

NOTICE PUBLICATION REGULATIONS SUBMISSION

NON-SUBSTANTIVE

STD. 400 (REV. 01-2013)

Instructions on (reverse)

For use by Secretary of State only

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-	REGULATORY ACTION NUMBER 2016-0413-05N	EMERGENCY NUMBER
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ENDORSED - FILED  
in the office of the Secretary of State  
of the State of California

MAY 25 2016  
2:03 PM

For use by Office of Administrative Law (OAL) only	
NOTICE	REGULATIONS

2016 APR 13 P 4: 25  
OFFICE OF ADMINISTRATIVE LAW

AGENCY WITH RULEMAKING AUTHORITY Department Public Health	AGENCY FILE NUMBER (if any) DPH-10-20
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A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY <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 Disapproved/Withdrawn	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER	PUBLICATION DATE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) Clinical Lab Standards (Proficiency Testing), Part 1	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)
SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)
ADOPT
AMEND 1050(d) per agency request
REPEAL 1050(a), (b), (c), (e), (f), (g), and (h)
TITLE(S) 17

3. TYPE OF FILING
<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346) <input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §11349.3, 11349.4) <input type="checkbox"/> Emergency (Gov. Code, §11346.1(b)) <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 Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)
<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h)) <input type="checkbox"/> File & Print <input type="checkbox"/> Other (Specify) _____
<input checked="" type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100) <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)

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 checked="" type="checkbox"/> §100 Changes Without Regulatory Effect <input type="checkbox"/> Effective other (Specify) _____

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"/> State Fire Marshal <input type="checkbox"/> Other (Specify) _____

7. CONTACT PERSON Linda M. Cortez	TELEPHONE NUMBER 916-440-7807	FAX NUMBER (Optional) 916-440-5747	E-MAIL ADDRESS (Optional) linda.cortez@cdph.ca.gov
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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 3/3/16
TYPED NAME AND TITLE OF SIGNATORY Karin S. Schwartz, Deputy Director and Chief Counsel	

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ENDORSED APPROVED

MAY 25 2016

Office of Administrative Law

**California Code of Regulations  
Title 17. Public Health  
Division 1. Department of Health Services  
Chapter 2. Laboratories  
Subchapter 1. Service Laboratories  
Group 2 Clinical Laboratory Regulations  
Article 5. Issuance of License**

Amend section 1050:

**§ 1050. Clinical Laboratory Standards.**

~~—(a) All licensed clinical laboratories shall be conducted, maintained, and operated without injury to the public health and shall maintain records, equipment, and facilities which are adequate and appropriate for the services rendered and demonstrate satisfactory performance in a proficiency program approved by the department.~~

~~—(b) Proficiency Testing.~~

~~—(1) The laboratory must participate in a state approved proficiency testing program and demonstrate satisfactory performance in all of the laboratory specialties that include tests performed in the laboratory. Proficiency shall be tested in the following specialties: microbiology, serology, clinical chemistry, hematology, and immunohematology.~~

~~—(2) The participating laboratory must test applicable materials each time they are distributed by the approved proficiency testing service according to a schedule approved by the department.~~

~~—(3) Those procedures performed by the laboratory for which test materials are provided by the approved proficiency testing service and which have been designated by the department as a requirement for measuring test performance, must be proficiency tested by the participating laboratory each time test materials are received.~~

~~—(4) The participating laboratory must authorize the approved proficiency testing service to report proficiency test results to the department.~~

- ~~—(6) Regularly consult with supervisors and other staff members.~~
- ~~—(7) Confer with those served by the laboratory on matters that relate to test performance and determine the nature and scope of technical and administrative information to be released by the laboratory staff.~~
- ~~—(8) Be available daily in any laboratory performing cytology and serve as director of no more than three (3) laboratories.~~
- ~~—(9) Cause a licensed physician or dentist, qualified in cytopathology, to personally examine and report findings on abnormal or questionable gynecologic and all non-gynecologic specimens.~~

(d) Facilities. The laboratory must provide for and assure that:

(4a) There is adequate space including working surface to conduct and control the performance of all test procedures performed in the laboratory.

(2b) There is adequate area for safe storage and use of equipment and supplies.

(3c) All areas are well lighted and properly ventilated.

(4d) Fume hoods and biological safety cabinets, properly installed and regulated, are used if required for safe performance of tests or for safe preparation of materials.

