as reference measurement methods to calibrate automated measurement systems shall be carried out in accordance with CEN-standards. If CEN standards are not available, ISO, national or international standards, which will ensure the provision of data of an equivalent scientific quality, shall apply.

# Documented Operating Procedures

- Documented SOPs in place for all relevant methods
  - Sampling/sample handling
  - Analysis
  - Calibration
  - Quality
  - Training

*ISO 78-2:1999 Chemistry --- Layout for standards--- Part 2:  
Methods of chemical analysis*

# Documented Operating Procedures

## 1. Safety Precautions

Hazards associated, precautions required

## 2. Introduction and Scope of Method

Define background to parameter, applicability and range of the test method

## 3. Principle

Chemical principles on which method is based

## 4. Interferences

Details of known interferences and remedial measures

## 5. Sampling and Preservations

Specific sampling preservation required and timeframe for completion of testing

## 6. Reagents and Materials

As required to carry out the test

## 7. Apparatus

As required to carry out analysis

# Documented Operating Procedures

## 8. Instrument calibration/Calibration standards

Preparation and storage of calibration standards and instrument calibration

## 9. QC Standards and procedures

Preparation and storage of AQC standards and application of controls

## 10. Analytical procedure

Systematic description of test procedure

## 11. Method detection limit

Procedure detection limit, limit of quantitation and measurement uncertainty

## 12. Expression of Results

Significant figures and decimal place precision if required

## 13. Waste Disposal

Disposal of waste test materials

## 14. References



# Documented Operating Procedures

## SOPs based on reference standard methods

- ISO 15705, 2002-11-15, Water Quality – Determination of the chemical oxygen demand index (ST-COD) – Small scale sealed – tube method.
- I.S. EN 27888: 1994 Water Quality – Determination of Electrical Conductivity
- I.S.EN 1899-1, 1899-2 *"Water Quality .. Determination of Biochemical Oxygen Demand after n days"*
- I.S. EN ISO 10304-2:1997 *"Water Quality – Determination of Dissolved Anions by Liquid Chromatography of Ions - Part 2: Determination of Bromide, Chloride, Nitrate, Orthophosphate and Sulphate in Wastewater"*

# Facilities and Equipment

## **Licence condition:**

Monitoring and analysis equipment shall be operated and maintained as necessary so that monitoring accurately reflects the emission or discharge.

# Facilities and Equipment

## ■ Facilities

- Adequate space
- Adequate storage
- Adequate segregation for incompatible activities
- Environmental conditions controlled and monitored
- General Good housekeeping measures

# Equipment

- Suitable Location
- Fit for purpose - validation
- Calibration – documented programme
- Maintenance
- Records

# Equipment Calibration

- Documented calibration programme in place
  - Equipment requiring calibration
  - Procedures for calibration
  - Acceptance criteria of calibrations
  - Documentation of calibration
  - Set calibration intervals
- Calibration records maintained

*ISO 10012:2003 --- Measurement management systems -- Requirements for measurement processes and measuring equipment*

# Traceability

‘Traceability is the property of a result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.’

- Traceability to the same stated reference is of essential importance for comparability of results.
- Comparability and reliability of measurement results between different laboratories are of utmost importance if they are to form an acceptable basis for decision making and implementation of regulations

# Equipment Calibration

## ■ Internal Calibration

- Appropriate reference standard
- Certificates of calibration
- Traceability to national standards
- Carried out by trained staff

## ■ External Calibration

- Description of calibration carried out
- Statement regarding traceability to National Standards
- Statement on uncertainty of measurement
- Statement regarding specification and compliance

# Equipment Maintenance

- Is equipment maintained according to manufacturers recommendations and recognised practices.
- Equipment location
- Maintenance records in place
- System suitability checks in place



# Laboratory Audit

## 2.3.1 : Equipment & Calibration

- Is a documented calibration programme in place for all necessary equipment?
- Are calibration records current for all equipment and maintained on file?
- Has traceability of the calibration been established to relevant SI units of measurement?
- Is a documented maintenance programme in place in accordance with manufactures/suppliers recommendations for equipment utilised?
- Are laboratory facilities appropriate for the range of tests carried out?
- Is laboratory equipment located and utilised in an appropriate manner?

