D5445

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§493.1256 Standard: Control procedures

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§493.1261 through 493.1278.

(d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.

(d)(3) At least once each day patient specimens are assayed or examined perform the following for:

Interpretive Guidelines §493.1256(d)

INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

INTRODUCTION

§493.1250 provides for HHS' approval of a procedure that provides equivalent quality testing as an alternative to meeting the Analytic Systems requirements in §493.1251 - §493.1283. CMS has *approved* use of an equivalent quality control procedure, which permits laboratories to develop and customize laboratory-specific quality control procedures for their healthcare setting(s). This procedure is termed Individualized Quality Control Plan (IQCP).

An IQCP is composed of three parts: a Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan. The RA is the identification, evaluation, and documentation of potential failures and errors in a testing process. The QCP documents a laboratory's standard operating procedure that describes the practices, resources, and procedures to control the quality of a test process. The QA consists of the laboratory's written policies and procedure for the ongoing monitoring of the effectiveness of their IQCP.

IQCP is only available for select quality control requirements, which are identified below in Table 1 "Eligibility for IQCP."

When the manufacturers' instructions do not address quality control or those instructions are less stringent than the regulatory control procedures for Analytic Systems (see Table 1), the laboratory needs to follow the regulatory requirements or develop an IQCP. Laboratories have the flexibility to follow all regulatory requirements as written or customize their control procedures using the IQCP procedure. Whichever option is selected laboratories are not permitted to establish quality control procedures that are less stringent than those specified by the manufacturer of the test system.

LABORATORY DIRECTOR RESPONSIBILITIES

Under subpart M, the laboratory director is responsible for ensuring that quality control (use D6020 or D6093 as appropriate) and quality assessment (use D6021 or D6094 as appropriate) programs are established and maintained to assure the quality

of laboratory services, including the identification of failures in quality as they occur (use D6022 or D6094).

The laboratory director is responsible for deciding whether a laboratory will seek to meet its CLIA quality control obligations through IQCP, and if the laboratory director decides to do so, the laboratory director is also responsible for ensuring that the QCP the laboratory develops meets the IQCP requirements.

The laboratory director must consider the laboratory's clinical and legal responsibility for providing accurate, reliable and timely patient test results (§493.1407 or §493.1445) prior to implementing a QCP that is less stringent than the applicable Analytic Systems control regulations listed in Table 1, Eligibility for IQCP.

REGULATORY CONSIDERATIONS WHEN USING IQCP

All CLIA regulations, other than those specifically designated as eligible for IQCP in Table 1, Eligibility for IQCP, continue to be in force and must be followed.

Table 1, Eligibility for IQCP, lists those specialties/subspecialties and general regulations which are designated as "eligible" for IQCP, that is, those specialties/subspecialties and general regulations for which the laboratory has the flexibility to develop control procedures using the IQCP procedure. Table 1 also lists those specialties/subspecialties and specialty/subspecialty regulations which are not eligible for IQCP.

- The first column lists the CLIA specialties/subspecialties: Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis, Endocrinology, Toxicology, Hematology, Immunohematology, Clinical Cytogenetics, Radiobioassay, Histocompatibility, Pathology, Histopathology, Oral Pathology and Cytology.

- The second column indicates whether or not each specialty/subspecialty is eligible for IQCP. The specialties/subspecialties eligible for IQCP are; Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis, Endocrinology, Toxicology, Hematology, Immunohematology, Clinical Cytogenetics, Radiobioassay and Histocompatibility. The specialties/subspecialties not eligible for IQCP are; Pathology, Histopathology, Oral Pathology and Cytology.

- The third column lists the general regulations that *are eligible for IQCP* and may be applied to the eligible specialty/subspecialties listed in column one: §493.1256(d)(3)-(5) and §493.1256(e)(1)-(4).

- The fourth column lists the specialty/subspecialty regulations that are eligible for IQCP:§493.1261, §493.1262, §493.1263, §493.1264,

§493.1265, §493.1267(b),(c), §493.1269, and §493.1278(b)(6),(c),(d)(6),(e)(3).

- The fifth column lists the specialty/subspecialty regulations that are not eligible for IQCP: §493.1267(a),(d), §493.1271, §493.1276, §493.1278(a),(b)(1-5),(d)(1-5),(d)(7),(e)(1-2),(f),(g), §493.1273 and §493.1274.