(5e) Instructions to be followed in case of fire and other emergencies are posted in a conspicuous place.

~~—(e) Equipment and Test Materials.~~

~~—(1) The laboratory must provide for and assure that equipment, instruments, glassware, and reagents are maintained in proper working order by periodic inspection, testing, or calibration in a manner acceptable to the department.~~

~~—(2) All reagents and stains shall be dated at the time of preparation and initialed by the person making the reagents or stains, or the date received and date opened if commercially prepared reagents or stains are used. All reagents and stains shall be labeled to indicate identity, and titer, strength, or concentration. Recommended storage temperature and expiration date, and other pertinent information necessary for quality control must be on the label.~~

~~—(f) Records.~~

~~4. Minimum information provided shall include: source of specimen (anatomic site), age of patient, previous therapy (endocrine, surgical, radiation, birth control, etc.), gynecologic history on cervical-vaginal specimens, including date and normalcy of patient's last menstrual period, duration of patient's current pregnancy, if any, and patient's menopausal status or essential history on non-gynecologic specimen.~~

~~5. The date the specimen was collected.~~

~~—(B) Reports shall contain at least the following information:~~

~~1. The dates the specimen was collected, received in the laboratory and reported by the laboratory, and the accession number.~~

~~2. The result of the laboratory examination.~~

~~—(3) Cytology Laboratory Records.~~

~~—(A) The laboratory director shall be responsible for the final laboratory report and shall sign all abnormal and all non-gynecological reports. Each report, or a laboratory copy, shall be signed or initialed by the cytopathologist and/or cytotechnologist who examined the preparation and evaluated the final report. The names of all persons who examined the specimen and their evaluation, if inconsistent with the final report, shall be indicated on the laboratory work sheet or report copy.~~

~~—(B) Duplicate copies of laboratory reports are filed in a manner which permits ready identification and accessibility.~~

~~—(C) Laboratories shall utilize reporting systems that are as explicit as is cytologically feasible and must include acceptable morphologic terminology.~~

~~—(D) If a specimen is judged by the laboratory director or cytotechnologist to be suboptimal, an accompanying statement shall indicate the reason, e.g., samples of sparse cellularity, poor preservation, or exhibiting other factors interfering with the laboratory evaluation, such as, excessive blood, inflammatory cells, etc.~~

~~—(g) Quality Control.~~

~~—(1) The laboratory must conduct, maintain, and operate programs for controlling the quality of test performance in a manner acceptable to the department.~~

~~—(2) Additional Cytology.~~

~~false negative and false positive results for each category of specimens, when such results are made available to them.~~

~~(h) Clinical Laboratory Test Results. Clinical laboratory test results shall not be reported from the laboratory until these results have been critically reviewed and verified for accuracy, reliability, and validity by a licensed physician and surgeon or a person, other than a trainee, duly licensed under Chapter 3, Division 2, Business and Professions Code (commencing with Section 1200).~~

Note: Authority cited: Sections 1224 and 1245, Business and Professions Code.  
Reference: Sections 1220, and 1224 and 1245, Business and Professions Code.

**California Code of Regulations  
Title 17. Public Health  
Division 1. Department of Health Services  
Chapter 2. Laboratories  
Subchapter 1. Service Laboratories  
Group 2 Clinical Laboratory Regulations  
Article 5. Issuance of License  
Section 1050 Clinical Laboratory Standards**

Pursuant to a request from the Office of Administrative Law, the California Department of Public Health Office of Legal Services includes this additional justification regarding the repeal of title 17 of the California Code of Regulations (CCR) section 1050 via title 1 of the CCR section 100. The following sections were identified:

- 1050(a)(2)(A)
- 1050(b)(2)
- 1050(b)(3)
- 1050(c)(1)
- 1050(c)(2)
- 1050(c)(7)
- 1050(e)(2)
- 1050(f)(2)
- 1050(f)(2)(A)(4)
- 1050(f)(3)(C)
- 1050(g)(2)(A)
- 1050(g)(2)(B)(2)
- 1050(g)(2)(B)(3)
- 1050(h)

Many of the above sections were superseded by newer statutes that legislators intended to reflect an update to laboratory operations. California Code of Regulations, title 17, section 1050 was promulgated in 1977 and last amended in 1978. When statutes are in conflict, the provisions found in later statutes or which are more specific would control.<sup>1</sup> Under the rules governing statutory construction, when the Legislature enacts an amendment or a new statute on the issue, courts presume that the authors of the legislation intended to change the original law by creating a new right or withdrawing an existing one.<sup>2</sup> Courts presume that legislators are aware of existing law when it passes legislation.<sup>3</sup> Generally, the same rules of construction apply in interpreting regulations as apply in interpreting statutes.<sup>4</sup>

<sup>1</sup> *Elsenheimer v Elsenheimer* (2004) 124 Cal.App.4th at 1540.

