

## NOTICE PUBLICATION/REGULATIONS SUBMISSION

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2016-0923-01	REGULATORY ACTION NUMBER	EMERGENCY NUMBER
For use by Office of Administrative Law (OAL) only			
RECEIVED DATE		PUBLICATION DATE	
SEP 23 '16		OCT 07 '16	
Office of Administrative Law			
NOTICE		REGULATIONS	
AGENCY WITH RULEMAKING AUTHORITY CALIFORNIA DEPARTMENT OF PUBLIC HEALTH			AGENCY FILE NUMBER (If any) DPH-15-013

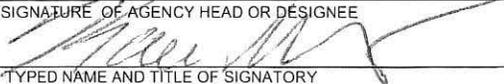
**A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)**

1. SUBJECT OF NOTICE 2003 CLIA CROSSWALK	TITLE(S) N/A	FIRST SECTION AFFECTED N/A	2. REQUESTED PUBLICATION DATE JULY 8, 2016 LC 10/7/16
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed <input checked="" type="checkbox"/> Regulatory Action	4. AGENCY CONTACT PERSON DAWN BASCIANO	TELEPHONE NUMBER 916-440-7367	FAX NUMBER (Optional) 916-440-5747
<b>OAL USE ONLY</b> <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER	PUBLICATION DATE

**B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)**

1a. SUBJECT OF REGULATION(S) 2003 CLIA CROSSWALK	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	
<b>SECTION(S) AFFECTED</b> (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT N/A
	AMEND N/A
TITLE(S) N/A	REPEAL N/A
3. TYPE OF FILING	
<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)
	<input type="checkbox"/> File & Print
	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
	<input checked="" type="checkbox"/> Other (Specify) <u>APA EXEMPT - B &amp; P CODE 1208(c)</u>
	<input type="checkbox"/> Print Only
4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1) N/A	
5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)	
<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State
<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input checked="" type="checkbox"/> Effective other (Specify) <u>10/06/2016 [B &amp; P CODE 1208(b)]</u>
6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY	
<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission
<input type="checkbox"/> Other (Specify)	<input type="checkbox"/> State Fire Marshal
7. CONTACT PERSON DAWN BASCIANO	TELEPHONE NUMBER 916-440-7367
FAX NUMBER (Optional) 916-440-5747	E-MAIL ADDRESS (Optional) DAWN.BASCIANO@CDPH.CA.GOV

8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE 	DATE 9/1/16
TYPED NAME AND TITLE OF SIGNATORY KARIN S. SCHWARTZ, DEPUTY DIRECTOR AND CHIEF COUNSEL	

For use by Office of Administrative Law (OAL) only

**CALIFORNIA DEPARTMENT OF PUBLIC HEALTH**  
**2003 CLIA CROSSWALK – DPH-Exempt-15-013**

**Notice Concerning Federal Clinical Laboratory Improvement Amendments Regulations  
Adopted as Final Rule by the Federal Health Care Financing Administration  
and the California Department of Public Health's Determination of Equivalency in  
California per Business and Professions Code section 1208**

Overview and Background

California's clinical laboratory licensing scheme incorporates the federal CLIA<sup>1</sup> regulations for proficiency testing, patient test management, and quality control.<sup>2</sup> When California first adopted subparts of the federal Clinical Laboratory Improvement Amendments (CLIA)<sup>3</sup> regulations under Senate Bill (SB) 113 (Maddy, Chapter 510, Statutes of 1995), the State expressly incorporated the version of the CLIA regulations in effect on January 1, 1994. Without any action by the California Department of Public Health (Department) (under the mechanism described below) or an act of the Legislature (through legislation), the January 1, 1994, version of the CLIA regulations remains effective in California despite federal updates to the underlying CLIA regulations.

The Legislature provided the Department with a mechanism to update the incorporated CLIA regulations to ensure that California remains consistent with the changes to the federal CLIA regulations that occur over time. Section 1208, subdivision (b), of the California Business and Professions Code states that any CLIA regulation adopted by the Health Care Financing Administration of the federal Department of Health and Human Services (HCFA)<sup>4</sup> as a final rule must be evaluated by the Department in consultation with the Department's multidisciplinary committee called the Clinical Laboratory Technical Advisory Committee (CLTAC).<sup>5</sup> (A final rule is a document that is published in the Federal Register which adds to, amends, or repeals a provision of the Code of Federal Regulations after a specified effective date.) In evaluating the final rule, the Department must determine whether the revised federal CLIA regulation is less stringent, equivalent to, or more stringent than an existing California law or regulation.

Any new federal CLIA requirement that the Department deems equivalent to or more stringent than an existing California requirement becomes effective in California by operation of law 60 days after the Department notices its determination in the California Regulatory Notice Register. Any new federal CLIA regulation that the

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<sup>1</sup> Bus. & Prof. Code, § 1220.

<sup>2</sup> Bus. & Prof. Code, § 1202.5, subd. (a).

<sup>3</sup> Clinical Laboratory Improvement Amendments (CLIA) of 1988 (Pub.L. No. 100-578 (Oct. 31, 1988); 42 U.S.C. § 263a).

<sup>4</sup> The Centers for Medicare and Medicaid Services (CMS) which administers the CLIA regulations was previously the federal Health Care Financing Administration (HCFA).

<sup>5</sup> Bus. & Prof. Code, § 1228.

Department determines is less stringent than California law must be noticed for a rulemaking proceeding pursuant to the Administrative Procedure Act (APA)<sup>6</sup> as a "comparable state regulation," to result in the adoption, amendment, or rejection of the less stringent provision.

On January 24, 2003, the Centers for Medicare and Medicaid Services published a final rule entitled "Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications," which, among other things, significantly revised the federal CLIA regulations by amending and consolidating portions of Subparts H, J, K, and P. The attached document, called the "2003 CLIA Crosswalk," represents a collaboration with CLTAC and the Department to make the required stringency determinations of the January 24, 2003 CMS final rule. The Department will publish the 2003 CLIA Crosswalk in the California Regulatory Notice Register, effectively updating the incorporated January 1, 1994, CLIA regulations to the version in effect on January 24, 2003.

#### CLIA 2003 Comparison

To date, the bulk of the 2003 CLIA Crosswalk project involved comparing changes in Subpart K of CLIA, relating to laboratory quality systems, between the 1994 version and the 2003 revisions. This portion of the 2003 CLIA Crosswalk was preempted by the legislature in 2015 when SB 75 (Ch. 18, Stats. 2015) amended Business and Professions Code, section 1220, subdivision (d)(2), effectively updating the incorporated version of the CLIA regulations for Subpart K to the version in effect on January 1, 2015. As a result, all the stringency determinations for Subpart K were removed from the 2003 CLIA Crosswalk, as they are now superseded by statute. The remainder of the 2003 CLIA Crosswalk compares revisions to the federal CLIA regulations under the final rule stated above in Subparts H and J. The latest version is intended to be comprehensive of the revisions in the final rule.

