

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; 493.1240; 493.1290
	Preanalytic systems .....	
	Postanalytic systems .....	
Procedures for specimen submission and handling:		
§ 493.1103(a) .....	Specimen identification and integrity .....	§§ 493.1232; 493.1242(a)(1) through (a)(6); 493.1251(b)(1)
	Specimen submission, handling, and referral	
§ 493.1103(b) .....	Procedure manual .....	§§ 493.1242(a)(8) and (d); 493.1251(b)(1)
	Specimen submission, handling, and referral	
§ 493.1103(c) .....	Procedure manual .....	
	Removed	
Test requisition:		
§ 493.1105—Introductory text .....	Retention requirements .....	§§ 493.1105(a)(1); 493.1241(a), (b), (c), and (d)
	Test request .....	§ 493.1241(c)(2)
§ 493.1105(a) .....	Test request .....	§ 493.1241(c)(1)
§ 493.1105(b) .....	Test request .....	§ 493.1241(c)(4)
§ 493.1105(c) .....	Test request .....	§ 493.1241(c)(6)
§ 493.1105(d) .....	Test request .....	§ 493.1241(c)(3) and (c)(7)
§ 493.1105(e) .....	Test request .....	§§ 493.1241(c)(3), (c)(5), and (c)(8)
§ 493.1105(f) .....	Test request .....	493.1242(a)(3)
	Specimen submission, handling, and referral	
Test records:		
§ 493.1107—Introductory text .....	Retention requirements .....	§§ 493.1105(a)(3); 493.1232;
	Specimen identification and integrity .....	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); 493.1283(a)(2)
	Test records .....	§ 493.1283(a)(3)
§ 493.1107(c) .....	Test records .....	§ 493.1283(a)(4)
§ 493.1107(d) .....	Test records .....	
Test report:		
§ 493.1109—Introductory text .....	Retention requirements .....	§§ 493.1105(a)(3)(ii), (a)(6)(i), (a)(6)(ii) and (b); 493.1290;
	Postanalytic systems .....	493.1291(b), (c)(3), and (f)
§ 493.1109(a) .....	Test report .....	§§ 493.1231; 493.1290;
	Confidentiality of patient information .....	493.1291(a) and (c)(3)
	Postanalytic systems .....	§§ 493.1291(c)(2), (c)(4), and (c)(6)
§ 493.1109(b) .....	Test report .....	§ 493.1291(c)(7)
§ 493.1109(c) .....	Test report .....	§ 493.1291(d)
§ 493.1109(d) .....	Test report .....	§ 493.1291(f)
§ 493.1109(e) .....	Test report .....	§§ 493.1251(b)(13); 493.1291(g)
§ 493.1109(f) .....	Procedure manual .....	
	Test report .....	