



1C. Quality Assurance vs. Quality Control

Introduction

Quality assurance (QA) and quality control (QC) both play a vital role in an organization's overall quality management system. QA and QC are often used interchangeably to refer to actions performed to ensure the consistent quality of a result. However, the terms have distinct definitions. QA is the framework or program put in place by an organization to provide confidence that the requirements of a quality management system are being met. QC, a subset of QA, is a piece of that framework put in place by an organization that focuses specifically on the operational activities used to fulfill quality management requirements. Both QA and QC reduce the risk of producing a result that does not meet an organization's quality expectations. Both QA and QC increase the probability of identifying a quality failure if one occurs, but neither is a guarantee of zero quality failures.

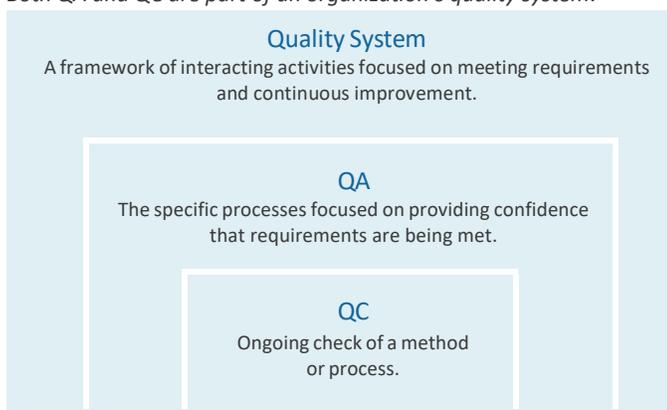
Quality Assurance and Quality Control Overview

QA and QC are used by organizations and industries, such as manufacturing, pharmaceutical, professional services, and information technology, to meet specific regulatory, industry, or customer requirements. The importance of QA and QC in forensic science was noted by both the [National Academy of Sciences](#) and the [National Commission on Forensic Science](#).

As noted in the introduction to this category of primers (Forensic Science: The Goal is to Produce Quality Results), conformity assessment requires an organization to have a management system with elements that focus on producing quality results. QA pulls these elements together to increase confidence in the reported results. QC provides the ongoing operational 'check' of a method or process. In the most basic terms, QA focuses on preventing nonconforming products and correcting nonconforming processes, and QC focuses on detecting a nonconforming product if one should occur. See Figure 1 for the relationship between a quality system, QA, and QC.

A forensic science service provider (FSSP) granted accreditation based on an International Organization for Standardization (ISO) standard has met its quality objectives by implementing a quality system that includes QA and QC, as well as quality planning (i.e., identifying and defining requirements) and quality improvement.

Figure 1 Quality control (QC) is an element of quality assurance (QA). Both QA and QC are part of an organization's quality system.



Quality Assurance

QA is a large encompassing framework focused on preventing quality issues and continuously improving processes. It creates a foundation for assessing risks and opportunities within the quality system.

In some organizations, an activity listed below as QA may be viewed as QC.

In addition to including QC, QA encompasses the following aspects of the entire process from sample recognition through reporting of results:

- Sampling or guidance on how sampling should be performed to ensure the best sample for testing, calibration, and inspection
- Item handling from receipt through disposal, including how the item is submitted, chain of custody, appropriate storage, and handling through testing, calibration, inspection, and reporting
- Initial training and competency testing of staff
- Staff and organization performance monitoring
- Staff certification
- Method validation or method verification
- Establishing and maintaining metrological traceability
- Equipment function checks
- Statistical process control
- Replicate testing, calibration, or inspection
- Retesting, recalibration, or reinspection
- Blind testing, calibration, or inspection
- Technical and administrative review
- Internal audit
- Document control
- Record control
- Suggestions from staff
- Customer feedback
- Management review
- Accreditation



Quality Control

QC is designed to detect nonconforming work at an operational level. Using QC samples, also called controls, is one way to ensure this. A QC sample is a material of known composition that is either tested or inspected alongside unknown samples to ensure the method's reliability at that time or used to verify calibration of measurement equipment.

The following parameters for QC samples will be defined by method validation or method verification data:

- Frequency – A control sample may be included each time the method is performed or at some set interval.
- Matrix – A close representation of the sample being tested, calibrated, or inspected (e.g., the weight of a baggie of a known material, length of a reference firearm, blood matrix in a blood ethanol method).
- Sample number – The number of QC samples may be one or more.
- Type – A calibrated reference standard or certified reference material (e.g., mass reference standard, length reference standard, certified ethanol reference material) provides information on method precision and bias. Use of a material of known origin that is not a calibrated reference standard or certified reference material provides information on method precision.
- Value – The concentration or value of one or more QC samples may be tied to a legal requirement (e.g., 0.08% ethanol QC sample in an antemortem blood ethanol method or a 1 gram mass reference standard QC sample in a seized drug weight method).