In the consultation process with CLTAC, the Department has prepared a justification document which includes the new CLIA regulation, an inventory of existing California law, and the legal rationale behind each proposed stringency determination. To the extent available, the comparison sheet also includes the federal Health and Human Services' supporting reasoning for changes to the CLIA regulations. For the purposes of the crosswalk, "more stringent" and "equivalent" have the same legal effect – i.e., when noticed, the provision is adopted as a California regulation by operation of law.

Each of the six CLIA revisions deemed "less stringent" related to California's three-year minimum retention period for laboratory and medical records under Business and Professions Code, section 1265, subdivision (j)(2), which is longer than CLIA's two-year retention period for a subset of those records. As indicated above, any new federal

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<sup>6</sup> 68 FR 3640-01 (Jan. 24, 2003).

CLIA regulations that the Department determines is less stringent must be addressed in a regulation adopted pursuant to the APA. As such, the Department has started on a second regulatory package to address these six "less stringent" revisions. At the culmination of this second package, the Department will update the California Code of Regulations (CCR) to include the citation for the California Regulatory Notice Register for the CLIA 2003 Crosswalk that includes the "more stringent" and "equivalent" determinations and will incorporate the Department's decision of adopting, rejecting or amending the remaining "less stringent" provisions.

#### INTERNET ACCESS

The 2003 CLIA Crosswalk that identifies the requirements the Department deems equivalent to, more stringent, or less stringent than an existing California requirement is available via the Internet. It may be accessed at [www.cdph.ca.gov](http://www.cdph.ca.gov) by clicking on these links, in the following order: Decisions Pending & Opportunities for Public Participation, Proposed Regulations.

#### CONTACT INFORMATION

Inquiries regarding the content of this notice or the 2003 CLIA Crosswalk may be directed to Tammy Pahland, Senior Staff Counsel, Office of Legal Services, (916) 440-7572. Inquiries regarding the regulatory process may be directed to Linda M. Cortez, Office of Regulations, at (916) 440-7807.

# 2003 CLIA Crosswalk – DPH-Exempt-15-013

## Revisions and Justifications

In consultation with the Clinical Laboratory Technical Advisory Committee (CLTAC)

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### Statute Mandating the Notice and Evaluation of CLIA Final Rules

Business and Professions Code § 1208 (New categories of licenses; regulations; The federal Health Care Financing Administration HCFA<sup>1</sup> adoption of CLIA regulations as final rules; evaluation; construction with state laws; notice)

(a) [ . . . ].

(b) Any CLIA regulation adopted by HCFA as a final rule after January 1, 1994, shall be evaluated by the department in consultation with the multidisciplinary committee appointed pursuant to Section 1228. Any new federal regulation that is deemed by the department to be equivalent to or more stringent than California laws or regulations, shall become effective by operation of law as a regulation adopted under this chapter, 90 days after adoption by HCFA and the department publishes the notice required by subdivision (c), or on January 1, 1996, whichever is later. After publishing the notice required by subdivision (c), any new federal regulation deemed by the department to be less stringent than current California law or regulation shall be noticed by the department as a comparable state regulation for a rulemaking proceeding in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, which shall result in the adoption, amendment, or rejection of that noticed state regulation.

(c) The department shall publish a notice in the California Regulatory Notice Register indicating that a CLIA regulation has been adopted by HCFA as a final rule. The notice shall include the citation to the Federal Register (Fed.Reg.) or the Code of Federal Regulations (CFR) for the CLIA regulation. The notice shall also include the department's determination regarding whether the regulation is more stringent, equivalent to, or less stringent than current California law or regulation.

#### Final Rule

"Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications", Final Rule, 68 Fed.Reg. 3640 (Jan. 24, 2003).

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<sup>11</sup> The Centers for Medicare and Medicaid Services (CMS), which administers the CLIA regulations, was previously the federal Health Care Financing Administration (HCFA).

## Revisions to Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

### HHS'S OVERVIEW OF CHANGES TO SUBPART H

#### Subpart H—Participation In Proficiency Testing for Laboratories Performing Nonwaived Testing

- We revised the heading of subpart H to read “Participation In Proficiency Testing for Laboratories Performing Nonwaived Testing.”
- We revised “§ 493.801(a)(2)(ii)” by removing the cross reference to “§ 493.1709” and adding, in its place, “§ 493.1236(c)(1).”
- We revised “§ 493.803(a)” by removing the words “tests of moderate complexity (including the subcategory), and/or high complexity” and adding, in their place, the words “nonwaived testing.”
- We revised the heading of § 493.807 to read “Condition: Reinstatement of laboratories performing nonwaived testing.”

### 1. Subpart H Heading – EQUIVALENT

#### **HHS Explanation of Change:**

11. *Revise the heading of Subpart H to read as set forth [below].*

#### **Revised text:**

“Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing”

- Existing California Law and Regulation
  - “Subpart H – Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both”
- Determination: Equivalent. “Nonwaived” testing and “Tests of Moderate or High Complexity, or Both” refer to the same set of covered tests. Accordingly, this technical revision to the heading is deemed equivalent.

### 2. Subpart H § 493.801(a)(2)(ii) – EQUIVALENT

#### **HHS Explanation of Change:**

12. *In § 493.801(a)(2)(ii), remove the cross reference to “§ 493.1709” and add, in its place, “§ 493.1236(c)(1).”*

#### **Revised text:**

“§493.801 Condition: Enrollment and testing of samples. (a) *Standard; Enrollment.* The laboratory must— [ . . . ] (2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with §493.1236(c)(1).”

- Existing California Law and Regulation
  - 493.801(a)(2)(ii) (Jan. 1, 1994): “For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with § 493.1701.”
- Determination: Equivalent. As part of this final rule, Subparts J, K, and P were consolidated into J and K (eliminating P, i.e., sections 1700 to 1770). In the Jan. 1, 1994 version of this section, currently incorporated into law, this provision read “ . . . in accordance with § 493.1709.” That section has been consolidated into 493.1236(c)(1), and this amendment reflects that change of reference. Because the change in reference is merely technical, it is deemed equivalent.

### 3. Subpart H § 493.803(a) – EQUIVALENT

**HHS Explanation of Change:**

13. In § 493.803(a), remove the words “tests of moderate complexity (including the subcategory) and/or high complexity” and add, in their place, the words “nonwaived testing”.

**Revised text:**

“§493.803 Condition: Successful participation. (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.”

- Existing California Law and Regulation
  - 493.803 (Jan. 1, 1994): “Each laboratory performing tests of moderate and/or high complexity must successfully participate in a proficiency testing program approved by HCFA, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certificated under CLIA.”
- Determination: Equivalent. “Nonwaived” testing and “Tests of Moderate or High Complexity, or Both” refer to the same set of covered tests. Accordingly, this technical revision to this subdivision is deemed equivalent.