# Licence Condition

‘Such procedures shall be subject to a programme of Analytical Quality Control using control standards with evaluation of test responses’

# Analytical Quality Control

‘The operational techniques and activities that are used to fulfil the requirements for quality.’

- Replicate analysis
- Quality control samples
- Certified reference materials
- Inter-laboratory proficiency tests

# Analytical Quality Control

Monitor routine performance, maintain control over the system, detect errors and evaluate on-going fitness for purpose

## ■ Accuracy

- Target/mean value
- Set limits
- Monitor trends

## ■ Precision

- Replicate analysis
- Set acceptance criteria

Principal Tool for this is the Control Chart

# Control Charts

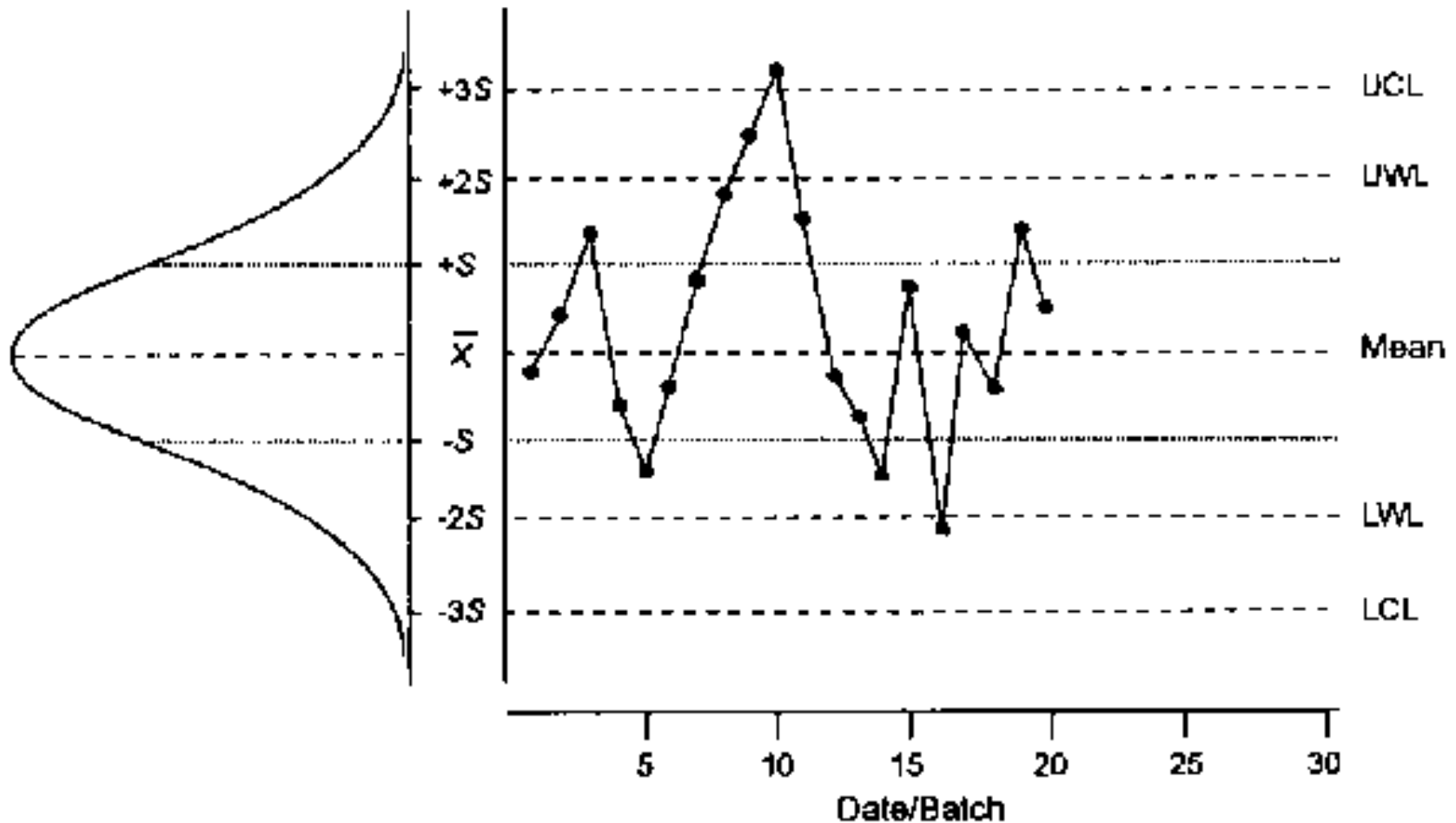
## Control of Accuracy

- Mean control Chart
- Recovery control chart
- Blank control Chart
- Interlaboratory comparisons

