DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-03-19

DATE: **May 8, 2003**

FROM: Director
Survey and Certification Group

SUBJECT: Policy for Interim Period Between the Effective Date of CMS-2226-F and Publication of Surveyor Guidelines

TO: Survey and Certification Regional Office Management (G5)

This memorandum addresses how survey and certification activities will proceed in the interim period between the April 24, 2003 effective date of CMS-2226-F ("Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications," 68 FR 3640) and the future date on which the new survey guidelines are published (most likely in October, 2003).

In large part, the final rule simply reorganized portions of the prior CLIA regulations. It also reduced the regulatory burden on certain bacteriology, mycology, syphilis serology, general immunology, hematology and histocompatibility provisions and increased the burden on a handful of other provisions (for example, it made the general quality control requirements effective for all non-waived testing). The following provisions resulted in reduced regulatory burdens on laboratories:

- **Bacteriology Requirements** (former section 493.1227, Final Rule section 493.1261)
    - Reduced burdens for catalase, Cefinase, coagulase, oxidase, bacitracin, optochin, OHPG, X, V and XV disks or strips in that laboratories are now only required to check each batch, lot number and shipment of reagents, disks, stains, antisera and identification system when prepared or opened for positive and negative reactivity (and graded reactivity, if applicable).
    - Reduced burdens for laboratories using antisera in that positive and negative reactivity now only needs to be tested when the product is prepared or opened, and once every six months thereafter.

- **Mycology Requirements** (former section 493.1231, Final Rule section 493.1263)
    - Reduced burdens for laboratories using fungal identifications tests (germ tubes) and reagents in that now only each batch, lot number and shipment must be tested when the products are prepared or opened for positive and negative reactivity (and graded reactivity, if applicable).
    - Reduced burdens for laboratories using lactopenol cotton blue in that now batches, lot numbers or shipments only need to be tested for the intended reactivity with a control organism(s) when prepared or opened.

- **Syphilis Serology and General Immunology** (former sections 493.1239 and 493.1241, Final Rule section 493.1256
    - Note: The Final Rule section 493.1256 addresses all specialties unless there are specific requirements elsewhere in the CLIA regulations that specifically addresses a particular specialty.
    - Reduced burdens for laboratories as now control testing need only be done as specified by the laboratory or manufacturer but no less than once per day.

- **Hematology** (former section 493.1253, Final Rule section 493.1256 and 493.1269)
    - Reduced the quality control testing burdens for automated hematology to that specified by the laboratory or manufacturer but no less than once per day.
    - Note: There has been no change to the quality control testing burdens for hematology manual cell counts using a hemocytometer or to quality control testing burdens for coagulation (manual or automated).

- **Histocompatibility** (former section 493.1259, Final Rule section 493.1278)
    - Reduced the regulatory burden by eliminating the requirement for a monthly evaluation of a specimen as an unknown by each laboratory's testing personnel.

In keeping with CMS' outcome-oriented approach to survey and certification, surveyors are being asked to only cite the most serious deficiencies (those that affect outcomes or potential outcomes) and to continue to offer education and technical assistance until the new survey guidelines are published. Futhermore, surveyors are being asked to take into account the limited number of reduced burdens that we have noted above as they conduct their surveys. Also, surveyors are not being asked to survey for compliance with any of the general quality control requirements that did not formerly apply to FDA approved moderate non-modified tests or any other increased regulatory burdens until the new survey guidelines are published.

When serious deficiencies are identified, surveyors may continue to cite to the various CLIA requirements by citing to the prior locations of applicable provisions until the new survey guidelines are published. The existing D-Tags and the October 1, 2002 (the most current paper publication of the Code of Federal Regulations) regulatory cites on the form CMS-2567 can therefore continue to be used, but we ask that any communications noting these tags and cites include the crosswalk from the final rule or some other means of denoting the cited requirements' new locations in the Code.

The crosswalk in the final rule can be found at pages 3642-3650 of the Federal Register and it is attached for your convenience.

Finally, until the new survey guidelines can be published, we ask that any letters that are issued to the laboratories summarizing survey findings contain explicit advisory language indicating that the survey guidelines from the former regulations were used with some modification to assess CLIA compliance. Please note that any such letters will only be treated as advisory communications with surveyed entities. Formal compliance actions will only be taken on findings based on the former survey guidelines after they have been individually reviewed and compared to the final regulations by the regional offices.

Use of the following language in letters summarizing survey findings would satisfy our desire to notify surveyed entities about how the survey and certification program is operating during this interim period:

> "This report was generated following the survey guidelines drafted for the CLIA regulation in effect as of October 1, 2002 (the most current paper publication of the Code of Federal Regulations). As you are aware, final regulations were published January 24, 2003 (68 Federal Register 3640) that in large part merely reorganized portions of these former regulations. The Final Rule also reduced the regulatory burden on certain bacteriology, mycology, syphilis serology, general immunology, hematology, and histocompatibility provisions of the former rule and increased the burden on a handful of other provisions (for example, it made the general quality control requirements effective for all non-waived testing). The increased regulatory burden like the general quality control requirements that did not formerly apply to FDA approved moderate non-modified tests were not considered during the survey from which this report was generated. (Compliance with these increased regulatory burdens will only be assessed after the new Surveyor Guidelines are published later this year.) The surveyor(s) that conducted the survey from which this report was generated were provided with summaries about which the former regulations had been replaced with less burdensome requirements by the January 24, 2003 Final Rule. They were instructed at that time not to cite deficiencies that were based on the prior, more stringent requirements.
>
> Citations in this report have been made to the former regulatory citations. If you wish to ascertain where the applicable provision lay in the final regulations, you can utilize the enclosed crosswalk that was published in the Final Rule at pages 3642-3650.
>
> This report should be considered purely advisory in nature. Until the new survey guidelines are published, formal compliance actions will only be taken on the basis of findings that have been individually reviewed and compared to the final regulations."

If you have questions or would like further clarification, please contact Judy Yost at 410-786-3407 or Virginia Wanamaker at 410-786-7304. We appreciate your ongoing dedication to effective administration of the CLIA program and your assistance during this interim period.