### 4. Subpart H § 493.807 – EQUIVALENT

**HHS Explanation of Change:**

14. Revise the heading of § 493.807 to read as follows: § 493.807 Condition: Reinstatement of laboratories performing nonwaived testing.

**Revised Text:**

“§493.807 Condition: Reinstatement of laboratories performing nonwaived testing.”

- Existing California Law and Regulation
  - 493.807 (Jan. 1, 1994): Condition: Reinstatement of laboratories performing tests of moderate or high complexity, or both, after failure to participate successfully.

- Determination: Equivalent. "Nonwaived" testing and "Tests of Moderate or High Complexity, or Both" refer to the same set of covered tests. Accordingly, this technical revision to the heading of subdivision 493.807 is deemed equivalent.

## Revisions to Subpart J—Facility Administration for Nonwaived Testing

### HHS'S OVERVIEW OF CHANGES TO SUBPART J

#### Subpart J—Facility Administration for Nonwaived Testing

- We revised the heading of subpart J to read Facility Administration for Nonwaived Testing.
- We revised subpart J to consist of §§ 493.1100 through 493.1105.
- We specified now at § 493.1100 that laboratories performing nonwaived testing must meet the applicable standard level requirements in §§ 493.1101 through 493.1105.
- We added the requirement now at § 493.1101(c) that laboratories must comply with Federal, State, and local requirements concerning laboratories and ensure that adequate safety precautions are in place to provide protection from laboratory hazards.
- We revised the language now at § 493.1101(d) (formerly at § 493.1204(b)) requiring safety procedures to be accessible rather than posted.
- We clarified the record keeping requirements now at § 493.1101(e) for laboratories to store and maintain records in a manner that ensures proper preservation. This clarification applies to the requirements now at § 493.1771(c) and (d), and former §§ 493.1105, 493.1107, and 493.1221 introductory text.
- We removed the language formerly at § 493.1103(c) regarding laboratories providing oral instruction to patients as a supplement to written instructions, when appropriate.
- We clarified the requirement now at § 493.1103(d) (formerly at § 493.1271) that the facility must report transfusion reactions to the laboratories and, as appropriate, to Federal and State authorities.
- We revised the language now at § 493.1105(a)(3)(i) (formerly at § 493.1221) to specify that the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under § 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.
- We revised the language now at § 493.1105(a)(3)(ii) (formerly § 493.1107 introductory text) and § 493.1105(a)(6)(i) (formerly § 493.1109 introductory text) to specify the record retention requirements for immunohematology and blood and blood products to ensure consistency with the FDA requirements.
- We revised the requirement now at § 493.1105(a)(6) (formerly § 493.1109 introductory text) to remove the words “exact duplicate” and specify that the laboratory must be able to retrieve a copy of the original report.

### 5. Subpart J Heading – EQUIVALENT

#### **HHS Explanation of Change:**

*“We revised the heading of subpart J to read Facility Administration for Nonwaived Testing.”*

#### **Revised Text:**

*“Subpart J—Facility Administration for Nonwaived Testing”*

- Existing California Law and Regulation
  - “Subpart J – Patient Test Management for Moderate or High Complexity Testing, or Both” (Jan. 1, 1994).

- Bus. & Prof. Code § 1220(d)(2)(A): “[Except for those clinical laboratories performing only tests or examinations classified as waived under CLIA, each clinical laboratory shall establish and maintain all of the following:] A patient test management system that meets the standards of CLIA in Subpart J (commencing with Section 493.1100) of Title 42 of the Code of Federal Regulations.”
- **Determination: Equivalent.** California law requires that a clinical laboratory performing non-waived tests establish and maintain a patient test management system under Subpart J of CLIA (see above). Under this final rule, Subpart P (Quality Assurance for Moderate or High Complexity Testing, or Both) was eliminated as a Subpart and consolidated into the remaining Subparts J and K. The Subpart J is now titled “Facility Administration for Nonwaived Testing,” which reflects the reorganization of standards that were previously located in Subparts K (relating to quality control) and P (relating to quality assurance). The revision to the heading title, which does not have a substantive legal effect, is deemed equivalent for the purposes of the crosswalk.

The department will pursue technical clean-up legislation to remove the phrase “patient test management system” from Bus. & Prof. Code § 1220(d)(2)(A) as it is no longer relevant to CLIA in Subpart J.

#### 6. Subpart J § 493.1100 – EQUIVALENT

##### **HHS Explanation of Change:**

*We revised subpart J to consist of §§ 493.1100 through 493.1105.*

*We specified now at § 493.1100 that laboratories performing nonwaived testing must meet the applicable standard level requirements in §§ 493.1101 through 493.1105.*

##### **Revised Text:**

“§ 493.1100 Condition: Facility administration. Each laboratory that performs nonwaived testing must meet the applicable requirements under §§ 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).”

- **Existing California Law and Regulation**
  - Bus. & Prof. Code § 1220(d)(2)(A): “[Except for those clinical laboratories performing only tests or examinations classified as waived under CLIA, each clinical laboratory shall establish and maintain all of the following:] A patient test management system that meets the standards of CLIA in Subpart J (commencing with Section 493.1100) of Title 42 of the Code of Federal Regulations.”
- **Determination: Equivalent.** Existing Bus. & Prof. Code § 1220(d)(2)(A) requires that a laboratory performing nonwaived testing meet the standards of CLIA in Subpart J (commencing with Section 493.1100). As the addition of this section functionally duplicates that requirement, the provision is deemed equivalent.

## 7. Subpart J § 493.1101(a)(1) – EQUIVALENT

### **Revised text:**

“§ 493.1101 Standard: Facilities.(a) The laboratory must be constructed, arranged, and maintained to ensure the following: (1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.”

- Existing California Law and Regulation
  - 17 CCR § 1050: “Facilities. The laboratory must provide for and assure that: (a) There is adequate space including working surface to conduct and control the performance of all test procedures performed in the laboratory. (b) There is adequate area for safe storage and use of equipment and supplies. (c) All areas are well lighted and properly ventilated.”
  - Bus. & Prof. Code § 1220(a)(1): “Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered.”
- Determination: Equivalent. The requirement of the revised subdivision is duplicated in California Bus. & Prof. Code § 1220(a)(1) and 17 CCR § 1050, i.e., to maintain adequate facilities (space, ventilation, equipment) for the services rendered.

## 8. Subpart J § 493.1101(a)(2) – MORE STRINGENT

### **Revised text:**

“(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.”

- Existing California Law and Regulation
  - Bus. & Prof. Code § 1220(a)(1): “Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered.”
  - 42 C.F.R. § 493.1254 (Standard: Maintenance and function checks), which specifies two distinct sets of criteria for equipment checks as follows:
    - “(a) Unmodified manufacturer's equipment, instruments, or test systems. The laboratory must perform and document the following:
      - (1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.
      - (2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.
    - (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(ii) Perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

- 42 CFR 493.1274: "Standard: Cytology; *Staining*. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: [ . . . ] (2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used."

