

# Unit title: **Quality Assurance and Quality Control**

Unit code: **F/601/0301**

QCF level: **4**

Credit value: **15**

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## **Aim**

This unit reviews quality assurance and quality control measures. Learners are provided with an understanding of quality control and assurance procedures, methods of expressing quality and the benefits of accreditation.

## **Unit abstract**

Laboratories carry out analysis for a number of reasons. For example, some laboratories support a manufacturing process while others are contracted by external organisations to carry out analysis. Analytical data must be sufficiently accurate for the customer to use. All laboratories have measures in place to ensure that results are fit for purpose.

In this unit learners will gain an understanding of the possible sources of inaccuracy within analytical processes and consider quality control measures required to improve data quality. The quality assurance procedures put in place to guarantee effective quality control are then reviewed. An efficient way of implementing quality assurance is to use a quality management system. Different quality management standards are examined along with how quality management systems are implemented. Finally, the benefits of external accreditation are reviewed.

## **Learning outcomes**

### **On successful completion of this unit a learner will:**

- 1 Understand how the quality of an analytical result may be expressed
- 2 Understand features of quality control and quality assurance
- 3 Understand quality management systems
- 4 Understand the accreditation process.

## Unit content

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### 1 Understand how the quality of an analytical result may be expressed

*Features of quality:* quality as closeness to the true value; accuracy; precision; repeatability; reproducibility

*Different types of error:* random; bias; reasons for error e.g. incompetence, calculation, transcription, unsuitable method used, contamination, extraction/sample preparation technique, interferences, calibration errors, sampling errors, losses and degradation; consequences of the reason for error

*Minimising types of error:* elimination of bias; minimisation of spread of random errors; ways of reducing error e.g. training, performing calculations on computer, system of double checking entry of data, method validation, steps to reduce contamination, optimising extraction/sample preparation, select method or modifying method to reduce interference, rigorous calibration procedures, validated sampling procedure, adequate sample storage

*Distribution of results:* mean result; distribution of results about mean; normal distribution curve; standard deviation from the mean; % results between  $\pm 2\sigma$  and  $\pm 3\sigma$

### 2 Understand features of quality control and quality assurance

*Internal quality control measures:* use of suitable quality materials; analysing blanks; analysing samples of known concentration/spiked samples; method validation; sampling method; sampling plan

*External quality control measures:* inter-laboratory comparisons; proficiency testing e.g. aquacheck, CONTEST, EQA, FAPAS, LEO, MAPS, QMS, QWAS, RICE, WASP; benefits; organisation; quantification of performance e.g. z score,  $E_n$  number, Q score, organisms isolated and identified (microbiology)

*Features of quality assurance:* activities providing confidence that results are correct e.g. staff training, record keeping, data management, provision of adequate laboratory, appropriate storage for samples and materials, sample entry procedures, traceability, calibration, maintenance, ensuring validated methods are used; carrying out documented statistical analysis on data

*Control charts:* calculation of standard deviation; setting confidence limits; Sewhart Chart; Moving Average Chart; CUSUM chart; confidence limits; actions when results are outside confidence limits

### 3 Understand quality management systems

*Features of a quality management system:* management structure; chain of responsibility; third party assessment; documentation; records e.g. calibration, validation, quality control; training; auditing; review; quality cycle

*Quality management standards:* ISO 9001; ISO/IEC 10725; ISO 15189; GLP; applicability to different types of laboratory

*Operation of a quality management system:* description specific to real workplace; quality manual; quality procedures; standard operation procedures; work instructions; locally held documents; records; controlled copies; audit e.g. internal, external; views e.g. management view of operation of processes, views of other staff of operation of processes, customer views; analysis e.g. analysis of data, records, audit report on reconciliation of processes, data and records

*Differences between quality management systems:* laboratories with different functions e.g. water analysis, food analysis, control of a manufacturing process, contract oil analysis, forensic, microbiological; laboratories of different sizes; allocation of roles of staff

#### 4 Understand the accreditation process

*Benefits of accreditation:* benefits to business e.g. economic benefits, reputation and competitiveness, customer/laboratory relationships, reliability reduces risks; benefits to government e.g. simplification, common standard across range of laboratories, improved public confidence; benefits to the individual e.g. confidence in contributing to a service of proven high quality