/s/
Steven A. Pelovitz

Attachment

three proposed alternative qualification pathways were as follows:

- On or after January 1, 2003, be certified and continue to be certified by a board approved by HHS.
- Before January 1, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least 2 years of laboratory training or experience, or both; and 2 years experience directing or supervising high complexity testing.
- Have at least 6 years of laboratory training or experience, or both, including 2 years of experience directing or supervising high complexity testing.

In this final rule, effective April 24, 2003, all laboratories must meet and follow the QC requirements. In addition, we are setting forth qualification requirements for an individual with a doctoral degree to serve as a director of a laboratory performing high complexity testing. Effective February 24, 2003, an individual with a doctoral degree may qualify to serve as a director of a laboratory that performs high complexity testing if he or she is certified and continues to be certified by a board approved by HHS; or before the effective date of this rule, has served or is serving as a director of a laboratory performing high complexity testing and has acquired at least 2 years of laboratory training or experience, or both, and 2 years of experience directing or supervising high complexity testing.

The qualification requirements for high complexity laboratory directors that are contained in this final rule will become effective February 24, 2003. To ensure a smooth transition to these new provisions, we will not be holding facilities out of compliance with the Board certified regulations of the former rule until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the regulations for laboratory directors.

In addition, we are addressing the comments received in response to the February 28, 1992 final rule with comment period concerning part 493 of title 42 of the Code of Federal Regulations (CFR), subparts I, J, K, M, and P; comments received in response to the date-extension rules for certain provisions of subparts K and M; and comments to the December 28, 2001 proposed rule regarding qualification requirements for directors of laboratories performing high complexity testing.

II. Highlights and Organization of Final Rule

This regulation contains revisions to part 493 of title 42 of the CFR. We have renamed, reorganized, and consolidated similar requirements into one section, deleted duplicate requirements, and reworded numerous requirements to maintain and/or clarify their original intent, making the revised regulation easier to read and understand. In addition to specific changes to subparts I, J, K, M, and P, applicable technical and conforming changes were also made to other subparts.

The organization of this regulation now reflects the flow of a patient specimen through the laboratory, that is, from receipt of the specimen with the test request through test performance and test result reporting. In addition, this final rule more accurately describes the testing requirements and laboratory assessment activities.

In this final rule, the former Subpart I—Proficiency Testing Programs for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests has been renamed Proficiency Testing Programs for Nonwaived Testing. In addition, in each specialty and subspecialty area of the subpart, we are restoring the requirement for the 80 percent agreement used by proficiency testing programs prior to the February 28, 1992 final rule with comment period.

The requirements formerly in Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests; Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests; and Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests, are consolidated and reorganized into a new Subpart J—Facility Administration for Nonwaived Testing, and Subpart K—Quality Systems for Nonwaived Testing.

As revised by this issuance, subpart J consolidates and clarifies the facility administration requirements for laboratories performing nonwaived testing. These include requirements for facility space, utilities and safety, transfusion services, and record and specimen retention. Also, subpart J now specifies that laboratories must comply with Federal, State, and local laboratory requirements. This will allow CMS to support a Federal, State, or local government that seeks to protect the public from actions it finds would be detrimental to public health. In addition, the requirements formerly at § 493.1111 (now at § 493.1242(c)) have been revised to allow CLIA-certified laboratories to refer specimens to laboratories operated under the Veterans Administration (VA), the Department of Defense (DOD), and CLIA-exempt laboratories within a State whose licensure program has been granted approval under subpart E.

Requirements pertaining to the total testing process (preanalytic, analytic, and postanalytic) are now in subpart K. Specifically, subpart K has been revised to eliminate the QC requirements formerly at § 493.1202 and provisions pertaining to the FDA review and approval of manufacturers' test system QC for CLIA purposes as specified at § 493.1203 in the February 28, 1992 final rule with comment period. Also, subpart K is now structured to correlate with the movement of a specimen through the laboratory from acquisition to examination or testing, and reporting of results. The requirements were not substantively changed to correspond to the testing process, but we did eliminate redundant requirements and revise others for clarification.

In addition, subpart K now incorporates the requirements formerly in Subpart P—Quality Assurance; Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests. These requirements are now located under the appropriate sections in subpart K, that is, General Laboratory Systems, Preanalytic Systems, Analytic Systems, and Postanalytic Systems. We listed the quality assurance (renamed quality assessment (QA) to more clearly reflect the activities performed) activities for each phase of testing. For example, QA requirements for preanalytic activities, such as monitoring the medical necessity and completeness of test request information solicited and obtained by the laboratory, now appear at the end of the preanalytic section of subpart K under § 493.1249. We believe that integrating the QA requirements into the various phases of the testing process enhances the understanding of the vital and important role QA plays in ensuring that quality services are provided by the laboratory throughout the entire testing process. To further emphasize and clarify the essential components of a comprehensive QA program, we are reiterating in each assessment section the laboratory's responsibility to: (1) Establish and follow written polices and procedures for an ongoing mechanism to monitor and assess each of its activities; (2) take corrective actions, as necessary, based on these assessments; (3) review the effectiveness of the assessments and corrective actions

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taken; (4) revise policies and procedures, as necessary, to prevent recurrences of problems; (5) discuss the assessment activities and findings with the appropriate staff; and (6) document all assessment activities. To ensure the clarity of this final rule, many of the QA requirements from the former subpart P had to be rewritten.

To conform with the names of the new subparts I, J, and K, the former Subpart M—Personnel for Moderate Complexity (Including the Subcategory) and High Complexity Testing has been renamed Personnel for Nonwaived Testing. In subpart M, we are finalizing the qualification requirements for directors of laboratories performing high complexity testing at § 493.1443(b)(3). In addition, we are revising § 493.1443(b)(3)(i) by removing the reference to specific boards approved by HHS. All HHS-approved boards are listed on the Internet at *http://cms.hhs.gov/clia/dirc/con.asp*. HHS-approved boards will also be listed in Appendix C of the State Operations Manual (CMS Pub. 7), subpart M. This change will allow greater flexibility to update the list of HHS-approved boards. Also, we are announcing two new HHS-approved boards; the National Registry for Clinical Chemistry at the doctoral level and the American Board of Forensic Toxicology.