**Determination: More stringent.** The general requirement to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is not duplicated elsewhere in existing California law or regulation (but see the specific requirement for cytology under the incorporated quality system CLIA standard). While this section does not include the word "calibration", it specifies function checks. As a general rule, function checks may include calibration. Accordingly, this requirement is classified as more stringent, as it may afford a new vehicle for citation.

#### 9. Subpart J § 493.1101(a)(3) – MORE STRINGENT

**Revised Text:**

"(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation."

- Existing California Law and Regulation
  - Bus. & Prof. Code § 1220(a)(1): "Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered."
- **Determination: More stringent.** The uni-directional workflow requirement for molecular amplification procedures not contained in closed systems, which would entail separate areas for the specified stages of the procedures, does not have a directly analogous provision existing in California law or regulation. Since this subdivision would add a material requirement to California law, it is classified more stringent.

## 10. Subpart J § 493.1101(b) – EQUIVALENT

### **Revised text:**

“(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.”

- Existing California Law and Regulation
  - Bus. & Prof. Code § 1220(a)(1): “Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered.”
  - 42 C.F.R. § 493.1254 (Standard: Maintenance and function checks), which specifies two distinct sets of criteria for equipment checks as follows:
    - “(a) Unmodified manufacturer’s equipment, instruments, or test systems. The laboratory must perform and document the following:
      - (1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.
      - (2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer’s established limits before patient testing is conducted.
    - (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:
      - (1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.
      - (ii) Perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.
      - (2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.
      - (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory’s established limits before patient testing is conducted.
- Determination: Equivalent. The requirement to maintain appropriate equipment for the type and volume of testing performed is functionally duplicated in Bus. & Prof. Code § 1220(a)(1) and 42 C.F.R. § 493.1254. Accordingly, this subdivision is deemed equivalent.

## 11. Subpart J § 493.1101(c) – EQUIVALENT

### **HHS Explanation of Change:**

*We added the requirement now at § 493.1101(c) that laboratories must comply with Federal, State, and local requirements concerning laboratories and ensure that adequate safety precautions are in place to provide protection from laboratory hazards.*

**Revised Text:**

“(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.”

- Existing California law and Regulation
  - Bus. & Prof. Code § 1202.5(a) (“CLIA” and “HCFA” defined): “For purposes of this chapter “CLIA” means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; P.L. 100-578) and the regulations adopted thereunder by the federal Health Care Financing Administration and effective on January 1, 1994, or any later date, when adopted in California pursuant to subdivision (b) of Section 1208.”
  - Bus. & Prof. Code § 1208(b): “Any CLIA regulation adopted by HCFA as a final rule after January 1, 1994, shall be evaluated by the department in consultation with the multidisciplinary committee appointed pursuant to Section 1228. Any new federal regulation that is deemed by the department to be equivalent to or more stringent than California laws or regulations, shall become effective by operation of law as a regulation adopted under this chapter, 90 days after adoption by HCFA and the department publishes the notice required by subdivision (c), or on January 1, 1996, whichever is later. After publishing the notice required by subdivision (c), any new federal regulation deemed by the department to be less stringent than current California law or regulation shall be noticed by the department as a comparable state regulation for a rulemaking proceeding in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, which shall result in the adoption, amendment, or rejection of that noticed state regulation.”
  - Bus. & Prof. Code § 1220(c)(4): “Each licensed or registered clinical laboratory shall be subject to inspections by HCFA or HCFA agents, as defined by CLIA, as a condition of licensure or registration.”
  - Bus. & Prof. Code § 1220(d)(2): “Except for those clinical laboratories performing only tests or examinations classified as waived under CLIA, each clinical laboratory shall establish and maintain all of the following: [requirements under CLIA in Subparts J, K, and P].”
  - Bus. & Prof. Code § 1325: “Notwithstanding Sections 1267 and 1322, the license or registration of a clinical laboratory that has been excluded from participation under the Medicare program (Title XVIII of the Social Security Act (42 U.S.C. Sec. 1395 et seq.)), under the Medicaid Program (Title XIX of the Social Security Act (42 U.S.C. Sec. 1396 et seq.)), or that had its certificate revoked under CLIA, shall be automatically suspended by the department for the period the laboratory is so excluded or has its certificate revoked.”
- Determination: Equivalent. The requirement to comply with “applicable” federal, state, and local laws is already enshrined in California law. California requires that every laboratory is subject to inspection by HCFA (i.e., CMS) agents as a condition of licensure or registration under Bus. & Prof. Code § 1220(c)(4), and automatically suspends the California license or registration of a clinical laboratory program that has its CLIA certificate revoked under Bus. & Prof. Code § 1325 by operation of law. Additionally, Chapter 3 (Clinical Laboratory Technology) of the Bus. & Prof. Code ties California’s requirements to the federal CLIA regulations under, *inter alia*, Bus. & Prof. Code §§ 1202.5(a), 1208, and 1220(d)(2). It is

axiomatic that a laboratory subject to a California license must follow California's laboratory requirements. Thus, for California's purposes, this revised subdivision is equivalent to existing law, to the extent that it requires compliance with "applicable" Federal, State, and local laboratory requirements.

#### 12. Subpart J § 493.1101(d) – MORE STRINGENT

**HHS Explanation of Change:**

*We revised the language now at § 493.1101(d) (formerly at § 493.1204(b)) requiring safety procedures to be accessible rather than posted.*

**Revised Text:**

"(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials."

- Existing California Law and Regulation
  - 17 CCR § 1050(e): "[The laboratory must provide for and assure that:] Instructions to be followed in case of fire and other emergencies are posted in a conspicuous place."
- Determination: More stringent. Existing California regulation, 17 CCR § 1050(e), requires that safety procedures in case of "fire and other emergencies" are posted in a conspicuous place. Subdivision (d) of § 493.1101 contains the same substantive requirement, with a small discrepancy as to the "established, accessible, and observed" verbiage, compared to "posted in a conspicuous place." In practical terms, the requirement to make safety and emergency procedures accessible would be satisfied by posting; however, physical "posting" of long-form safety procedures may not be technically feasible. Although the terms may be functionally equivalent, subdivision (d) goes further than existing law by requiring that the safety procedures are "observed," rather than merely posted or made accessible. Owing to the additional requirement that safety procedures are observed, subdivision (d) is deemed more stringent.

#### 13. Subpart J § 493.1101(e) – MORE STRINGENT

**HHS Explanation of Change:**

*We clarified the record keeping requirements now at § 493.1101(e) for laboratories to store and maintain records in a manner that ensures proper preservation. This clarification applies to the requirements now at § 493.1771(c) and (d), and former §§ 493.1105, 493.1107, and 493.1221 introductory text.*

**Revised text:**

"(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation."