*Accreditation procedures:* accreditation bodies e.g. United Kingdom Accreditation Service (UKAS), Clinical Pathology Accreditation (UK) Ltd, GLP Monitoring Authority; accreditation process e.g. UKAS (accreditation standard, application, pre-assessment visit, initial assessment visit, actions, approval, reassessment)

*Influence of accreditation:* effect on quality management system e.g. suggestions for improvement implemented ahead of planned time, greater emphasis on record keeping and maintenance of standard procedures; case study on an accredited laboratory

## Learning outcomes and assessment criteria

<b>Learning outcomes</b> On successful completion of this unit a learner will:	<b>Assessment criteria for pass</b> The learner can:
LO1 Understand how the quality of an analytical result may be expressed	1.1 discuss features of the quality of analytical results 1.2 evaluate different types of error 1.3 explain how errors may be minimised 1.4 express the distribution of results in statistical terms
LO2 Understand features of quality control and quality assurance	2.1 explain internal quality control measures 2.2 review the benefits of external quality control 2.3 discuss the features of quality assurance 2.4 explain the use of control charts
LO3 Understand quality management systems	3.1 review the features of a quality management system 3.2 compare quality management standards 3.3 explain the operation of a quality management system 3.4 analyse the differences between quality management systems in two laboratories
LO4 Understand the accreditation process	4.1 explain the benefits of accreditation 4.2 discuss laboratory accreditation procedures 4.3 analyse how accreditation may influence the quality management system

## Guidance

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### Links

This unit has particular links with the following units within this qualification:

- *Unit reference number F/601/0220: Analysis of Scientific Data and Information*
- *Unit reference number L/601/0222: Laboratory Management*

This unit also links with the following NOS:

- NVQ L4 Laboratory and Associated Technical Activities (LATA).

### Essential requirements

#### Delivery

This unit must be delivered in the context of a science-based industry or service, for example the pharmaceutical industry, health sciences. Learners must carry out technical work that would be undertaken by a person employed in the science field. Learners' experiences of working in a science-based industry or service can also be used for delivery.

Learners who work in analysis will find many of the concepts covered in the unit straightforward and will be able to work on assignments with little direction.

Learners who are not employed in an analytical laboratory will need to visit laboratories and discuss how they operate to maintain the high quality of their data. Repetitive analysis and simulation may support learner understanding. Although the emphasis is on analytical chemistry results, most of the features of quality management systems also apply to other types of analysis, for example microbiology. Technicians who do not carry out this type of analysis may still appreciate features such as statistical treatment of numerical results.

For learning outcome 1, learners must have experience of carrying out routine analysis. Where distribution of results is concerned, learners could be given data to analyse.

Visits to analytical laboratories will help learners who do not work in the industry to identify the features of quality control and quality assurance. Many UKAS accredited laboratories routinely use control charts.

The UKAS website provides useful information about the benefits of accreditation and the accreditation process. This can be supplemented by visiting speakers from a laboratory which has gone through the accreditation process.

#### Assessment

Evidence for achieving this unit must be in a scientific context. Scientific terminology, protocols and documentation (such as report writing and logbooks) should be used where appropriate.

For learning outcome 1, learners must have a specific context in which to set their analysis, for example their workplace or the centre environment. Learners must complete tasks covering features of quality, different types of error and how errors may be minimised. Learners could be given data to analyse. Learners can then discuss how data follow a normal distribution curve or are skewed in some way. Ideally, the context used for learning outcome 1 will be used for the other learning outcomes.

For learning outcome 2, learners could produce a suitable document containing their reflections on the features of quality control and quality assurance apparent in a laboratory they are familiar with. Learners could then explain the actions taken when results fall outside the parameters set on control charts and how control charts are updated on a regular basis.

For learning outcome 3, learners will require case studies or observations from visits, on which to base their work and generate evidence towards meeting the assessment criteria.

For learning outcome 4, learners could carry out a case study. They could design and deliver a presentation explaining the benefits of accreditation, the accreditation process and how a quality management system may be affected by accreditation.

## **Resources**

Learners require access to a laboratory where routine analysis can be performed.

## **Employer engagement and vocational contexts**

Learners will benefit more from this unit if they work in an analytical laboratory or can visit a suitable laboratory. Details of the elements of a quality management system, and control of the analytical process, are more easily understood where learners have access to an industrial laboratory.