<sup>2</sup> *Donorovich-Odonnell v. Harris* (2015) 241 Cal. App. 4th 1118 at 1132.

<sup>3</sup> *Hall v. United States* (2012) 132 S. Ct. 1882 at 1889.

<sup>4</sup> *Department of Alcoholic Beverage Control v. Alcoholic Beverage Control Appeals Bd.* (2003) 109 Cal.App.4th 1687 at 1695.

**1. 17 CCR §1050(a)**

As noted in the original justification, the requirement that a laboratory must “demonstrate satisfactory performance in a proficiency testing program approved by the department” is outdated and less specific than later statutes. Business and Professions Code (BPC) section 1272 was enacted in 1989 reflecting CLIA requirements for proficiency testing. California later adopted CLIA requirements (subpart H, I, J, and K) with an amendment to BPC section 1220, subdivision (a)(2)(A) via Senate Bill (SB) 113 (Maddy 1995) that went into effect in California on January 1, 1996. Subpart K of CLIA was further updated and adopted by California with SB 75 (Chapter 18, Statutes of 2015).

BPC 1220 subdivision (a)(2)(A) is broader and conflicts with 17 CCR 1050(a) for proficiency testing requirements because it allows for the approval of the proficiency testing program to be approved by the department or by HCFA (now CMS) whereas 17 CCR §1050 only allows for approval by the department. Further, this provision of the CCR conflicts with CLIA which state that waived labs are not required to enroll in a proficiency testing program unless the manufacturer’s instructions require it. See chart below for a side-by-side comparison of the language to illustrate that the department has no discretion but to repeal the regulations because the newer statute (BPC sections 1220 and 1272) must be followed and due to the conflict, the courts must presume that there was an intent to change law.

17 CCR §1050 (a)		CLIA (in effect 1994), Subpart H and Subpart I
“ <u>All</u> licensed clinical laboratories <u>shall</u> ...”	<p><b>BPC §1220 (a)(2)(A)</b> “Except for tests or examinations classified as waived under CLIA, <u>each</u> clinical laboratory <u>shall</u>”</p> <p><b>BPC §1272</b>          “A clinical laboratory <u>shall</u> participate in a state-approved proficiency testing program and demonstrate satisfactory performance in <u>all</u> of the laboratory <u>specialties</u> that include tests performed in the laboratory. Proficiency shall be tested in the following specialties: microbiology, serology, clinical chemistry, hematology, cytology, and immunohematology.”</p>	<p><b>42 CFR §493.10</b> - Laboratories are categorized as performing waived tests, tests of moderate complexity or high complexity.</p> <ul style="list-style-type: none"> <li>- <u>Waived tests</u> or examinations = current law already does not require that these tests enroll in proficiency testing. Waived tests or examinations are simple laboratory examinations and procedures and follow manufacturer’s instructions for test performance.<sup>5</sup> If the manufacturer’s instructions require proficiency testing for a specific waived test, then the laboratories tests must demonstrate satisfactory proficiency testing requirements.<sup>6</sup></li> <li>- Tests of Moderate or High Complexity must enroll in proficiency testing per CLIA Subpart H and I (commencing with 42 CFR §493.801)</li> </ul>

<sup>5</sup> 42 CFR 493.15 (in effect 1994) and BPC 1220(d)(1).

<sup>6</sup> One exception is human immunodeficiency virus screening testing (HIV). Under 17 CCR §1230, a laboratory that performs waived tests that screen for HIV must shall establish and maintain a quality assurance program that includes “assessment and documentation of test performance by testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples at least twice yearly and monitored by the laboratory director”.