- Existing California Law and Regulation

- Bus. & Prof. Code § 1220(a)(1): "Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered."
  - Bus. & Prof. Code § 1265(j)(2)(A): "Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department."
  - Bus. & Prof. Code § 1271(g): "Each clinical laboratory shall retain all cytology slides and cell blocks examined for a minimum of five years and all cytology reports for a minimum of 10 years."
  - 17 CCR 1050(b): "There is adequate area for safe storage and use of equipment and supplies."
- Determination: More stringent. Existing California law and regulation requires that records are maintained (Bus. & Prof. Code § 1220(a)(1)), and that medical records and laboratory records be retained for a specified period of time (Bus. & Prof. Code § 1265(j)(2)(A)), and that there is adequate area for "safe storage" (17 CCR 1050(d)). However, there is no independent requirement that the laboratory ensure that records are stored under conditions that would ensure their proper preservation. Accordingly, this requirement is appropriately deemed more stringent.

#### 14. Subpart J § 493.1103(a) – EQUIVALENT

##### **Revised text:**

"§493.1103 Standard: Requirements for transfusion services. A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities. (a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products."

- Current California Law and Regulation:
  - Health and Safety Code § 1602.5: "(a) No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following: (1) The standards set forth in the 13th Edition of "Standards for Blood Banks and Transfusion Services," as published by the American Association of Blood Banks and in effect on November 15, 1989, or any amendments thereto or later published editions or amendments thereto. These shall be the standards for all licensed blood banks and blood transfusion services in the state."

- Standards for Blood Banks and Transfusion Services, 4.2.2 (29th Ed.): “The responsibilities for activities covered by these BB/TS Standards when more than one facility is involved shall be specified by agreement.”
- Determination: Equivalent. Health and Safety Code § 1602.5 requires human whole blood or human whole blood derivatives be collected, prepared, labeled, and stored in accordance with the “Standards for Blood Banks and Transfusion Services.” The current version of the text is the 29th edition. This CLIA subdivision and the relevant portion of the Standards agree as to the requirement to have service agreements to the extent that more than one facility is involved in services ancillary to the laboratory’s transfusion related services. Accordingly, they are deemed equivalent.

**15. Subpart J § 493.1103(b) – EQUIVALENT**

**Revised Text:**

**“(b) Provision of testing. The facility must provide prompt ABO grouping, D(Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.”**

- Current California Law and Regulation
  - Health and Safety Code § 1602.5: “(a) No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following: (1) The standards set forth in the 13th Edition of “Standards for Blood Banks and Transfusion Services,” as published by the American Association of Blood Banks and in effect on November 15, 1989, or any amendments thereto or later published editions or amendments thereto. These shall be the standards for all licensed blood banks and blood transfusion services in the state.”
  - Standards for Blood Banks and Transfusion Services, 5.8.1 (Determination of ABO Group for All Collections): “The ABO group shall be determined for each collection by testing the red cells with anti-A and anti-B reagents and by testing the serum or plasma for expected antibodies with A1 and B reagent red cells.”
  - Standards for Blood Banks and Transfusion Services, 5.8.2 (Determination of Rh Type for All Collections): “The Rh type shall be determined for each collection with anti-D reagent. If the initial test with anti-D is negative, the blood shall be tested using a method designed to detect weak D. When either test is positive, the label shall read “Rh POSITIVE.” When the tests for both D and weak D are negative, the label shall read “Rh NEGATIVE.””
  - Standards for Blood Banks and Transfusion Services, 5.8.3 (Detection of Unexpected Antibodies to Red Cell Antigens for Allogeneic Donors): “Serum or plasma from donors shall be tested for un-expected antibodies to red cell antigens.”
  - Standards for Blood Banks and Transfusion Services, 5.16.1 (Serologic Crossmatch): “Before issue, a sample of the recipient’s serum or plasma shall be

crossmatched against a sample of donor cells from an integrally attached Whole Blood or Red Blood Cell segment. The crossmatch shall use methods that demonstrate ABO incompatibility and clinically significant antibodies to red cell antigens and shall include an antiglobulin test as described in Standard 5.14.3.”

- o Standards for Blood Banks and Transfusion Services, 7.4.2 (Laboratory Evaluation and Reporting of Immediate Transfusion Reactions): “The blood bank or transfusion service shall have policies, processes, and procedures for the evaluation and reporting of suspected transfusion reactions, including prompt evaluation, review of clerical information by the blood bank or transfusion service, and notification of the blood bank or transfusion service medical director.”
- **Determination: Equivalent.** This CLIA subdivision requires that a facility providing transfusion services have certain processes, which are coincident with the Standards for Blood Banks and Transfusion Services incorporated under Health and Safety Code § 1602.5: ABO grouping under § 5.8.1; D(Rho) typing under § 5.8.2; unexpected antibody detection under § 5.8.3; compatibility testing under 5.16.1; and investigation of transfusion reactions under 7.4.2. When construed in harmony, this CLIA subdivision does not contravene the associated Standards for Blood Banks and Transfusion Services, and a clinical laboratory performing transfusion services subject to a California license is bound by both sources of law. Accordingly, this subdivision is deemed equivalent.

#### 16. Subpart J § 493.1103(c)(1) – EQUIVALENT

##### **HHS Explanation of Change:**

*We removed the language formerly at § 493.1103(c) regarding laboratories providing oral instruction to patients as a supplement to written instructions, when appropriate.*

##### **Revised Text:**

“(c) Blood and blood products storage and distribution. (1) If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.”

- **Current California Law and Regulation**
  - o Health and Safety Code § 1602.5: “(a) No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following: (1) The standards set forth in the 13th Edition of “Standards for Blood Banks and Transfusion Services,” as published by the American Association of Blood Banks and in effect on November 15, 1989, or any amendments thereto or later published editions or amendments thereto. These shall be the standards for all licensed blood banks and blood transfusion services in the state.”

- Standards for Blood Banks and Transfusion Services, 3.6.1: "Storage devices shall have the capacity and design to ensure that the proper temperature is maintained. Standard 5.1.8.1.3 applies."
  - Standards for Blood Banks and Transfusion Services, 5.1.8.1.3: "For storage of blood or blood components, the temperature shall be monitored continuously and recorded at least every 4 hours."
  - Standards for Blood Banks and Transfusion Services, 5.1.8.1.3.1: "If blood or blood components are stored in an open storage area, the ambient temperature shall be recorded at least every 4 hours."
  - Standards for Blood Banks and Transfusion Services, 3.7 (Alarm Systems): "Storage devices for blood, blood components, tissue, and derivatives shall have alarms and shall conform to the following standards (Standard 5.1.3 applies)."
  - Standards for Blood Banks and Transfusion Services, 3.7.1: "The alarm shall be set to activate under conditions that will allow proper action to be taken before blood, blood components, tissue, or derivatives reach unacceptable conditions."
- **Determination: Equivalent.** This CLIA subdivision requires that for blood or blood products stored outside of a monitored refrigerator, the facility must ensure that conditions are appropriate to prevent deterioration. The incorporated Standards for Blood Banks and Transfusion Services under Health and Safety Code § 1602.5 address the CLIA requirement in Standard 5.1.8.1.3.1 (requiring the monitoring of ambient temperature for storage in open areas) and Standard 3.7 *et seq.* (requiring an alarm system to ensure stored blood and blood products do not reach an unacceptable condition). Since the two sources of law may be construed in harmony with each other, this subdivision is deemed equivalent.