## Control of Precision

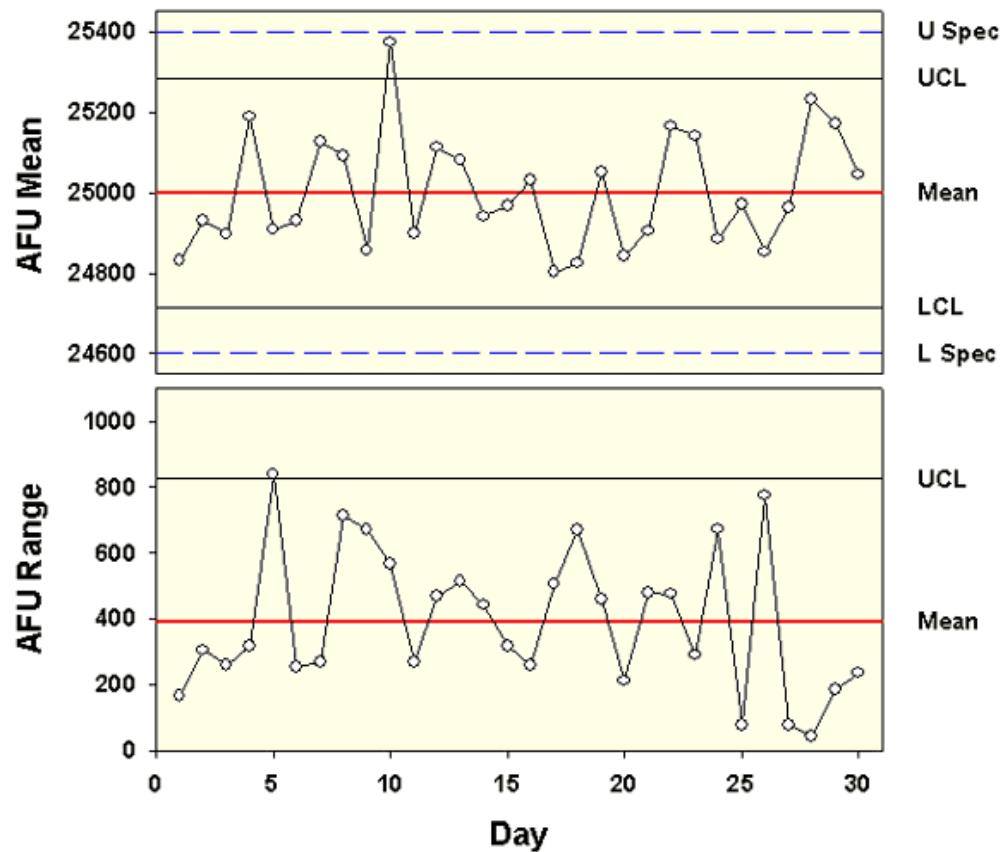
- Range Chart

# AQC Chart



# AQC Chart

Xbar and Range Charts



# Laboratory Audit

## 2.5 QUALITY CONTROL

### INTERNAL QUALITY CONTROL

- Does the Laboratory have a documented internal quality control procedure in place?
- Are all relevant methods subject to internal AQC?
- Are AQC subject to evaluation (*are Charts maintained, are actions taken upon failure*)?
- Are acceptance criteria set for AQC fit for purpose?†



# Laboratory Audit

## External Quality Control:

- Is the laboratory a participant in a laboratory proficiency scheme?
- Are procedures in place to deal with proficiency scheme failures?

# AQC References

- ISO 13530:1997 Water quality – a guide to Analytical quality control for the Water Industry
- Nordtest Report TR 569 - - Internal Quality control – handbook for Chemical laboratories
- ISO 7870:1993 Control Charts – General guide and introduction
- ISO 8258:1991 Shewhart control charts