

Compliance Tool: CLIA IQCP Quality Assessment (QA) Worksheet

Instead of the cookie-cutter quality control (QC) procedures CLIA regulations require, labs that perform nonwaived tests have the option of implementing an individualized quality control plan (IQCP) tailored to their unique testing environment and patients. In addition to supporting CLIA compliance, the IQCP helps you identify and eliminate issues in your testing systems that can lead to errors and compromise quality. There are three phases of IQCP implementation:

1. Risk Assessment (RA)
2. Quality Control Plan (QCP)
3. Quality Assessment (QA)

Here's a worksheet for the QA process based on the template and examples sketched out in the Centers for Medicare & Medicaid Services IQCP implementation [guidelines](#).

IQCP Quality Assessment Worksheet

Laboratory Name: _____ Test System Name: _____

| QA Activity to Monitor | Frequency | Assessment of QA Activity <i>(Variation from established policies and procedures?)</i> | Corrective Action(s) |
|---|--|---|----------------------|
| Review temperature logs; ensure room, refrigerator, and freezer temperatures were monitored according to QCP and appropriate corrective action(s) taken | Monthly | | |
| Review specimen receipt log for unacceptable conditions and ensure appropriate action(s) taken | Weekly | | |
| Review manufacturer's instructions | After each new lot, shipment, or software change | | |
| Review internal QC logs to ensure appropriate corrective action(s) taken for any unacceptable values | Monthly | | |

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|---|--|--|--|
| Update policies and procedures for competency assessment; review personnel records/ documentation to ensure competency assessments meet CLIA requirements | As specified in laboratory policies and procedures | | |
| Review scheduled maintenance records/ documentation for test system(s) for completeness per laboratory policies and procedures | As specified in laboratory policies and procedures | | |
| Other QA activities to monitor | | | |

Source: Adapted from U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, and Centers for Disease Control and Prevention, *Developing an IQCP: A Step-by-Step Guide*.