Table 1: Eligibility for IQCP

CLIA Specialty/ Subspecialty	Eligible for IQCP?	General Regulations Eligible for IQCP	Specialty/ Subspecialty Regulations Eligible for IQCP	Specialty/ Subspecialty Regulations NOT Eligible for IQCP
Bacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1261	N/A
Mycobacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1262	N/A
Mycology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1263	N/A
Parasitology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1264	N/A
Virology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1265	N/A
Syphilis Serology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
General Immunology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Routine Chemistry	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1267(b),(c)	§493.1267(a), (d)
Urinalysis	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Endocrinology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Toxicology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Hematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1269	N/A
Immunohematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1271
Clinical Cytogenetics	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1276
Radiobioassay	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Histocompatibility	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1278(b)(6), (c), (d)(6), (e)(3)	§493.1278(a), (b)(1-5), (d)(1-5), (d)(7), (e)(1-2), (f), (g)

Pathology	No	None (Not eligible for IQCP)	N/A	N/A
Histopathology	No	None (Not eligible for IQCP)	N/A	§493.1273
Oral Pathology	No	None (Not eligible for IQCP)	N/A	N/A
Cytology	No	None (Not eligible) for IQCP)	N/A	§493.1274

Probe(s) §493.1256(d)

For each test system, does the laboratory perform quality control testing procedures as specified in the manufacturer's instructions? Use D5411.

If the manufacturer's instructions are less stringent than the CLIA regulatory requirements for control procedures, did the laboratory perform an IQCP or are they following the CLIA regulatory requirements for control procedures?

As stated above, an IQCP must include:

- Risk Assessment (RA)
- Quality Control Plan (QCP)
- Quality Assessment (QA)

Risk Assessment

Risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process.

Risk assessments for IQCP must include, at a minimum, an evaluation of the following five components:

- Specimen
- Test system
- Reagent
- Environment
- Testing personnel

The scope of risk assessments must encompass the entire testing process - preanalytic, analytic, and postanalytic phases - and include, at a minimum, the evaluation of the five risk assessment components listed above for each test for which the laboratory wishes to employ IQCP. Use D5445.

The laboratory director has the responsibility for ensuring that the risk assessment considers the CLIA Quality System requirements at 42 C.F.R. 493, Subpart K for accurate, reliable, and timely test results and that test result quality is appropriate for patient care. Re-evaluation of the RA must be considered by the director or his/her designee when changes occur in any of the following components: specimen, test system, reagent, environment and testing personnel.

Conducting the Risk Assessment

To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error on test quality.

In-house data, established by the laboratory in its own environment and by its own personnel, must be utilized to demonstrate that the stability of the test system as it is used in that laboratory supports the number and frequency of the QC documented in the QCP. Use D5425. Data from verification or establishment of performance specifications, historical (existing) QC data, and data/documentation compiled to meet other existing CLIA Quality System regulations at 42 C.F.R. 493, Subpart K can be included. Published data or data from manufacturers (e.g. package inserts) may be taken into consideration, but may not be used as the sole criteria for decision-making. The laboratory must document all activities completed for the risk assessment, including data to support their risk assessment decisions. Use D5481. *All* RA documentation must be maintained for at least two years after the corresponding QCP has been discontinued. Use D3029.

NOTE: Manufacturer-provided tools and templates, if available, may be helpful for laboratories implementing IQCP; however, laboratories will need to supplement these materials with laboratory-specific information as part of the Risk Assessment. The manufacturer information is not sufficient in and of itself.

Laboratories must assess information provided by manufacturers as part of the RA, such as the manufacturer's instructions (e.g. intended use, limitations, interferences, recommendations). If additional information is required to conduct the risk assessment, that is not available in the manufacturer's instructions, the laboratory should contact the manufacturer to request the needed information.