When nonconforming work is identified through a QC or QA activity, the nonconforming work must be corrected and evaluated for significance, including impact on past work. A corrective action is taken, when applicable, to reduce the risk of a recurrence.

Forensic Science Examples

ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories and *ISO/IEC 17020, Conformity assessment — Requirements for the operation of various types of bodies performing inspection* both serve as the foundation for accreditation of FSSPs and include requirements related to QA and QC.

Other Standards

Many of the standards listed on the Organization of Scientific Area Committees (OSAC) for Forensic Science Registry contain aspects of QA and QC. Here is an example from [ANSI/ASB 054 Standard for a Quality Control Program in Forensic Toxicology Laboratories](#):

8.1 At a minimum, the following apply to the use of controls in all forensic toxicology analyses.

- a) All controls shall be tested and treated the same as case samples.
- b) Negative and positive controls shall be included with each analytical batch.
- c) Process controls shall be included when a procedure includes a technique such as hydrolysis or oxidation.
- d) The laboratory shall define parameters for accepting or rejecting controls (Section 8.3). Each control sample shall be checked for acceptability using these predefined criteria.

Other standards used by FSSPs that contain requirements related to QA and QC include:

- [FBI Quality Assurance Standards for Forensic DNA Testing Laboratories](#)
- [NAME Inspection and Accreditation Checklist](#)
- [ABFT Forensic Toxicology Laboratory Accreditation Checklist](#)

Key Takeaways

- 1 QA is the group of inter-related processes and procedures that focus on ensuring the production of quality results.
- 2 QC is a component of QA.
- 3 QC is put in place to confirm a method is still operating as validated.
- 4 QA is continuously improved to reduce risk and enhance opportunity.

Related Primers

Accreditation and Certification

Method Validation and Method Verification

Metrological Traceability

Performance Monitoring: Methods, People, Organizations

Learn More

For additional information on QA and QC, visit American Society for Quality (ASQ):

- [Quality Assurance & Quality Control](#)
- [Learn About Quality](#)
- [Quality Glossary](#)



Glossary: Primer 1C Quality Assurance vs. Quality Control

Term	Definition	Reference	Primer Nos.
Product	Output of an organization that can be produced without any transaction taking place between the organization and the customer	ISO 9000:2015 Quality management systems — Fundamentals and vocabulary, International Organization for Standardization, Geneva, Switzerland	1C Quality Assurance vs. Quality Control
Quality	The degree to which a set of inherent characteristics of an object fulfills requirements	ISO 9000:2015 Quality management systems — Fundamentals and vocabulary, International Organization for Standardization, Geneva, Switzerland	1C Quality Assurance vs. Quality Control; 1D Method Validation & Method Verification
Quality assurance	A part of quality management focused on providing confidence that quality requirements will be fulfilled	ISO 9000:2015 Quality management systems — Fundamentals and vocabulary, International Organization for Standardization, Geneva, Switzerland	1C Quality Assurance vs. Quality Control
Quality control	A part of quality management focused on fulfilling quality requirements	ISO 9000:2015 Quality management systems — Fundamentals and vocabulary, International Organization for Standardization, Geneva, Switzerland	1C Quality Assurance vs. Quality Control
Quality management	Management with regard to quality	ISO 9000:2015 Quality management systems — Fundamentals and vocabulary, International Organization for Standardization, Geneva, Switzerland	1C Quality Assurance vs. Quality Control
Quality requirement	A requirement related to quality	ISO 9000:2015 Quality management systems — Fundamentals and vocabulary, International Organization for Standardization, Geneva, Switzerland	1C Quality Assurance vs. Quality Control
Requirement	A need or expectation that is stated, generally implied, or obligatory	ISO 9000:2015 Quality management systems — Fundamentals and vocabulary, International Organization for Standardization, Geneva, Switzerland	1C Quality Assurance vs. Quality Control



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Result	The product of the forensic service provider. This term is broad and includes observations, data, calculations, interpretations, and opinions	Organization of Scientific Area Committees for Forensic Sciences. (2022). Retrieved from OSAC Lexicon: https://www.nist.gov/glossary/osac-lexicon	1C Quality Assurance vs. Quality Control; 1D Method Validation & Method Verification