To clarify these changes, we have provided a distribution table, which contains a detailed list of sections that have been removed or redesignated.

III. Distribution Table

The following crosswalk table enables the reader to easily locate where the requirements from the former rule have been relocated. It lists the former section titles along with the section titles as they appear in this final rule. In addition, the reorganized regulation now follows the path of patient specimens as they proceed through the clinical laboratory. This organizational structure was adopted at the recommendation of the Clinical Laboratory Improvement Advisory Committee to assist laboratories in better understanding the basic CLIA requirements.

TABLE.—CROSSWALK

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
Patient test management; moderate complexity (including the subcategory), or high complexity testing, or any combination of these tests:		
§ 493.1101—Introductory text	Specimen identification and integrity	§§ 493.1232;
	Preanalytic systems	493.1240;
	Postanalytic systems	493.1290
Procedures for specimen submission and handling:		
§ 493.1103(a)	Specimen identification and integrity	§§ 493.1232;
	Specimen submission, handling, and referral	493.1242(a)(1) through (a)(6);
	Procedure manual	493.1251(b)(1)
§ 493.1103(b)	Specimen submission, handling, and referral	§§ 493.1242(a)(8) and (d);
	Procedure manual	493.1251(b)(1)
§ 493.1103(c)	Removed	
Test requisition:		
§ 493.1105—Introductory text	Retention requirements	§§ 493.1105(a)(1);
	Test request	493.1241(a), (b), (c), and (d)
§ 493.1105(a)	Test request	§ 493.1241(c)(2)
§ 493.1105(b)	Test request	§ 493.1241(c)(1)
§ 493.1105(c)	Test request	§ 493.1241(c)(4)
§ 493.1105(d)	Test request	§ 493.1241(c)(6)
§ 493.1105(e)	Test request	§ 493.1241(c)(3) and (c)(7)
§ 493.1105(f)	Test request	§§ 493.1241(c)(3), (c)(5), and (c)(8)
	Specimen submission, handling, and referral	493.1242(a)(3)
Test records:		
§ 493.1107—Introductory text	Retention requirements	§§ 493.1105(a)(3);
	Specimen identification and integrity	493.1232;
	Test records	493.1283(a)(4) and (b)
§ 493.1107(a)	Test records	§ 493.1283(a)(1)
§ 493.1107(b)	Specimen submission, handling, and referral	§§ 493.1242(b);
	Test records	493.1283(a)(2)
§ 493.1107(c)	Test records	§ 493.1283(a)(3)
§ 493.1107(d)	Test records	§ 493.1283(a)(4)
Test report:		
§ 493.1109—Introductory text	Retention requirements	§§ 493.1105(a)(3)(ii), (a)(6)(i), (a)(6)(ii) and (b);
	Postanalytic systems	493.1290;
	Test report	493.1291(b), (c)(3), and (f)
§ 493.1109(a)	Confidentiality of patient information	§§ 493.1231;
	Postanalytic systems	493.1290;
	Test report	493.1291(a) and (c)(3)
§ 493.1109(b)	Test report	§§ 493.1291(c)(2), (c)(4), and (c)(6)
§ 493.1109(c)	Test report	§ 493.1291(c)(7)
§ 493.1109(d)	Test report	§ 493.1291(d)
§ 493.1109(e)	Test report	§ 493.1291(f)
§ 493.1109(f)	Procedure manual	§§ 493.1251(b)(13);
	Test report	493.1291(g)

TABLE.—CROSSWALK—Continued

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
§493.1109(g)	Test report	§493.1291(e)
§493.1109(h)	Test report	§493.1291(j)
Referral of specimens:		
§493.1111—Introductory text	Specimen submission, handling, and referral	§493.1242(c)
§493.1111(a)	Test report	§493.1291(i)(1)
§493.1111(b)	Test report	§493.1291(i)(2)
§493.1111(c)	Test report	§493.1291(i)(3)
General quality control; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests:		
§493.1201(a)	Removed	
§493.1201(a)(1)	Removed	
§493.1201(a)(2)	Facility Administration	§§493.1100
	General laboratory systems	493.1230
	Preanalytic systems	493.1240
	Analytic systems	493.1250
	Control Procedures	493.1256(d)
	Postanalytic systems	493.1290
§493.1201(b)	Analytic systems	§§493.1250;
	Procedure manual	493.1251(b)(7)
Moderate or high complexity testing, or both, Effective from September 1, 1992 to December 13, 2000:		
§493.1202(a)	Facility administration	§§493.1100;
	Subpart K—Quality systems for nonwaived testing.	493.1201 through 493.1227
§493.1202(b)	Facility administration	§§493.1100;
	Subpart K—Quality systems for nonwaived testing.	493.1201 through 493.1227
§493.1202(c)	Facility administration	§§493.1100;
	Subpart K—Quality systems for nonwaived testing.	493.1201 through 493.1227
§493.1202(c)(1)	Test systems, equipment, instruments, reagents, materials, and supplies.	§§493.1252(a);
	Maintenance and function checks	493.1254(a)(1) and (a)(2)
	Control procedures	493.1256(d)(2)
§493.1202(c)(2)	Procedure manual	§493.1251
§493.1202(c)(3)	Calibration and calibration verification procedures.	§493.1255
§493.1202(c)(4)	Control procedures	§493.1256
§493.1202(c)(5)	Control procedures	§493.1256(d)(1)
§493.1202(c)(6)	Corrective actions	§493.1282
§493.1202(c)(7)	Retention requirements	§493.1105(a)(3)
Moderate or high complexity testing, or both effective beginning 12/31/00:		
§493.1203—Introductory text	Removed	
§493.1203(a)	Removed	
§493.1203(b)	Removed	
Facilities:		
§493.1204—Introductory text	Facilities	§493.1101(a)
§493.1204(a)	Facilities	§§493.1101(a)(1) and (a)(2)
§493.1204(b)	Facilities	§493.1101(d)
Test methods, equipment, instrumentation, reagents, materials, and supplies:		
§493.1205—Introductory text	Facility Test systems, equipment, instruments, reagents, materials, and supplies.	§§493.1101(b); 493.1252
§493.1205(a)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(a)
§493.1205(b)	Facilities	§493.1101(b)
§493.1205(c)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(b)
§493.1205(c)(1)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(b)
§493.1205(c)(1)(i)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(b)(1)
§493.1205(c)(1)(ii)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(b)(2)
§493.1205(c)(1)(iii)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(b)(3)