<p>“demonstrate satisfactory performance in a proficiency testing program approved by the department”</p>	<p><b>BPC §1220(a)(2)(A)</b> “enroll, and demonstrate successful participation, as defined under CLIA, for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, <u>in a proficiency testing program approved by the department or by HCFA,</u></p> <p style="text-align: center;">- <b>to the same extent as required by CLIA in <u>Subpart H (commencing with Section 493.801) of Title 42 of the Code of Federal Regulations.</u></b> This requirement shall not be interpreted to prohibit a clinical laboratory from performing clinical laboratory tests or examinations in a specialty or subspecialty for which there is no department or HCFA approved proficiency testing program.”</p> <p><b>BPC §1220(d)(1)</b> “Each clinical laboratory <u>shall</u> perform all clinical laboratory tests or examinations classified as <u>waived</u> under CLIA in conformity with the manufacturer’s instructions.”</p>	<p><b>42 CFR § 493.801</b> defines <b>Subpart H - Participation in Proficiency Testing for Laboratories Performing Test of Moderate or High Complexity, or Both</b></p> <p>“Each laboratory <u>must</u> enroll in a proficiency testing (PT) program that meets the criteria in <b>Subpart I</b> of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification....”</p>
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**2. 17 CCR §1050(b)(2) – Proficiency Testing**

As noted above, 1050 subdivision (b) is superseded and in conflict with BPC section 1220 (which incorporates various CLIA regulations including Subpart H and I) where in both scenarios – department approved or CMS approved proficiency programs, the proficiency programs must follow Subpart I. Subpart I requires that all approved proficiency testing programs provide five samples (i.e. challenges) per testing event, and three testing events per year versus the schedule approved by the department. See chart below for a side-by-side comparison of the language to illustrate that the department has no discretion but to repeal the regulations because the newer statute must be followed due to conflict and the courts must presume that there was an intent to change law.

17 CCR §1050(b)(2)	BPC §1220(a)(2)(A) (incorporating CLIA Subparts H, I, J, K)	<b>New requirements under Subpart I is defined by 42 CFR commencing with Section 493.901 - Proficiency Testing Programs by Specialty and Subspecialty</b>
"The participating laboratory must test applicable materials <u>each time</u> they are distributed by the approved proficiency testing service according to a schedule approved by the department."	<p><b>BPC §1220(a)(2)(A)</b> "enroll, and demonstrate successful participation, as defined under CLIA, for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, <u>in a proficiency testing program approved by the department or</u> by HCFA,</p> <p>- <b>to the same extent as required by CLIA in Subpart H<sup>7</sup> (commencing with Section 493.801) of Title 42 of the Code of Federal Regulations.</b>"</p>	<p><b>42 CFR §493.909</b> – The subspecialties under the specialty of microbiology include bacteriology, mycobacteriology, mycology, parasitology and virology. Each of these subspecialties has the same material requirement for testing schedule and frequency.</p> <ul style="list-style-type: none"> <li>- See, e.g., 42 C.F.R. § 493.911(b) "Program content and frequency of challenge. To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of <u>five</u> samples per testing event. There must be at least three testing events at approximately equal intervals per year";</li> <li>- 42 C.F.R. § 493.913(b) Mycobacteriology; same requirement;</li> <li>- 42 C.F.R. §493.915(b) Mycology; same requirement;</li> <li>- 42 C.F.R. § 493.917(b) Parasitology; same requirement;</li> <li>- 42 CFR § 493.919(b) Virology; same requirement.</li> </ul>

**3. 17 CCR §1050(b)(3) – Proficiency Testing**

Subdivision (b)(3) requires that a laboratory perform a proficiency test each time test materials are received by an approved proficiency testing service. BPC 1220(a)(2)(A) supersedes this requirement by further expanding the responsibilities of the laboratory. Rather than require the laboratory to follow the testing schedule of lab procedures (as approved by the department and determined by the proficiency testing company), the laboratory must test based upon a different schedule -- at the same number of times and the same manner that it tests patient samples. Therefore, based upon the chart below which provides a side-by-side comparison of the conflicting law, the department has no discretion but to repeal section 1050 subdivision(b)(3) because when there is a conflict, the later adopted statute prevails because it is presumed that the legislators intended to change law when it passed later statutes.