**17. Subpart J § 493.1103(c)(2) – EQUIVALENT**

**Revised Text:**

**"(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product beneficiary."**

- **Existing California Law and Regulation**
  - Health and Safety Code § 1602.5: "(a) No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of the following: (1) The standards set forth in the 13th Edition of "Standards for Blood Banks and Transfusion Services," as published by the American Association of Blood Banks and in effect on November 15, 1989, or any amendments thereto or later published editions or amendments thereto. These shall be the standards for all licensed blood banks and blood transfusion services in the state."
  - Standards for Blood Banks and Transfusion Services, 5.11 (Samples and Requests): "Identifying information for the patient and the sample shall correspond and be confirmed at the time of collection using two independent identifiers."

- Standards for Blood Banks and Transfusion Services, 5.11.1 (Requests): "Requests for blood, blood components, tests, tissue, and derivatives and records accompanying samples from the patient shall contain sufficient information to uniquely identify the patient, including two independent identifiers. The transfusion service shall accept only complete, accurate, and legible requests."
  - Standards for Blood Banks and Transfusion Services, 5.11.2 (Patient Samples): "Patient samples shall be identified with an affixed label bearing sufficient information for unique identification of the patient, including two independent identifiers."
  - Standards for Blood Banks and Transfusion Services, 5.11.2.3: "The transfusion service shall accept only those sam-ples that are completely, accurately, and legibly la-beled."
  - Standards for Blood Banks and Transfusion Services, 5.22 (Final Inspection Before Issue): "Blood, blood components, tissue, and derivatives shall be inspected at the time of issue."
  - Standards for Blood Banks and Transfusion Services, 5.23 (Issue of Blood and Blood Components): "At the time a unit is issued, there shall be a final check of transfusion service records and each unit of blood or blood component. Verification shall include: 1) The intended recipient's two independent identifiers, ABO group, and Rh type . . . ."
- **Determination: Equivalent.** This CLIA subdivision requires that a facility establish and follow policies to ensure positive identification of the recipient of blood or blood products. The Standards for Blood Banks and Transfusion Services, incorporated under Health and Safety Code § 1602.5, satisfy the CLIA requirement by, among other things, specifying that samples indicate the intended recipient of blood or blood products with two unique identifiers (see, e.g., § 5.23). Since the two authorities can be harmonized together, this subdivision is deemed equivalent.

#### 18. Subpart J § 493.1103(d) – EQUIVALENT

##### **HHS Explanation of Change:**

*We clarified the requirement now at § 493.1103(d) (formerly at § 493.1271) that the facility must report transfusion reactions to the laboratories and, as appropriate, to Federal and State authorities.*

##### **Revised Text:**

"(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities."

- **Existing California Law and Regulation**
  - Health and Safety Code § 1602.5: "(a) No person shall engage in the production of human whole blood or human whole blood derivatives unless the person is licensed under this chapter and the human whole blood or human whole blood derivative is collected, prepared, labeled, and stored in accordance with both of

the following: (1) The standards set forth in the 13th Edition of "Standards for Blood Banks and Transfusion Services," as published by the American Association of Blood Banks and in effect on November 15, 1989, or any amendments thereto or later published editions or amendments thereto. These shall be the standards for all licensed blood banks and blood transfusion services in the state."

- Standards for Blood Banks and Transfusion Services, 7.4.2 (Laboratory Evaluation and Reporting of Immediate Transfusion Reactions): "The blood bank or transfusion service shall have policies, processes, and procedures for the evaluation and reporting of suspected transfusion reactions, including prompt evaluation, review of clerical information by the blood bank or transfusion service, and notification of the blood bank or transfusion service medical director."
- Health and Safety Code § 1279.1(a): "A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law."
- Determination: Equivalent. This CLIA subdivision is substantially the same as the Standards for Blood Banks and Transfusion Services, 7.4.2 (Laboratory Evaluation and Reporting of Immediate Transfusion Reactions), incorporated by Health and Safety Code § 1602.5, in that both require procedures for preventing, identifying, and reporting transfusion reactions. Section 7.4.2 specifies that the facility must notify the blood bank or transfusion service medical director in the case of a reaction, whereas the CLIA subdivision requires that the facility report reactions to the laboratory, and to Federal and State authorities, as appropriate. Both authorities may be harmonized without conflict (i.e., in the case of a reaction, all of the foregoing entities must be contacted, as appropriate). Facilities are also bound by Health and Safety Code § 1279.1(a), specifying the timeline for reporting adverse events (including transfusion reactions) to the Department of Public Health. Because a facility can accomplish all of the foregoing requirements without conflict, this subdivision is deemed equivalent.

#### 19. Subpart J § 493.1105(a), (a)(1) – LESS STRINGENT

**Revised Text:**

"§493.1105 Standard: Retention requirements.(a) The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows: (1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years."

- Existing California Law and Regulation
  - 493.1105 (Jan. 1, 1994): "Records of test requisitions or test authorizations must be retained for a minimum of two years. The patient's chart or medical record, if used as the test requisition, must be retained for a minimum of two years and

must be available to the laboratory at the time of testing and available to HHS upon request.”

- 493.1241(d) (Jan. 1, 2015): “The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.”
  - Bus. & Prof. Code § 1265(j)(2)(A): “Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.”
  - Bus. & Prof. Code § 1265(j)(2)(B): “For purposes of this subdivision, ‘medical records’ means the test requisition or test authorization, or the patient's chart or medical record, if used as the test requisition, the final and preliminary test or examination result, and the name of the person contacted if the laboratory test or examination result indicated an imminent life-threatening result or was of panic value.”
- **Determination: Less Stringent.** In this final rule, 42 CFR § 493.1105 was amended by moving the requirement that a patient’s chart or medical record must be available to the laboratory or HHS (CMS) upon request if used as the test requisition to 42 CFR § 493.1241(d). The remaining portion, which states that the test requisition and authorization be retained for two (2) years, is in conflict with Bus. & Prof. Code § 1265(j)(2), which requires that a medical record, which includes test requisition or test authorization, be retained for a minimum of three (3) years. Accordingly, this provision is less stringent than California law.

## 20. Subpart J § 493.1105(a)(2) – LESS STRINGENT

### **Revised Text:**

“(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.”

- **Existing California Law and Regulation**
  - Bus. & Prof. Code § 1265(j)(2)(A): “Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.”
  - Bus. & Prof. Code § 1265(j)(2)(C): “For purposes of this subdivision, “laboratory records” means records showing compliance with CLIA and this chapter during a

laboratory's operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.