TABLE.—CROSSWALK—Continued

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
§493.1205(c)(1)(iv)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(b)(4)
§493.1205(c)(2)	Corrective actions	§493.1282(b)(3)
§493.1205(d)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(c)
§493.1205(d)(1)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(c)(1)
§493.1205(d)(2)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(c)(2)
§493.1205(d)(3)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(c)(3)
§493.1205(d)(4)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(c)(4)
§493.1205(e)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(d)
§493.1205(e)(1)	Test systems, equipment, instruments, reagents, materials, and supplies.	§§493.1252(d);
	Immunohematology	493.1271(b)
§493.1205(e)(2)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(e)
Procedure manual:		
§493.1211(a)	Procedure manual	§493.1251(a)
§493.1211(b)	Procedure manual	§493.1251(b)
§493.1211(b)(1)	Procedure manual	§493.1251(b)(1)
§493.1211(b)(2)	Procedure manual	§493.1251(b)(2)
§493.1211(b)(3)	Procedure manual	§§493.1251(b)(3);
	Histocompatibility	493.1278(d)(7)
§493.1211(b)(4)	Procedure manual	§493.1251(b)(4)
§493.1211(b)(5)	Procedure manual	§493.1251(b)(5)
§493.1211(b)(6)	Procedure manual	§493.1251(b)(6)
§493.1211(b)(7)	Procedure manual	§493.1251(b)(7)
§493.1211(b)(8)	Procedure manual	§493.1251(b)(8)
§493.1211(b)(9)	Procedure manual	§493.1251(b)(9)
§493.1211(b)(10)	Procedure manual	§493.1251(b)(10)
§493.1211(b)(11)	Procedure manual	§493.1251(b)(11)
§493.1211(b)(12)	Procedure manual	§493.1251(b)(12)
§493.1211(b)(13)	Specimen submission, handling, and referral	§§493.1242(a)(4);
	Procedure manual	493.1251(b)(1)
§493.1211(b)(14)	Procedure manual	§493.1251(b)(13)
§493.1211(b)(15)	Procedure manual	§493.1251(b)(14)
§493.1211(b)(16)	Procedure manual	§493.1251(b)(1)
§493.1211(c)	Procedure manual	§493.1251(c)
§493.1211(d)	Procedure manual	§493.1251(d)
§493.1211(e)	Procedure manual	§493.1251(d)
§493.1211(f)	Procedure manual	§493.1251(d)
§493.1211(g)	Retention requirements	§§493.1105(a)(2);
	Procedure manual	493.1251(e)
Establishment and verification of method performance specifications:		
§493.1213—Introductory text	Removed	
§493.1213(a)	Establishment and verification of performance specifications.	§493.1253(a)
§493.1213(b)(1)	Removed	
§493.1213(b)(2)	Establishment and verification of performance specifications.	§§493.1253(b)(1) and (2)
§493.1213(b)(2)(i)	Establishment and verification of performance specifications.	§§493.1253(b)(1) and (b)(2)
§493.1213(b)(2)(i)(A)	Establishment and verification of performance specifications.	§§493.1253(b)(1)(i)(A) and (b)(2)(i)
§493.1213(b)(2)(i)(B)	Establishment and verification of performance specifications.	§§493.1253(b)(1)(i)(B) and (b)(2)(ii)
§493.1213(b)(2)(i)(C)	Establishment and verification of performance specifications.	§493.1253(b)(2)(iii)
§493.1213(b)(2)(i)(D)	Establishment and verification of performance specifications.	§493.1253(b)(2)(iv)
§493.1213(b)(2)(i)(E)	Establishment and verification of performance specifications.	§§493.1253(b)(1)(i)(C) and (b)(2)(v)
§493.1213(b)(2)(i)(F)	Establishment and verification of performance specifications.	§§493.1253(b)(1)(ii) and (b)(2)(vi)
§493.1213(b)(2)(i)(G)	Establishment and verification of performance specifications.	§493.1253(b)(2)(vii)

