The Joint Commission

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Prepublication Requirements

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online E-dition®), accredited organizations and paid subscribers can also view them in the monthly periodical *The Joint Commission Perspectives®*. To begin your subscription, call 800-746-6578 or visit http://www.jcrinc.com.

Joint Commission Requirement

New and Revised Standards for Individualized Quality Control Plans (IQCP)

APPLICABLE TO LABORATORIES

Effective January 1, 2016

Quality System Assessment for Nonwaived Testing (QSA)

Standard QSA.02.01.01
The laboratory verifies tests, methods, and instruments in order to establish quality control procedures.

Note: *This standard also applies to instruments on loan when the original instrument is under repair.*

Element of Performance for QSA.02.01.01

A 7. The laboratory's quality control procedure for each testing system or methodology includes the following:

- The range of quality control values used
- The frequency of quality control testing
- Adherence to the manufacturer's recommendations
- The predicted reliability based on history
- The specialty and subspecialty requirements included in this chapter

Note: *If the manufacturer's quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.*

~~**Standard QSA.02.04.01**~~
~~The laboratory evaluates instrument-based testing with electronic or internal systems prior to using them for routine quality control.~~

~~**Elements of Performance for QSA.02.04.01**~~

~~A 1. When the laboratory evaluates instrument-based testing with electronic or internal systems, the test being performed is a moderately complex test in routine chemistry or hematology.~~

~~A 2. (D) For each test system, the laboratory evaluates the sources of error, including personnel, training, and competency, and determines whether the electronic or internal quality controls monitor the entire analytical process or a portion of the analytical process. The results are documented. R~~

~~**Note:** *This information may be included in the manufacturer's package insert or requested from the manufacturer via written documentation.*~~

~~A 3. (D) The laboratory conducts an evaluation of the electronic or internal quality controls by testing external quality controls in parallel with the electronic or internal quality controls for the following:~~

- ~~10 consecutive days of testing for test systems that monitor the entire analytical process~~
- ~~30 consecutive days of testing for test systems that monitor a portion of the analytical process~~

~~The evaluation of the electronic or internal quality controls is documented.~~

~~**Note:** *Consecutive days include only those days when*~~

Key **A** indicates scoring category A; **C** indicates scoring category C; (D) indicates that documentation is required; (M) indicates Measure of Success is needed; ⚠ indicates an Immediate Threat to Health or Safety; ⚠ indicates situational decision rules apply; ⚠ indicates direct impact requirements apply; R indicates an identified risk area

~~*the laboratory actually performs or would perform the test.*~~

~~A 4.~~ ~~Through its evaluation and data analysis activities, the laboratory defines the variety and frequency of external quality control sufficient to prevent clinically significant errors in patient test results.~~

~~Note 1: *Unless the manufacturer requires more frequent testing, the frequency of testing external quality controls may be reduced from daily to at least the following:*~~

- ~~Once monthly for test systems that monitor the entire analytical process~~
- ~~Once weekly for test systems that monitor a portion of the analytical process~~

~~Note 2: *For a test system without internal quality controls, frequency of external quality controls may not be reduced.*~~

~~C 5.~~ ~~Ⓓ The laboratory performs at least two levels of electronic or internal quality controls at the same frequency as required in the specialty and subspecialty sections of this manual, or more frequently if recommended by the manufacturer or defined by laboratory procedure. The electronic or internal quality control results are documented. Ⓜ~~

~~Note: *The minimum frequency for performing two levels of electronic or internal quality controls can be found at the following specialties/subspecialties:*~~

- ~~Routine chemistry (refer to QSA.06.01.01)~~
- ~~Blood gases (refer to QSA.06.02.01)~~
- ~~Coagulation (refer to QSA.11.02.01)~~

~~A 6.~~ ~~Ⓓ The laboratory performs external quality controls at the following frequencies:~~

- ~~As defined by the evaluation (either weekly or monthly)~~
- ~~According to the manufacturer's recommendations~~
- ~~With each new lot number, shipment, or package of reagents~~

~~The external quality control results are documented.~~

~~A 7.~~ ~~Ⓓ The laboratory performs external quality controls at the number of levels specified by the specialty and subspecialty requirements (for example, blood gases require three levels of quality control). The external quality control results are documented.~~

~~A 8.~~ ~~Ⓓ The laboratory conducts an investigation, identifies the root causes, performs corrective action, and restarts the evaluation of the electronic or internal quality controls if any of the following occur:~~

- ~~Proficiency testing is unsatisfactory~~
- ~~Analytic system quality assessment is unacceptable~~
- ~~Competency assessment is unacceptable~~
- ~~There are two consecutive unacceptable quality control results (internal or external) for the same level or measurement either during the evaluation process or after the laboratory has reduced the frequency of testing external quality control materials. (After the first unacceptable quality control result, the laboratory repeats the quality control and meets the criteria for acceptability before reporting patient results.)~~

~~The corrective action is documented. (See also QSA.02.12.01, EPs 4-8).~~

Standard QSA.02.04.01

The laboratory develops an individualized quality control plan (IQCP) in an eligible specialty or subspecialty.

Elements of Performance for QSA.02.04.01

A 1. Laboratories that develop an individualized quality control plan (IQCP) include the following: A complete IQCP that consists of the following three parts:

- Risk assessment
- Quality control plan
- Quality assessment

A 2. Ⓓ Laboratories that develop an individualized quality control plan (IQCP) include the following: A risk assessment that is established by the laboratory in its own environment by its own testing personnel.