The following list contains additional possible sources of information for conducting a risk assessment:

- Regulatory requirements
- Manufacturer's package insert (including intended use, limitations, environmental requirements, QC frequency, specimen requirements, reagent storage, maintenance, calibration, interfering substances, etc.)
- Manufacturer's operator manual
- Troubleshooting guide

- Manufacturers' alerts and bulletins
- Verification or establishment of performance specifications
- Testing personnel qualifications, training and competency records
- QC data
- Proficiency testing data
- QA information, including corrective action
- Scientific publications
- Other information as appropriate

In laboratories with multiple identical devices (same make and model), a single risk assessment may be performed for the test system. However, differences in testing personnel and environments where the device will be used must be taken into consideration when performing the risk assessment; therefore, there may be a need to customize a QCP for each individual location and/or device.

NOTE: Multiple devices may be included in a single QCP; however, performance specifications must be established or verified for each individual device and each analyte.

Probes §493.1256(d)

Does the laboratory's RA support its procedures for testing quality control samples, including the frequency of testing? Use D5445.

Has the laboratory included all five components and all phases of testing in their risk assessment, and have they reasonably identified and evaluated the potential failures and sources of error? Use D5445.

Has the laboratory conducted a risk assessment for each location where testing is performed on multiple numbers of identical devices (i.e. same make, model)?

For example, has the laboratory conducted a risk assessment with respect to:

- Multiple laboratory/testing locations within a single CLIA number
- Point-of -care devices throughout health care/laboratory systems
- Multiple identical devices or kits in a single location
- Differences in testing personnel

Has the laboratory's RA identified the sources of potential failures and sources of error contained in the most current version of the manufacturer's instructions?
Has the laboratory documented all activities completed for the risk assessment? Does the laboratory have documentation, including data, to support their risk assessment decisions? Use D5481.

SPECIMEN

Probe §493.1256(d)

Has the laboratory identified and evaluated the potential failures and sources of error in the preanalytic phase, as applicable, for:

- Patient preparation
- Specimen collection
- Specimen labeling
- Specimen storage, preservation and stability
- Specimen transportation
- Specimen processing
- Specimen acceptability and rejection
- Specimen referral

TEST SYSTEM

The risk assessment must include consideration of the manufacturer instructions for function checks and maintenance checks. In addition, the risk assessment should take into consideration the laboratory's test volume, and intended use of the test results (i.e. screening or diagnostic).

Additional factors to consider in the risk assessment for analyte and test systems may include, but are not limited to potential failures and sources of error due to:

- Inadequate sampling
- Clot detection capabilities
- Capabilities for detection of interfering substances (e.g., hemolysis, lipemia, icterus, turbidity)
- Calibration associated issues
- Mechanical/electronic failure of test system
- Optics
- Pipettes or pipettors
- Barcode readers
- Failure of system controls and function checks
- Built-in procedural and electronic controls (internal controls)
- External or internal liquid quality control (assayed vs. unassayed)
- Temperature monitors and controllers
- Software/Hardware
- Transmission of data to Laboratory Information System

- Result reporting

REAGENT

Factors to consider in the risk assessment for reagents, quality control materials, calibrators, and similar materials may include, but are not limited to potential failures and sources of error related to:

- Shipping/Receiving
- Storage condition requirements
- Expiration Date (may vary based on storage requirements)
- Preparation

Probes §493.1256(d)

Has the laboratory assessed potential test system failures or sources of error, which may result from reagent, quality control material, and calibrator contamination or deterioration and reagent lot variation?

Has the laboratory assessed potential test system failures or sources of error due to the risk of inadvertently mixing reagents from different kits or lot numbers, if applicable?

ENVIRONMENT

Probes §493.1256(d)

Has the laboratory evaluated environmental conditions, which may affect test system performance including, but not limited to potential failures and sources of error due to:

- Temperature
- Airflow/ventilation
- Light intensity
- Noise and vibration
- Humidity
- Altitude
- Dust
- Water
- Utilities (e.g. Electrical failure/power supply variance or surge)
- Adequate space

Has the laboratory evaluated potential failures and sources of error due to the transport of instruments and reagents in a mobile laboratory?

TESTING PERSONNEL

Testing personnel must participate in the process of conducting the risk assessment. It is not necessary for all personnel to be involved.

Probe §493.1256(d)

Has the laboratory assessed the potential failures and sources of error due to testing personnel by evaluating the following:

- Training
- Competency
- Appropriate education and experience qualifications
- Adequate staffing

After the laboratory has identified the sources of potential failures and errors for a testing process and evaluated the frequency and impact of those failures and errors on test quality, the resulting risk assessment is then used to develop the Quality Control Plan (QCP).