TABLE.—CROSSWALK—Continued

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
§493.1213(b)(2)(ii)	Establishment and verification of performance specifications.	§493.1253(b)(3)
§493.1213(c)	Establishment and verification of performance specifications.	§493.1253(c)
Equipment maintenance and function checks:		
§493.1215—Introductory text	Removed	
§493.1215(a)—Title only	Removed	
§493.1215(a)(1)	Removed	
§493.1215(a)(1)(i)	Removed	
§493.1215(a)(1)(ii)	Removed	
§493.1215(a)(2)—Lead-in only	Removed	
§493.1215(a)(2)(i)	Maintenance and function checks	§493.1254(b)(1)(i)
§493.1215(a)(2)(ii)	Maintenance and function checks	§493.1254(b)(1)(ii)
§493.1215(a)(2)(iii)	Maintenance and function checks	§493.1254(b)(1)(ii)
§493.1215(b)	Removed	
§493.1215(b)(1)	Removed	
§493.1215(b)(1)(i)	Removed	
§493.1215(b)(1)(ii)	Removed	
§493.1215(b)(2)	Removed	
§493.1215(b)(2)(i)	Maintenance and function checks	§493.1254(b)(2)(i)
§493.1215(b)(2)(ii)	Maintenance and function checks	§493.1254(b)(2)(ii)
§493.1215(b)(2)(iii)	Maintenance and function checks	§493.1254(b)(2)(ii)
Calibration and calibration verification procedures:		
§493.1217—Introductory text	General Provisions—Definitions Calibration and calibration verification procedures.	§§493.2; 493.1255
§493.1217(a)	Removed	
§493.1217(b)—Lead-in only	Removed	
§493.1217(b)(1)	Calibration and calibration verification procedures.	§493.1255(a)
§493.1217(b)(1)(i)	Calibration and calibration verification procedures.	§493.1255(a)(1)
§493.1217(b)(1)(ii)	Calibration and calibration verification procedures.	§493.1255(a)(2)
§493.1217(b)(1)(ii)(A)	Calibration and calibration verification procedures.	§493.1255(a)(2)(ii)
§493.1217(b)(1)(ii)(B)	Calibration and calibration verification procedures.	§493.1255(a)(2)(i)
§493.1217(b)(1)(iii)	Calibration and calibration verification procedures.	§493.1255(a)(3)
§493.1217(b)(2)	Calibration and calibration verification procedures.	§493.1255(b)
§493.1217(b)(2)(i)	Calibration and calibration verification procedures.	§493.1255(b)(1)
§493.1217(b)(2)(ii)	Calibration and calibration verification procedures.	§493.1255(b)(2)
§493.1217(b)(2)(ii)(A)	Calibration and calibration verification procedures.	§493.1255(b)(2)(i)
§493.1217(b)(2)(ii)(B)	Removed	
§493.1217(b)(2)(ii)(B)(1)	Removed	
§493.1217(b)(2)(ii)(B)(2)	Calibration and calibration verification procedures.	§493.1255(b)(2)(ii)
§493.1217(b)(2)(ii)(C)	Calibration and calibration verification procedures.	§493.1255(b)(3)
§493.1217(b)(2)(ii)(C)(1)	Calibration and calibration verification procedures.	§493.1255(b)(3)(i)
§493.1217(b)(2)(ii)(C)(2)	Calibration and calibration verification procedures.	§493.1255(b)(3)(ii)
§493.1217(b)(2)(ii)(C)(3)	Calibration and calibration verification procedures.	§493.1255(b)(3)(iii)
§493.1217(b)(2)(ii)(C)(4)	Calibration and calibration verification procedures.	§493.1255(b)(3)(iv)
§493.1217(b)(3)	Calibration and calibration verification procedures.	§493.1255(a) and (b)
Control procedures:		
§493.1218	Control procedures	§493.1256(a)
§493.1218(a)	Removed	
§493.1218(b)—Partial removed	Control procedures	§493.1256(b), (c)(1), and (c)(2)
§493.1218(b)(1)	Control procedures	§493.1256(d)(3)(ii)
§493.1218(b)(2)	Control procedures	§493.1256(d)(3)(i)
§493.1218(b)(3)	Control procedures	§493.1256(d)(5)

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Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
§493.1218(b)(3)(i)	Control procedures	§493.1256(d)(5)
§493.1218(b)(3)(ii)	Control procedures	§493.1256(d)(5)
§493.1218(b)(4)	Control procedures	§§493.1256(d)(3)(ii) and (d)(3)(iv)
§493.1218(b)(5)	Control procedures	§493.1256(h)
§493.1218(c)	Control procedures	§493.1256(d)(8)
§493.1218(d)	Control procedures	§493.1256(d)(10)(i)
§493.1218(d)(1)	Control procedures	§493.1256(d)(10)(ii)
§493.1218(d)(2)	Control procedures	§493.1256(d)(10)(iii)
§493.1218(e)	Control procedures	§493.1256(f)
§493.1218(f)	Control procedures	§493.1256(e)
§493.1218(f)(1)	Control procedures	§493.1256(e)(1)
§493.1218(f)(2)	Control procedures	§493.1256(e)(2)
§493.1218(f)(3)	Control procedures	§§493.1256(e)(3);
	Histopathology	493.1273(a)
§493.1218(f)(4)	Control procedures	§493.1256(e)(4)(5)
Remedial actions:		
§493.1219—Introductory text	Corrective actions	§493.1282(a) and (b)
§493.1219(a)	Corrective actions	§493.1282(b)(1)
§493.1219(a)(1)	Corrective actions	§493.1282(b)(1)(i)
§493.1219(a)(2)	Corrective actions	§493.1282(b)(1)(ii)
§493.1219(a)(3)	Corrective actions	§493.1282(b)(1)(iii)
§493.1219(b)	Corrective actions	§493.1282(b)(2)
§493.1219(c)	Test report	§493.1291(h)
§493.1219(d)	Test report	§493.1291(k)
§493.1219(d)(1)	Test report	§493.1291(k)(1)
§493.1219(d)(2)	Test report	§493.1291(k)(2)
§493.1219(d)(3)	Retention requirements	§§493.1105(a)(6);
	Test report	493.1291(k)(3)
Quality control records:		
§493.1221	Retention requirements	§493.1101(e); 493.1105(a)(3)(i) through (a)(3)(ii);
	Test systems, equipment, instruments, reagents, material, and supplies performance.	493.1252(b);
	Establishment and verification of performance	493.1253(c);
	Maintenance and function checks	493.1254(a), (b)(1)(ii), and (b)(2)(ii);
	Calibration and calibration verification procedures.	493.1255(a) and (b);
	Control procedures	493.1256(g);
	Bacteriology	493.1261(c);
	Mycobacteriology	493.1262(c);
	Mycology	493.1263(c);
	Parasitology	493.1264(d);
	Virology	493.1265(b);
	Routine chemistry	493.1267(d);
	Hematology	493.1269(d);
	Immunohematology	493.1271(f);
	Histopathology	493.1273(f);
	Cytology	493.1274(h);
	Clinical Cytogenetics	493.1276(e);
	Histocompatibility	493.1278(g)
Quality control-specialties and subspecialties for tests of moderate or high complexity; or both:		
§493.1223	Control Procedures	§§493.1256(a), (b), (c), (d)(1), and (2);
Microbiology:		
§493.1225	Removed	
Bacteriology:		
§493.1227—Introductory text	Bacteriology	§493.1201
§493.1227(a)—Partially removed	Bacteriology	§493.1261(a)
Bacteriology:		
§493.1227(a)(1)—Partially removed	Control procedures	§§493.1256(d)(3)(ii), (d)(3)(iv), and (e)(1);
	Bacteriology	493.1261(a)(1)
§493.1227(a)(2)	Control procedures	§§493.1256(e)(1) and (e)(2);
	Bacteriology	493.1261(a)(2)
§493.1227(a)(3)	Bacteriology	§493.1261(a)(3)
§493.1227(b)	Control procedures	§493.1256(e)(1)
§493.1227(c)	Bacteriology	§493.1261(b)
§493.1227(c)(1)	Bacteriology	§493.1261(b)(2)
§493.1227(c)(2)	Bacteriology	§493.1261(b)(1)
Mycobacteriology:		
§493.1229—Introductory text	Mycobacteriology	§493.1202