Note: *The risk assessment may include test, method, or instrument verification data; performance specifications; or historical quality control data. Published or manufacturer data may also be included, but cannot be the only data source for the risk assessment.*

A 3. Ⓓ Laboratories that develop an individualized quality control plan (IQCP) include the following: A risk assessment that contains an evaluation of the following five components:

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

A 4. Ⓓ Laboratories that develop an individualized quality control plan (IQCP) include the following: A risk assessment that encompasses the following three phases of the entire testing process:

- Preanalytic
- Analytic
- Postanalytic

Note: *The risk assessment identifies the sources of potential failures and errors for a testing process, and evaluates the frequency and impact of those failures and sources of error.*

A 5. Ⓓ Laboratories that develop an individualized quality control plan (IQCP) include the following: A risk assessment that includes the manufacturer's instructions or other information needed to assess risk in all three phases of the testing process.

Note: *The risk assessment includes function and maintenance checks as required by, and not less than, manufacturers' instructions.*

A 6. Ⓓ Laboratories that develop an individualized quality control plan (IQCP) include the following: A quality control plan for devices at each location throughout a facility.

A 7. Ⓓ Laboratories that develop an individualized quality control plan (IQCP) include the following: A quality control plan (or changes in the plan) that the laboratory director signs and dates before implementation. (See also LD.04.05.09, EP 2).

A 8. Ⓓ Laboratories that develop an individualized quality control plan (IQCP) include the following: A quality assessment that includes documentation of corrective action and preventive action to monitor ongoing effectiveness.

~~**Standard QSA.02.05.01**~~

~~The laboratory evaluates noninstrument-based testing with internal quality control systems prior to using them for routine quality control.~~

~~**Elements of Performance for QSA.02.05.01**~~

~~A 1. If the laboratory uses noninstrument-based testing with internal positive and negative quality controls as the daily quality control, it performs an evaluation of the internal quality controls against the external quality controls.~~

~~A 2. Ⓓ If the laboratory uses noninstrument-based testing with internal positive and negative quality controls as the daily quality control, it defines in writing the frequency of external quality controls based on the following:~~

- ~~Its evaluation~~
- ~~An interval that meets manufacturers' recommendations~~
- ~~The use of each new lot number, shipment, or package of reagents~~

~~A 3. Ⓓ If the laboratory uses noninstrument-based testing with internal positive and negative quality controls as the daily quality control, it performs external quality controls at its defined frequencies. The internal and external quality control results are documented.~~

Standard QSA.02.06.01

Each laboratory specialty and subspecialty has a quality control policy.

Element of Performance for QSA.02.06.01

A 2. The quality control policy defines the number, type, and frequency of quality control materials according to the following:

- Manufacturers' recommendations
- Performance specifications verified or established by the laboratory
- Specialty and subspecialty requirements found in this chapter for quality control testing

Note: *If the manufacturer's quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.*

Standard QSA.02.10.01

The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.

Note: *This standard is considered in combination with the specialty and subspecialty requirements found in this chapter (for example, blood gas testing requires three levels of quality control materials each day of patient testing).*

Element of Performance for QSA.02.10.01

C 2. The laboratory uses quality control materials at levels and a frequency consistent with manufacturers' recommendations. Ⓜ

Note: *If the manufacturer's quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.*

Standard QSA.02.10.01

The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.

Note: *This standard is considered in combination with the specialty and subspecialty requirements found in this chapter (for example, blood gas testing requires three levels of quality control materials each day of patient testing).*

Elements of Performance for QSA.02.10.01

C 1. Ⓓ The laboratory uses quality control materials that challenge each step of the testing process. The quality control results are documented. Ⓜ

C 2. The laboratory uses quality control materials at levels and a frequency consistent with manufacturers' recommendations. Ⓜ

C 3. Ⓓ The laboratory uses two quality control materials of different concentrations for each quantitative procedure on each day the procedure is performed. The quality control results are documented. Ⓜ

C 4. Ⓓ The laboratory uses negative and positive control material for each qualitative procedure on each day the procedure is performed. The quality control results are documented. Ⓜ

C 5. Ⓓ The laboratory uses a negative and graded or titered positive reactivity control material for procedures that produce graded or titered results each day the procedure is performed. The quality control results are documented. Ⓜ

C 6. Ⓓ The laboratory uses a negative and positive reactivity control material to test staining materials for intended reactivity each day the procedure is performed. The quality control results are documented. Ⓜ

C 7. Ⓓ The laboratory uses a negative and positive reactivity control material to check fluorescent and immunohistochemical stains for intended reactivity each day the procedure is performed. The quality control results are documented. Ⓜ

C 8. Ⓓ When direct antigen systems include an extraction phase, the laboratory uses two quality control materials, one of which is capable of detecting extraction errors. The quality control results are documented. Ⓜ

C 9. Ⓓ For each electrophoretic determination, the laboratory tests at least one quality control material containing the substances being identified or measured in patient testing. The quality control material is tested concurrent with patient specimens. The quality control result is documented. Ⓜ

C 10. Ⓓ For thin layer chromatography, each plate or card is spotted with a calibrator containing the substances or drug groups identified or reported by the laboratory. The calibrator includes at least one control material on each plate or card and is processed through each step of patient testing, including the extraction phase. The quality control result is documented. Ⓜ

C 11. Ⓓ If quality control materials are not available, the laboratory performs alternative quality control testing. The alternative quality control results are documented. Ⓜ