

Figure 1 illustrates the relationship of these three elements and the basic ingredients of a laboratory quality assurance (QA) and a laboratory quality control (QC) program, required for verification of compliance. Table 1 presents some of the basic components of the quality control segment of a typical laboratory quality program. Table 2 presents some of the basic components of a typical laboratory assessment program. These two activities form the backbone of a laboratory quality assurance program.

The other component that is critical to quality assurance is a validated sample handling program, since the analysis can be no better than the sample acquisition and handling procedures. A sample management information system is required to maintain a valid chain of custody and validate the analysis reported. Such a system can be manual through bound, controlled manuals or automated through local secured computers. Table 3 provides the basic components of a laboratory sample control and reporting system.

There are three basic types of quality assurance that should be considered in order to assure that the laboratory data developed is high quality with accurate results reported. Some activities are specific to the instrumentation, some to the analytical method and others to the general laboratory quality assurance requirements. Each of these types of quality assurance is essential to assure the generation of accurate, precise and reliable data.

The first type of QA relates directly to the performance of the instrumentation being used for the particular analysis. It includes basic operations such as the proper tuning of the instrument to make sure that it is monitoring the correct wavelength or the correct ion mass, as well as the performance of routine maintenance operations that assure optimum sensitivity, stability and reproducibility of the response. Typically this type of QA operation is carried out when the instrument is installed or when major changes are made, such as replacement of parts. It is also carried out on a routine basis at prescribed times (preventative maintenance).

Analytical method QA is related to the performance of the specific method. This includes items such as verification that the solvents, reagents and glassware are free of target analyte contamination and that the method can accurately and precisely determine the levels of the target analyte. Other items include verification of chromatographic resolution, detector sensitivity and stability of the response. This type of QA is usually defined in the method and is carried out prior to sample analysis as well as on a routine basis at prescribed times. Method QA is usually well defined in the written procedure. A properly designed method