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Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
§493.1229(a)	Mycobacteriology	§493.1262(a)
§493.1229(b)	Control procedures	§493.1256(e)(3)
§493.1229(c)	Control procedures	§§493.1256(e)(2);
	Mycobacteriology	493.1262(a)
§493.1229(d)	Mycobacteriology	§§493.1262(b)(1) through (b)(3)
Mycology:		
§493.1231—Introductory text	Mycology	§493.1203
§493.1231(a)	Control procedures	§§493.1256(e)(1) and (e)(4)
§§493.1231(b)	Control procedures	§493.1256(e)(1)
§493.1231(c)	Control procedures	§493.1256(e)(2)
§493.1231(d)	Mycology	§§493.1263(b)(1) through (b)(3)
Parasitology:		
§493.1233—Introductory text	Parasitology	§493.1204
§493.1233(a)	Parasitology	§493.1264(a)
§493.1233(b)	Parasitology	§493.1264(b)
§493.1233(c)	Parasitology	§493.1264(c)
Virology:		
§493.1235—Introductory text	Virology	§493.1205
§493.1235(a)	Facilities	§§493.1101(b);
	Test systems, equipment, instruments, reagents, material, and supplies.	493.1252(a)
§493.1235(b)	Virology	§§493.1265(b);
	Test records	493.1283(a)(4)
§493.1235(c)	Virology	§493.1265(a)
Diagnostic immunology:		
§493.1237	Removed	
Syphilis serology:		
§493.1239—Introductory text	Syphilis serology	§493.1207
§493.1239(a)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(a)
§493.1239(b)	Control procedures	§493.1256(d)(3)(iii)
§493.1239(c)	Control procedures	§§493.1256(a) and (d)(3)(ii);
§493.1239(d)	Control procedures	§493.1256(f)
§493.1239(e)	Immunohematology	§493.1271(b)
General immunology:		
§493.1241	General immunology	§493.1208
§493.1241(a)	Control procedures	§493.1256(d)(3)(iii)
§493.1241(b)	Control procedures	§493.1256(a)
§493.1241(c)	Control procedures	§493.1256(f)
§493.1241(d)—Lead-in only	Removed	
§493.1241(d)(1)	Immunohematology	§493.1271(b)
§493.1241(d)(2)	Immunohematology	§493.1271(b)
Chemistry:		
§493.1243	Removed	
Routine chemistry:		
§493.1245—Introductory text	Routine chemistry	§§493.1210; 493.1267
§493.1245(a)	Routine chemistry	§493.1267(a)
§493.1245(b)	Routine chemistry	§493.1267(b)
§493.1245(c)	Routine chemistry	§493.1267(b)
§493.1245(d)	Routine chemistry	§493.1267(c)
Endocrinology:		
§493.1247	Endocrinology	§493.1212
Toxicology:		
§493.1249—Introductory text	Toxicology	§§493.1213;
	Control procedures	493.1256(d)(4)
§493.1249(a)	Control procedures	§493.1256(d)(4)(i)
§493.1249(b)	Control procedures	§493.1256(d)(4)(ii)
Urinalysis:		
§493.1251—Introductory text only	Urinalysis	§493.1211
Hematology:		
§493.1253	Hematology	§493.1215
§493.1253(a)	Hematology	§§493.1269(a)(1) and (a)(2)
§493.1253(b)	Control procedures	§493.1256(d)
§493.1253(c)	Hematology	§493.1269(b)
§493.1253(d)	Hematology	§493.1269(c)
§493.1253(d)(1)	Hematology	§493.1269(c)(1)
§493.1253(d)(2)	Hematology	§493.1269(c)(2)
Pathology:		
§493.1255	Removed	
Cytology:		
§493.1257—Introductory text	Cytology	§493.1221