- 42 CFR § 493.1251(e) (Standard: Procedure Manual) (Jan. 1, 2015): "The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in §493.1105(a)(2)."
- Determination: Less stringent. Bus. & Prof. Code § 1265(j)(2) requires that laboratory records, which includes records showing compliance with CLIA for quality control, are maintained for a minimum of three (3) years. As part of the quality control system in Subpart K, 42 CFR § 493.1251(e) states that a laboratory must maintain of copy of each test procedure. Since the copy of each test procedure is a record showing compliance with CLIA quality control, it must be retained for three (3) years, rather than the two (2) year requirement specified in this subdivision. Accordingly, this subdivision is less stringent than California law.

#### 21. Subpart J § 493.1105(a)(3) – LESS STRINGENT

##### **Revised Text:**

"(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in §§493.1252 through 493.1289 for at least 2 years. In addition, retain the following."

- Existing California Law and Regulation
  - 493.1107 (Jan. 1, 1994): "Records of patient testing, including, if applicable, instrument printouts, must be retained for at least two years."
  - Bus. & Prof. Code § 1265(j)(2)(A): "Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department."
  - Bus. & Prof. Code § 1265(j)(2)(C): "For purposes of this subdivision, "laboratory records" means records showing compliance with CLIA and this chapter during a laboratory's operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media."
- Determination: Less Stringent. Under Bus. & Prof. Code § 1265(j)(2), records showing compliance with CLIA during the laboratory's operations, including records of quality control, must be retained for at least three (3) years. This subdivision requires that quality control, patient test records, and records documenting all analytical system activities in the specified sections of CLIA Subpart K (quality systems) are maintained for two (2) years. Because the activities under Subpart K

fall under the broad umbrella of quality control, the CLIA minimum retention period is a year shorter than California's, and is thus less stringent.

## 22. Subpart J § 493.1105(a)(3)(i) – LESS STRINGENT

### **HHS Explanation of Change:**

*We revised the language now at § 493.1105(a)(3)(i) (formerly at § 493.1221) to specify that the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under § 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.*

### **Revised Text:**

“(i) Records of test system performance specifications that the laboratory establishes or verifies under §493.1253 for the period of time the laboratory uses the test system but no less than 2 years.”

- Existing California Law and Regulation
  - 493.1253 (“Standard: Establishment and verification of performance specifications”; Jan. 1, 2015): (b)(1) *Verification of performance specifications*. Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: [ . . . ] (c) *Documentation*. The laboratory must document all activities specified in this section.
  - Bus. & Prof. Code § 1265(j)(2)(A): “Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.”
  - Bus. & Prof. Code § 1265(j)(2)(C): “For purposes of this subdivision, “laboratory records” means records showing compliance with CLIA and this chapter during a laboratory's operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.”
- Determination: Less stringent. 42 CFR § 493.1253(c) (Jan. 1, 2015), incorporated by Bus. & Prof. Code § 1220(d)(2)(B), requires that performance specifications for approved test systems must be established, and that the laboratory must document all activities specified in that section. Bus. & Prof. Code § 1265(j)(2) requires that laboratory records, which includes records showing compliance with CLIA, including quality control and quality assurance, are maintained for at least three (3) years, unless a longer retention period is required pursuant to any other provision of law. The noticed CLIA provision requires that records of test system performance specifications, part of CLIA's quality control system, be maintained for as long as the system is in use, but no less than 2 years. As applied, the retention period remains

less stringent than California law, because Bus. & Prof. Code § 1265(j)(2) would require that the record is maintained three (3) years after cessation, whereas the noticed CLIA provision would only require that it is retained for two (2) years. Accordingly, this provision is deemed less stringent than California law.

#### 23. Subpart J § 493.1105(a)(3)(ii) – MORE STRINGENT

##### **HHS Explanation of Change:**

*We revised the language now at § 493.1105(a)(3)(ii) (formerly § 493.1107 introductory text) and § 493.1105(a)(6)(i) (formerly § 493.1109 introductory text) to specify the record retention requirements for immunohematology and blood and blood products to ensure consistency with the FDA requirements.*

##### **Revised Text:**

“(ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v) and (d).”

- Existing California Law and Regulation
  - 493.1107 (Jan. 1, 1994): “Immunohematology records and transfusion records must be retained for no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d).”
- Determination: More Stringent. 21 CFR § 606.160(d) has been revised since the Jan. 1, 1994 version of CLIA, which then required that immunohematology records, transfusion records, and records of blood product testing be maintained for a minimum of five (5) years. The retention period under 21 CFR § 606.160(d) has been lengthened, and now requires a minimum ten (10) year retention period (“[r]ecords shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. You must retain individual product records no less than 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely.”). Accordingly, the noticed CLIA provision is more stringent than existing California law or regulation.

#### 24. Subpart J § 493.1105(a)(4) – EQUIVALENT

##### **Revised Text:**

“(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.”

- Existing State Law and Regulation
  - 42 CFR 493.801(5) (Jan 1, 1994): “The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a

copy of all records [ . . . ] for a minimum of two years from the date of the proficiency testing event.”

- Bus. & Prof. Code § 1265(j)(2)(A): “Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.”
- Bus. & Prof. Code § 1265(j)(2)(C): “For purposes of this subdivision, “laboratory records” means records showing compliance with CLIA and this chapter during a laboratory’s operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.”
- **Determination: Equivalent.** The noticed CLIA provision requires that all proficiency testing records are retained for at least two years, which accords with the previous version of this requirement, then located at 42 CFR 493.801(5) (Jan. 1, 1994), requiring the same. Bus. & Prof. Code § 1265(j)(2) sets a statutory minimum of a three (3) year retention period for laboratory records; however, proficiency testing records is not included in the exhaustive listing of record types, and thus doesn’t qualify as a “laboratory record” for the purpose of that section (“laboratory records” means records showing compliance with CLIA and this chapter during a laboratory operation [ . . . ] for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.”). Since § 1265(j)(2) doesn’t apply, the revision in organization is merely technical, and is thus deemed equivalent.

#### 25. Subpart J § 493.1105(a)(5) – LESS STRINGENT

##### **Revised Text:**

“(5) Quality system assessment records. Retain all laboratory quality systems assessment records for at least 2 years.”

- **Current California Law and Regulation**
  - Bus. & Prof. Code § 1265(j)(2)(A): “Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.”
  - Bus. & Prof. Code § 1265(j)(2)(C): “For purposes of this subdivision, “laboratory records” means records showing compliance with CLIA and this chapter during a laboratory’s operation that are actual or true copies, either photocopies or

electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.”

- **Determination: Less stringent.** The noticed CLIA provision requires that records of quality system assessments be retained for two (2) years. California statute requires that records of quality control and quality assurance are retained for at least three (3) years under Bus. & Prof. Code § 1265(j)(2). Since California requires a longer minimum retention period, this provision is deemed less stringent.

