Individualized Quality Control Plan Policy

Document no.	Version	Effective date	Supersedes	Approved by (laboratory director)
IQ-01	1.4			

How to use this document. This PDF lets you fill in names, dates, signatures and form entries in any PDF reader. To change the policy wording itself, use the Word version.

1. Purpose

This policy describes when this laboratory uses an Individualized Quality Control Plan (IQCP) and how each plan is developed, approved and kept current.

2. When an IQCP is used

The default control procedures in the regulation apply to every nonwaived test system unless an IQCP is in place for it. An IQCP is used when the laboratory runs controls less often than the default and the manufacturer's instructions permit it. A plan never requires less than the manufacturer's instructions.

IQCP is optional and applies only to nonwaived testing. It is not available for the specialty of pathology. Laboratories with a Certificate of Accreditation follow their accreditation organization's IQCP requirements, which may be stricter.

3. Parts of an IQCP

1. Risk assessment (IQ-02): identifies and evaluates possible sources of error in the specimen, test system, reagent, environment and testing personnel, across the preanalytic, analytic and postanalytic phases, using the laboratory's own data.
2. Quality control plan (IQ-03): states the number, type and frequency of controls and the criteria for acceptable results.
3. Quality assessment (IQ-04): monitors whether the plan is working and triggers a new risk assessment when it is not.

4. Responsibilities

- The laboratory director is responsible for every IQCP and signs, dates and approves each quality control plan before it is used. That approval cannot be delegated. The director may assign specific IQCP tasks to others in writing but keeps overall responsibility.
- The technical consultant or technical supervisor prepares the risk assessment and gathers the supporting data (IQ-05).
- Testing personnel follow the quality control plan and report failures.

5. One plan per test system

A separate IQCP is prepared for each test system, even where methods are similar. One risk assessment may cover several analytes on the same test system. Identical test systems at more than one location may share a risk assessment, but each location has its own quality control plan and quality assessment.

6. Review

Each IQCP is reviewed through the quality assessment program at the frequency the laboratory director sets, here [at least annually], and whenever quality assessment finds a problem, the manufacturer changes the instructions, or the instrument, reagent, environment or staffing changes in a way that could affect risk.

Template source: CLIA Templates. The laboratory director must review, adapt and approve this document before use.

Sample from cliatemplates.com. The purchased kit includes this document in Word and as a fillable PDF, without the watermark.

SAMPLE

Regulatory basis: 42 CFR 493.1256(d); State Operations Manual, Appendix C (IQCP). CMS, IQCP frequently asked questions (August 2016). CMS and CDC, Developing an IQCP: A Step-by-Step Guide.

Approval and review

Role	Printed name	Signature	Date
Laboratory director (approval)			

Review date	Reviewed by	Changes made (or none)	Director signature

Template notice. Checked against 42 CFR Part 493: 16 November 2026. This template is a starting point, not regulatory or legal advice. State, local and accreditation requirements may be stricter than CLIA.

SAMPLE

Sample from cliatemplates.com. The purchased kit includes this document in Word and as a fillable PDF, without the watermark.