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§493.1257(a)	Cytology	§493.1274(b)
§493.1257(a)(1)	Cytology	§493.1274(b)(1)
§493.1257(a)(2)	Cytology	§493.1274(b)(2)
§493.1257(a)(3)	Cytology	§493.1274(b)(3)
§493.1257(a)(4)	Cytology	§493.1274(e)(4)
§493.1257(a)(5)	Cytology	§493.1274(a)
§493.1257(b)	Cytology	§493.1274(d)
§493.1257(b)(1)	Cytology	§§493.1274(d)(2) and (d)(2)(iv)
§493.1257(b)(2)	Cytology	§493.1274(d)(2)(iii)
§493.1257(b)(3)	Cytology	§493.1274(g)
§493.1257(b)(3)(i)	Cytology	§493.1274(d)(2)(i)
§493.1257(b)(3)(ii)	Cytology	§493.1274(d)(2)(ii)
§493.1257(c)	Cytology	§493.1274(e)(1)
§493.1257(c)(1)	Cytology	§§493.1274(e)(1)(i) through (e)(1)(v), and (e)(2)
§493.1257(c)(2)	Cytology	§493.1274(e)(3)
§493.1257(c)(3)	Cytology	§493.1274(d)(1)(i)(B)
§493.1257(c)(4)	Cytology	§493.1274(d)(1)
§493.1257(c)(4)(i)	Cytology	§§493.1274(d)(1)(i) and (d)(4)
§493.1257(c)(4)(ii)	Cytology	§493.1274(d)(1)(ii)
§493.1257(d)	Cytology	§493.1274(c)
§493.1257(d)(1)	Cytology	§493.1274(c)(1)
§493.1257(d)(1)(i)	Cytology	§493.1274(c)(1)(i)
§493.1257(d)(1)(ii)	Cytology	§493.1274(c)(4)
§493.1257(d)(1)(iii)	Cytology	§493.1274(c)(1)(ii)
§493.1257(d)(2)	Cytology	§493.1274(c)(2)
§493.1257(d)(3)	Cytology	§493.1274(c)(3)
§493.1257(d)(4)	Cytology	§§493.1274(c)(5)(i) through (c)(5)(vi)
§493.1257(d)(5)	Cytology	§493.1274(c)(6)
§493.1257(e)—Lead-in only	Removed	
§493.1257(e)(1)	Cytology	§493.1274(e)(4)
§493.1257(e)(2)	Cytology	§493.1274(e)(5)
§493.1257(f)	Cytology	§493.1274(e)(6)
§493.1257(g)	Retention requirements, Cytology	§§493.1105(a)(7)(i)(A); 493.1274(f)(2) through (f)(4)
Histopathology:		
§493.1259—Introductory text	Histopathology	§493.1219
§493.1259(a)	Histopathology	§493.1273(a)
§493.1259(b)	Retention requirements, Histopathology	§§493.1105(a)(7)(i)(B) and (a)(7)(ii); 493.1273(b)
§493.1259(c)	Facilities; Retention requirements, Histopathology.	§§493.1101(e); 493.1105(a)(7)(iii); 493.1273(b)
§493.1259(d)	Histopathology	§493.1273(d)
§493.1259(e)	Histopathology	§493.1273(e)
Oral pathology:		
§493.1261	Oral pathology	§493.1220
Radiobioassay:		
§493.1263	Radiobioassay	§493.1226
Histocompatibility:		
§493.1265—Introductory text	Histocompatibility	§493.1227
§493.1265(a)	Histocompatibility	§493.1278(f)
§493.1265(a)(1)	Histocompatibility	§493.1278(e)(2)
§493.1265(a)(1)(i)	Histocompatibility	§493.1278(e)(2)(i)
§493.1265(a)(1)(ii)	Histocompatibility; Procedure manual	§§493.1278(e)(1); 493.1251(b)(3)
§493.1265(a)(1)(iii)	Histocompatibility	§493.1278(e)(2)(ii)
§493.1265(a)(1)(iv)	Procedure manual	§§493.1251(b)(3) and (b)(13)
§493.1265(a)(2)	Histocompatibility	§493.1278(f)
§493.1265(a)(2)(i)	Histocompatibility	§493.1278(f)(2)
§493.1265(a)(2)(ii)	Histocompatibility	§§493.1278(d)(4) through (d)(5)
§493.1265(a)(3)—Lead-in only	Removed	
§493.1265(a)(3)(i)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(b);
	Specimen submission, handling, and referral	§493.1242(a)(4)
§493.1265(a)(3)(ii)	Histocompatibility	§493.1278(a)(1)
§493.1265(a)(3)(iii)—Partially removed	Specimen identification and integrity, Histocompatibility; Test records.	§§493.1232; 493.1278(a)(2) 493.1283(a)(1)
§493.1265(a)(4)	Histocompatibility	§493.1278(a)(3)
§493.1265(a)(5)	Test systems, equipment, instruments, reagents, materials, and supplies.	§§493.1252(c)(1) through (c)(4)
§493.1265(a)(6)	Histocompatibility	§493.1278(b)
§493.1265(a)(6)(i)	Histocompatibility	§493.1278(b)(2)

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§493.1265(a)(6)(ii)	Histocompatibility	§493.1278(b)(3)
§493.1265(a)(6)(iii)	Histocompatibility	§493.1278(b)(5)(v)
§493.1265(a)(7)	Histocompatibility	§493.1278(b)(5)
§493.1265(a)(7)(i)	Histocompatibility	§493.1278(b)(5)(i)
§493.1265(a)(7)(ii)	Histocompatibility	§493.1278(b)(5)(ii)
§493.1265(a)(7)(iii)	Histocompatibility	§493.1278(b)(5)(iv)
§493.1265(a)(7)(iv)	Histocompatibility	§493.1278(b)(5)(iii)
§493.1265(a)(8)	Histocompatibility	§493.1278(d)
§493.1265(a)(8)(i)	Histocompatibility	§493.1278(d)(5)
§493.1265(a)(8)(i)(A)	Histocompatibility	§493.1278(d)(5)
§493.1265(a)(8)(i)(B)	Histocompatibility	§493.1278(d)(5)
§493.1265(a)(8)(ii)	Histocompatibility	§493.1278(d)(3)
§493.1265(a)(8)(ii)(A)	Histocompatibility	§493.1278(d)(3)
§493.1265(a)(8)(ii)(B)	Test systems, equipment, instruments, reagents, materials, and supplies.	§493.1252(b)
§493.1265(a)(9)—Lead-in only	Removed	
§493.1265(a)(9)(i)	Histocompatibility	§§493.1278(b)(6) and (d)(6)
§493.1265(a)(9)(i)(A)	Histocompatibility	§§493.1278(b)(6)(i) and (d)(6)(i)
§493.1265(a)(9)(i)(B)	Histocompatibility	§§493.1278(b)(6)(ii) and (d)(6)(ii)
§493.1265(a)(9)(i)(C)	Histocompatibility	§493.1278(b)(6)(iii)
§493.1265(a)(9)(ii)	Histocompatibility	§§493.1278(c) and (e)(3)
§493.1265(a)(10)	Histocompatibility	§§493.1278(a) and (f)
§493.1265(a)(11)	Immunohematology	§493.1271
§493.1265(a)(12)	Histocompatibility	§493.1278(a)(4)
§493.1265(a)(13)	Removed	
§493.1265(a)(14)	Histocompatibility	§493.1278(a)(5)
§493.1265(b)	Histocompatibility	§493.1278(f)
§493.1265(b)(1)	Histocompatibility	§493.1278(f)(1)
§493.1265(b)(2)	Histocompatibility	§493.1278(f)(1)
§493.1265(b)(3)	Histocompatibility	§493.1278(f)(3)
§493.1265(c)	Histocompatibility	§§493.1278(a) through (c)
§493.1265(d)	Immunohematology	§493.1271(b)
Clinical cytogenetics:		
§493.1267—Introductory text	Clinical cytogenetics	§493.1225
§493.1267(a)	Cytogenetics	§493.1276(c)
§493.1267(b)	Cytogenetics	§§493.1276(b)(1) through (b)(3)
§493.1267(c)	Cytogenetics	§493.1276(a)
§493.1267(d)	Cytogenetics	§493.1276(d)
Immunohematology:		
§493.1269—Introductory text	Immunohematology	§493.1217
§493.1269(a)	Immunohematology	§493.1271(a)(1)
§493.1269(b)	Immunohematology	§493.1271(a)(2)
§493.1269(c)	Immunohematology	§493.1271(a)(3)
§493.1269(d)	Immunohematology	§493.1271(a)
Transfusion services and bloodbanking:		
§493.1271—Partially removed	Requirements for transfusion services and Subpart M.	§493.1103; §493.1449(b) and (q)
Immunohematological collection, processing, dating periods, labeling and distribution of blood and blood products:		
§493.1273—Introductory text	Immunohematology	§493.1271(b)
§493.1273(a)	Immunohematology	§493.1271(b)
§493.1273(b)	Immunohematology	§493.1271(b)
§493.1273(c)	Immunohematology	§493.1271(b)
§493.1273(d)	Requirements for transfusion services	§493.1103(c)(2)
Blood and blood products storage facilities:		
§493.1275(a)	Immunohematology	§493.1271(c)
§493.1275(a)(1)	Immunohematology	§493.1271(c)(1)
§493.1275(a)(2)	Immunohematology	§493.1271(c)(2)
§493.1275(b)	Requirements for transfusion services	§493.1103(c)(1)
Arrangement for services:		
§493.1277	Requirements for transfusion services	§493.1103(a)
Provision of testing:		
§493.1279—Partially removed	Requirements for transfusion services	§§493.1103(b)
Retention of samples of transfused blood:		
§493.1283	Immunohematology	§493.1271(d)
Investigation of transfusion reactions:		
§493.1285	Requirements for transfusion services; Immunohematology.	§§493.1103(d); 493.1271(e)(1) and (e)(2)