#### 26. Subpart J § 493.1105(a)(6) – LESS STRINGENT

##### **HHS Explanation of Change:**

*We revised the requirement now at § 493.1105(a)(6) (formerly § 493.1109 introductory text) to remove the words “exact duplicate” and specify that the laboratory must be able to retrieve a copy of the original report.*

##### **Revised Text:**

“(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following:”

- **Existing California Law and Regulation**
  - Bus. & Prof. Code § 1265(j)(2)(A): “Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.”
  - Bus. & Prof. Code § 1265(j)(2)(C): “For purposes of this subdivision, “laboratory records” means records showing compliance with CLIA and this chapter during a laboratory’s operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.”
  - 493.1109 (Jan. 1., 1994): “The original report or an exact duplicate of each test report, including final and preliminary report, must be retained by the testing laboratory for a period of at least two years after the date of reporting.”
  - 493.1109(h) (Jan. 1, 1994): “The original report or exact duplicates of test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.”
- **Determination: Less stringent.** First, to the extent that the CLIA regulations were clarified to specify that a laboratory must be able to retrieve copies of original test reports, this revision is consistent with Bus. & Prof. Code § 1265(j)(2)(C) (“... records showing compliance with CLIA and this chapter during a laboratory’s

operation that are *actual or true copies*. . .”) Second, Bus. & Prof. Code § 1265(j)(2)(B) requires a minimum three year retention period for “laboratory records”. A “test report” would qualify as a “laboratory record” as a record of patient test management. Therefore, to the extent that California statute requires a three (3) year minimum retention period, whereas the noticed CLIA provision requires a two (2) year minimum retention period, this subdivision is less stringent than California law.

#### 27. Subpart J § 493.1105(a)(6)(i) – MORE STRINGENT

##### **HHS Explanation of Change:**

*We revised the language now at § 493.1105(a)(3)(ii) (formerly § 493.1107 introductory text) and § 493.1105(a)(6)(i) (formerly § 493.1109 introductory text) to specify the record retention requirements for immunohematology and blood and blood products to ensure consistency with the FDA requirements.*

##### **Revised Text:**

“(i) Immunohematology reports as specified in 21 CFR 606.160(d).”

- Existing California Law and Regulation
  - 493.1109 (Jan. 1, 1994): “Immunohematology reports and transfusion records must be retained for no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d).”
- Determination: More Stringent. 21 CFR § 606.160(d) has been revised since the Jan. 1, 1994 version of CLIA, which then required that immunohematology records, transfusion records, and records of blood product testing be maintained for a minimum of five (5) years. The retention period under 21 CFR § 606.160(d) has been lengthened, and now requires a minimum ten (10) year retention period (“[r]ecords shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. You must retain individual product records no less than 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely.”). Accordingly, the noticed CLIA provision is more stringent than existing California law or regulation.

#### 28. Subpart J § 493.1105(a)(6)(ii) – EQUIVALENT

##### **Revised Text:**

“(ii) Pathology test reports for at least 10 years after the date of reporting.”

- Current California Law and Regulation

- 493.1109 (Jan. 1, 1994): "For pathology, test reports must be retained for a period of at least ten years after the date of reporting."
  - 493.1271(f) (Jan. 1, 2015): "*Record and slide retention.* (1) The laboratory must retain all records and slide preparations as specified in §493.1105."
  - Bus. & Prof. Code § 1271(g): "Each clinical laboratory shall retain all cytology slides and cell blocks examined for a minimum of five years and all cytology reports for a minimum of 10 years."
- **Determination: Equivalent.** The requirement to retain pathology test reports for at least 10 years after the date of reporting was moved from 42 CFR § 493.1109 (Jan. 1, 1994) to this subdivision, but is otherwise identical. Because the reorganization is merely technical, it is deemed equivalent.

**29. Subpart J § 493.1105(a)(7) – EQUIVALENT**

**Revised Text:**

"(7) Slide, block, and tissue retention—(i) Slides. (A) Retain cytology slide preparations for at least 5 years from the date of examination (see §493.1274(f) for proficiency testing exception). (B) Retain histopathology slides for at least 10 years from the date of examination. (ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination. (iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen."

- **Current California Law and Regulation**
  - 493.1271(f) ("Standard: Cytology"; Jan. 1, 2015): "*Record and slide retention.* (1) The laboratory must retain all records and slide preparations as specified in §493.1105."
  - 493.1273(b) ("Standard: Histopathology"; Jan. 1, 2015): "The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in §493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under §493.1449(b), (l), or (m)."
- **Determination: Equivalent.** In this final rule, portions of Subpart K relating to cytology and histopathology retention requirements were consolidated and moved to 493.1105(a)(7). The underlying retention dates remain the same (see chart below for comparison). The Jan. 1, 2015 versions of 42 CFR §§ 493.1271(f) (cytology) and 493.1273(b) (histopathology), incorporated by Bus. & Prof. Code § 1220(d)(2)(B), already specify that a clinical laboratory must retain the slides, blocks, and tissue in accordance with § 493.1105. Accordingly, this change is deemed equivalent.

Subpart J – 42 CFR 493.1105(a)(7)	Subpart K (Jan. 1, 1994)
<u>Slide, block, and tissue retention—(i) Slides. (A) Retain cytology slide preparations for at least 5 years from the date of examination (see §493.1274(f) for proficiency testing exception).</u>	493.1257(g) (Jan. 1, 1994): "The laboratory must retain all slide preparations for five years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of

	maintaining them for this time period, provided the laboratory receives written acknowledgement of the receipt of slides by the proficiency testing program and maintains the acknowledgement to document the loan of such slides. . . .”
<u>(B) Retain histopathology slides for at least 10 years from the date of examination.</u>	493.1259(b) (Jan. 1, 1994): “The laboratory must retain stained slides at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination.”
<u>(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination.</u>	493.1259(b) (Jan. 1, 1994): “The laboratory must retain stained slides at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination.”
<u>(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</u>	493.1259(c) (Jan. 1, 1994): “The laboratory must retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made. . . .”

**30. Subpart J § 493.1105(b) – EQUIVALENT**

**Revised Text:**

“(b) If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section.”

- Current California Law and Regulation
  - Bus. & Prof. Code § 1265 (j)(2)(A): “Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.”
- Determination: Equivalent. This subdivision, directing laboratories to make provisions to ensure that all records are retained after the laboratory ceases operations in accordance with the time periods specified in § 493.1105, is consistent with California law to the extent that Bus. & Prof. Code § 1265(j)(2)(A) also specifies that the minimum retention period for laboratory records and medical records applies to “those laboratories that cease operations.” Certain retention periods of § 493.1105 are less stringent (shorter) than California’s minimum retention period; however, those deemed less stringent will not be

adopted into California regulation. The remaining retention periods that are equivalent or more stringent than existing California law or regulation will control following the integration of this crosswalk, and so this subdivision could be appropriate deemed "equivalent" or "more stringent" to the extent that the remaining underlying retention periods are both equal to or longer than existing California law or regulation.