

Content Sheet 6-1: Process Control—Introduction to Quality Control

Role in quality management system

Process control is an essential element of the quality management system, and refers to control of the activities employed in the handling of samples and examination processes in order to ensure accurate and reliable testing. Sample management, discussed in Module 5, and all quality control processes are a part of process control.

Quality control (QC) monitors activities related to the examination (analytic) phase of testing. The goal of quality control is to detect, evaluate, and correct errors due to test system failure, environmental conditions, or operator performance, before patient results are reported.



What is QC?

Quality control is the part of quality management focused on fulfilling quality requirements (ISO 9000:2000 [3.2.10]). Simply put, it is examining “control” materials of known substances along with patient samples to monitor the accuracy and precision of the complete analytic process. QC is required for accreditation purposes.

In 1981, WHO used the term ‘Internal Quality Control’ (IQC), which it defined as “a set of procedures for continuously assessing laboratory work and the emergent results.” The terms QC and IQC are sometimes used interchangeably; cultural setting and country may influence preferences for these terms.

In the past few years, the term ‘internal quality control’ has become confusing in some settings because of the different meanings that have been associated with the term. Some manufacturers of test kits for qualitative tests have integrated ‘built-in’ controls into the design of their kits, which they sometimes refer to as internal controls. Other manufacturers include their own control materials with the kits they sell, and they refer to these as ‘internal controls,’ meaning that the materials are meant specifically for that manufacturer’s kit. Finally, some people refer to any quality control materials that are used in conjunction with test runs as IQC, as in the 1981 WHO definition

To avoid confusion, the term ‘quality control’ will be used here to mean use of control materials to monitor the accuracy and precision of all the processes associated with the examination (analytic) phase of testing.

QC for varying methods

Quality control processes vary, depending on whether the laboratory examinations use methods that produce quantitative, qualitative, or semi-quantitative results. These examinations differ in the following ways.

Quantitative examinations measure the quantity of an analyte present in the sample, and measurements need to be accurate and precise. The measurement produces a numeric value as an end-point, expressed in a particular unit of measurement. For example, the result of a blood glucose might be reported as 5 mg/dL.

Qualitative examinations are those that measure the presence or absence of a substance, or evaluate cellular characteristics such as morphology. The results are not expressed in numerical terms, but in qualitative terms such as “positive” or “negative”; “reactive” or “non-reactive”; “normal” or “abnormal”; and “growth” or “no growth”. Examples of qualitative examinations include microscopic examinations, serologic procedures for presence or absence of antigens and antibodies, and many microbiological procedures.

Semi-quantitative examinations are similar to qualitative examinations, in that the results are not expressed in quantitative terms. The difference is that results of these tests are expressed as an **estimate** of how much of the measured substance is present. Results might be expressed in terms such as “trace amount”, “moderate amount”, or “1+, 2+, or 3+”. Examples are urine dipsticks, tablet tests for ketones, and some serological agglutination procedures. In the case of other serologic testing, the result is often expressed as a titer – again involving a number but providing an estimate, rather than an exact amount of the quantity present.

Some microscopic examinations are considered semi-quantitative because results are reported as estimates of the number of cells seen per low power field or high power field. For example, a urine microscopic examination might report 0-5 red blood cells seen per high power field.

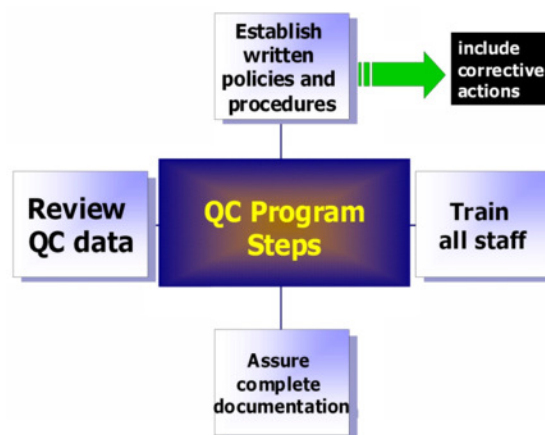
Because quality control processes differ for these various types of examinations, the presentations for QC will be divided into two modules. Module 7 will address QC for quantitative examinations, and Module 8 will address QC for qualitative and semi-quantitative examinations.

Elements of a QC program

Regardless of the type of examination that is performed, steps for implementing and maintaining a QC program include:

- establishing written policies and procedures, including corrective actions;
- training all laboratory staff;
- assuring complete documentation;
- reviewing quality control data.

These responsibilities will be described in more detail in Modules 7 and 8.



Summary

- QC is part of the quality management system, and is used to monitor the examination (analytic) phase of testing.
- The goal of QC is to detect, evaluate, and correct errors due to test system failure, environmental conditions, or operator performance, before patient results are reported.
- Different QC processes are applied to monitor quantitative, qualitative, and semi-quantitative tests.