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Quality assurance for Moderate Complexity (including the Subcategory) or High Complexity Testing, or Any Combination of These Tests:		
§493.1701	Introduction; General laboratory systems; General laboratory systems assessment; Preanalytic Systems; Test request; Preanalytic systems assessment; Analytic Systems; Analytic systems assessment; Postanalytic Systems; Postanalytic systems assessment.	§§493.1200; 493.1230; 493.1239; 493.1240; 493.1241(e); 493.1249; 493.1250; 493.1289; 493.1290; 493.1299
Patient test management assessment:		
§493.1703—Introductory text	General laboratory systems; General laboratory systems assessment; Preanalytic Systems; Preanalytic systems assessment; Postanalytic Systems; Postanalytic systems assessment.	§§493.1230; 493.1239(a) and (b); 493.1240; 493.1249(a) and (b); 493.1290; 493.1299(a) and (b)
§493.1703(a)	Preanalytic systems assessment	§§493.1249(a) and (b)
§493.1703(b)	Preanalytic systems assessment	§§493.1249(a) and (b)
§493.1703(c)	Preanalytic systems assessment	§§493.1249(a) and (b)
§493.1703(d)	Postanalytic systems assessment	§§493.1299(a) and (b)
§493.1703(e)	Test Report; Postanalytic systems assessment.	§§493.1291(a), (g), and (h); 493.1299(a) and (b)
§493.1703(f)	Facilities; Postanalytic systems assessment	§§493.1101(e) 493.1299(a) and (b)
Quality control assessment:		
§493.1705—Introductory text	Analytic Systems; Analytic system assessment.	§§493.1250; 493.1289(a) and (b)
§493.1705(a)	Analytic system assessment	§§493.1289(a) and (b)
§493.1705(b)	Analytic system assessment	§§493.1289(a) and (b)
§493.1705(c)	Analytic system assessment; Postanalytic systems assessment.	§§493.1289(a) and (b); 493.1299(a) and (b)
Proficiency testing assessment:		
§493.1707	General laboratory systems; Evaluation of proficiency testing; General laboratory systems assessment.	§§493.1230; 493.1236(a)(1); 493.1239(a) and (b)
Comparison of test results:		
§493.1709		
§493.1709(a)	Comparison of test results	§493.1281(a)
§493.1709(b)	Evaluation of proficiency testing	§493.1236(c)(1)
Relationship of patient information to patient test results:		
§493.1711—Introductory text	Comparison of test results; Analytic systems assessment.	§§493.1281(b); 493.1289(a) and (b)
§493.1711(a)	Comparison of test results	§493.1281(b)(1)
§493.1711(b)	Comparison of test results	§493.1281(b)(2)
§493.1711(c)	Comparison of test results	§493.1281(b)(3)
§493.1711(d)	Comparison of test results	§493.1281(b)(4)
§493.1711(e)	Comparison of test results; Analytic systems assessment.	§§493.1281(b)(5); 493.1289(a) and (b)
Personnel assessment:		
§493.1713	Personnel competency assessment policies; General laboratory systems assessment.	§§493.1235; 493.1239(a) and (b)
Communications:		
§493.1715	Communications; General laboratory systems assessment.	§§493.1234; 493.1239(a) and (b)
Complaint investigations:		
§493.1717	Complaint investigations; General laboratory systems assessment.	§§493.1233; 493.1239(a) and (b)
Quality assurance review with staff:		
§493.1719	General laboratory systems assessment; Preanalytic systems assessment; Analytic systems assessment; Postanalytic systems assessment.	§§493.1239(b) and (c); 493.1249(b) and (c); 493.1289(b) and (c); 493.1299(b) and (c)
Quality assurance records:		
§493.1721	Retention requirements; General laboratory systems assessment; Analytic systems assessment.	§§493.1105(a)(5) and (b); 493.1239(c); 493.1249(c); 493.1289(c); 493.1299(c)