

detect problems arising from deteriorated or contaminated calibrating solutions. The commenter also recommended the reference to calibrators be deleted from these sections and that control testing be performed using only control material.

Response: We agree with this commenter. It was never our intent to infer by the wording of these requirements that calibration material used to calibrate a test system could be used as a control to monitor the test system's performance. However, we allow the use of calibration material as a control material provided it is from a different lot number than that used to calibrate the test system or establish a cut-off. Therefore, we are clarifying the use of calibration materials as control materials (now at § 493.1256(d)(9)), and eliminating the terms "calibration" and "calibration material" from the blood gas analysis requirements (now at § 493.1267).

Comment: One commenter stated testing one sample of blood gas control per 8 hours of patient testing is not sufficient and is inconsistent with the general requirement for quantitative tests at § 493.1218(b)(2) that requires two controls of different concentrations with each run of patient specimens. This commenter recommended that at least two levels of control be required every 8 hour shift.

Response: We revised the general control requirement formerly at § 493.1218(b) (now at § 493.1256(d)). The requirement now specifies, at a minimum, assaying two levels of control materials each day patient specimens are tested. We are deleting the term "run" from the regulation. Also, laboratories must perform control testing using the number and frequency specified by the manufacturer or established by the laboratory when those frequencies meet or exceed the minimum requirement. Therefore, the minimum control requirement for quantitative tests, unless a more frequent interval is recommended by the test system's manufacturer or the laboratory, is two control materials of different concentrations each day patient specimens are tested.

The requirement for one control material per 8 hours for blood gas analyses, formerly at § 493.1245 (now at § 493.1267) exceeds these general QC requirements. The blood gas control requirements also require the laboratory to use a combination of control materials that check low and high values each day of testing. In addition, for blood gas instruments that do not internally verify calibration at least every 30 minutes, the laboratory must

include one sample of control material each time patient samples are tested. This final rule provides minimum requirements. Based on the laboratory's verification of the test system's performance specifications before routine patient use (now at § 493.1253) and establishment of its control procedures (now at § 493.1256(d)), the laboratory may determine that it needs to run additional control materials or run control materials at a more frequent interval to assure accurate and reliable test results.

Section 493.1249 Condition: Toxicology

Specific comments received and response to comments regarding § 493.1249 are set forth below.

Comment: One commenter asked that the term "drug abuse screening using thin layer chromatography" at § 493.1249, Toxicology be modified to read "drugs-of-abuse screening using thin layer chromatography" ("drugs-of-abuse" is defined by the National Institute for Drugs of Abuse now National Substance Abuse and Mental Services Health Administration Laboratory Certification Program). This commenter also requested deletion of the requirement under § 493.1249(b) for at least one control sample to be processed and included in each chamber, stating that all environmental, chemical and material variables within a chamber are visualized by running calibration materials. The commenter added that controls should be analyzed with each run, and that each run should not exceed a 24 hour period.

Response: We agree with the commenter that the control requirements formerly at § 493.1249 are not clear; therefore, we are revising the language to clarify the requirements. We are moving the requirements for thin layer chromatography to § 493.1256(d)(4) under Control procedures. In addition, we are revising the term "drug abuse screening" to read "all known substances or drug groups" identified and reported by the laboratory, to accommodate the wider use of the technology. However, we disagree with the commenter's statement that analyzing one control material per 24 hours is sufficient. If extractions and tests are performed more frequently than once per 24 hours, each "plate" or "card" (formerly referred to as "chamber") must be spotted with at least one sample of control material to ensure that appropriate separation, and as applicable, extraction took place. The inclusion of a calibration material containing all known substances or drug

groups reported by the laboratory using thin layer chromatography on each plate or card ensures appropriate identification of the substances or drugs in patient specimens.

Section 493.1253 Condition: Hematology

Specific comments received and response to comments regarding § 493.1253 are set forth below.

Comment: We received several comments requesting the deletion of QC requirements in hematology because they would increase laboratory costs.

Response: We agree with the commenters that the requirement to include two levels of control material each 8 hours of testing for automated hematology analyzers (for example, cell counters and differential counters) is somewhat excessive in light of the proven stability and reliability of these instruments. Therefore, we are deleting the specialty-specific control requirement for automated hematology analyzers formerly at § 493.1253(b), and are requiring laboratories to meet the general control requirements (now at § 493.1256(d)) when using automated hematology analyzers. However, the manufacturer's instructions and the laboratory's evaluation of the instruments' stability, environmental effects, and operator variance will determine the actual number, type, and frequency of testing control materials. At a minimum, the laboratories will have to test two control materials of different concentrations each day.

Comment: One commenter requested that we remove the requirement for duplicative testing of patient and control specimens for manual coagulation tests, as required at § 493.1253(d)(2), since proficiency testing requirements do not allow for duplicative testing.

Response: We disagree with the commenter and are retaining the requirement for duplicative testing of patient specimens and control materials for manual coagulation testing (now at § 493.1269(c)(2)). CLIA regulations for proficiency testing (PT) (§ 493.801(b)(2)) require the laboratory to test PT samples the same number of times that it routinely tests patients' samples. Therefore, since patient specimens must be routinely tested in duplicate, PT samples for manual coagulation testing must also be tested in duplicate.

Section 493.1257 Condition: Cytology and Section 493.1259 Condition: Histopathology

Approximately 66 percent of the 1,030 comments received concerning the final rule with comment period,