Quality Control Plan

A QCP is a document that describes the practices, resources, and procedures to control the quality of a particular test process. The QCP must ensure accurate, reliable and timely test results, and that test result quality is appropriate for patient care. The QCP must be available to, and followed by, laboratory personnel. Use D5401.

The QCP must provide for the immediate detection of errors that occur due to test system failure, adverse environmental conditions, and operator performance. It must also monitor, over time, the accuracy and precision of test performance that may be influenced by changes in the test system, environmental conditions, or variance in operator performance. Use D5441.

The QCP must at least include the number, type, frequency of testing and criteria for acceptable result(s) of the quality control(s). Use D5441 or D5469, as appropriate.
If indicated by the evaluation of the risk assessment, the QCP may also include:

- Electronic controls
- Procedural controls
- Training and competency assessment
- Other specified quality control activities

Laboratories implementing IQCP for new tests are encouraged to perform control procedures at more frequent intervals during initial implementation, allowing the laboratory to identify performance issues that could indicate a need to adjust the QCP.

The task of development and implementation of QCPs may be delegated (in writing) to a qualified individual (§493.1407(e)(14) or §493.1445(e)(15)). However, the laboratory director has the ultimate responsibility for the proper development and implementation of a QCP. (§493.1407(b) or §493.1445(b)). There must be documented evidence that the laboratory director has approved, signed and dated the QCP (§493.1251(d)). Use D5407. Re-evaluation of the QCP must be considered by the director or his/her designee when changes occur in any of the following components: specimen, test system, reagent, environment and testing personnel.

Probes §493.1256(d)

Does the laboratory have a written QCP for each test system, as applicable? Use D5441 or D5445, as appropriate.

Does the QCP specify the number, type, and frequency of testing of the quality control material(s)? Does the QCP provide for immediate detection of errors? Use D5441.

Does the QCP contain criteria to determine acceptable quality control results? Use D5469.

Does the QCP require that the laboratory perform QC as specified by the manufacturer's instructions? Regardless, if the laboratory is performing QC less frequently than required by the manufacturer, use D5411 or D5445, as appropriate.

Is there documented evidence of laboratory director approval of the QCP before it was put into use? Use D5407.

Quality Assessment

All IQCP Quality Assessment monitoring must be part of the laboratory's overall Quality Assessment plan. The laboratory must establish and follow written policies and procedures for the ongoing monitoring of the effectiveness of their IQCP. The monitoring should include, but is not limited to, the following components: specimen, test system, reagent, environment and testing personnel. Re-evaluation of the RA and the QCP must be considered by the director or his/her designee when changes occur in any of the above components.

Laboratories implementing IQCP for new tests are encouraged to perform monitoring activities at more frequent intervals during initial implementation, allowing the laboratory to identify performance issues that could indicate a need to adjust the QCP.

Documents to consider for QA review may include, but are not limited to:

- QC review
- Proficiency testing records (e.g. scores, testing failures, trends)
- Patient results review
- Specimen rejection logs
- Turnaround time reports
- Records of preventive measures, corrective actions, & follow-up
- Personnel Competency Records

When the laboratory discovers a testing process failure, the laboratory must conduct an investigation to identify the cause of the failure, its impact on patient care, appropriate corrective action for affected patients and appropriate modifications to their QCP to prevent recurrence, as applicable. The investigation must include documentation of all corrections, corresponding corrective actions for all patients affected by the testing process failure, and evaluation of the effectiveness of the corrective action(s). The laboratory must implement the correction(s) and corresponding corrective action(s) necessary to resolve the failure and reduce the risk of recurrence of the failure in the future. If necessary, the laboratory must update the risk assessment with the new information and modify the QCP, as needed.

Probes §493.1256(d)

Has the laboratory established written policies and procedures for the ongoing monitoring of the QCP (use D5391, D5791 or D5891 as appropriate) and evaluation of its effectiveness? (Use D5393, D5793 or D5893 as appropriate)

In the event of a testing process failure, has the laboratory evaluated all patient test results since the last acceptable quality control? Use D5783.