<sup>7</sup> Subpart H incorporates Subpart I as noted in 17 CCR 1050(a)

17 CCR §1050(b)(3)	BPC 1220(a)(2)(A) (incorporating CLIA Subparts H, I, J, K)	Subpart H is defined by 42 CFR commencing with §493.801
"Those procedures performed by the laboratory for which test materials are provided by the approved proficiency testing service and which have been designated by the department as a requirement for measuring test performance, must be proficiency tested by the participating laboratory <u>each time test materials are received.</u> "	Same language as noted in above table for item #2. The later adopted statute prevails over 17 CCR 1050(b)(3)	<ul style="list-style-type: none"> <li>- <b>42 CFR §493.801(b)</b> "The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the <u>same manner</u> as it tests patient samples.</li> <li>- <b>42 CFR §493.801(b)(2)</b> "The laboratory must test samples the same number of times that it routinely tests patient samples.</li> </ul>

**4. 17 CCR §1050(c) – Director responsibilities.**

After 17 CCR 1050 was promulgated, director responsibilities shifted to less hands-on, on-site supervision to overseeing the "overall operation and administration" of the laboratory by managing the personnel who oversee the laboratories.<sup>8</sup> The trend was to delegate director responsibilities to other supervisors such as technical supervisors, clinical supervisors, clinical consultants, and general supervisors.<sup>9</sup> Directors ensured these supervisors met training, experience and educational requirements.<sup>10</sup> The expansion of specialties such as cytogenetics has necessitated a further division of labor because laboratory directors cannot be knowledgeable in all areas of laboratory testing.<sup>11</sup> Duties within the laboratories became even more separated with the expansion of different clinical laboratory personnel licensure within California.<sup>12</sup> Post-1978 laboratory personnel categories include cytologists, phlebotomist, medical laboratory technician, clinical cytogeneticists, and clinical genetic molecular biologistS.

California later adopted statutes to reflect this change in a laboratory director's role and the operation of a clinical laboratory. BPC section 1209 was first enacted in 1995 via SB 113. It was amended in 2007 (SB 1048) by expanding the number of laboratories a director may serve from the 17 CCR 1050 limit of three to CLIA limits (five for non-waived laboratories and unlimited for waived laboratories).<sup>13</sup> BPC 1209 conflicts with 17 CCR 1050 subdivision (c) as noted in the language of the below chart, the department has no discretion but to repeal section 1050 subdivision (c) because when there is a conflict, the later adopted statute prevails because it is presumed that the legislators intended to change law when it passed later statutes.

<sup>8</sup> See BPC § 1209(b)(1).

<sup>9</sup> See BPC § 1209(a).

<sup>10</sup> See BPC § 1209(d).

<sup>11</sup> See 17 CCR §1031.2.

<sup>12</sup> See various new and updated scopes of practice for personnel licensure under BPC commencing with section 1200.

<sup>13</sup> See BPC § 1209(j) which incorporates 42 CFR §§ 493.1407 and 493.1445.

<p>17 CCR §1050 (c) "The person or persons directing a licensed clinical laboratory shall assume the following responsibilities:"</p>	<p>Conflicting law</p>
<p>17 CCR §1050(c)(1)</p>	<ul style="list-style-type: none"> <li>- "Determine what laboratory procedures will be performed,</li> <li>- the techniques that will be followed and</li> <li>- the equipment and reagents that will be used."</li> </ul> <p><b>BPC §1209 (b)(1)</b>"The laboratory director is responsible for the <u>overall operation and administration</u> of the clinical laboratory, including <u>administering</u> the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and <u>active participation</u> in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be <u>responsible for the proper performance of all laboratory work of all subordinates</u> and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter."</p>
<p>17 CCR §1050(c)(2)</p>	<ul style="list-style-type: none"> <li>- "Determine the scope and nature of procedures to control the reliability of test performance</li> <li>- and <u>personally</u> monitor these control programs."</li> </ul> <p><b>BPC 1209(e) shifts the responsibility under 17 CCR 1050(c)(2) to the technical consultant or technical supervisor.</b></p> <p>"The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a <u>technical consultant or a technical supervisor</u> under CLIA depending on the type and complexity of tests being offered by the laboratory. (1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following: (A) <b>Direct observations of routine patient test performance</b>, including patient preparation, if applicable, and specimen handling, processing, and testing. (B) Monitoring the recording and reporting of test results. (C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. (D) Direct observation of performance of instrument maintenance and function checks. (E) <b>Assessment of test performance</b> through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. (F) Assessment of problem solving skills. (2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation."</p>

<p>17 CCR §1050(c)(7)</p>	<ul style="list-style-type: none"> <li>• Confer with those served by the laboratory on matters that relate to <u>test performance</u> and</li> <li>• determine the <u>nature and scope</u> of technical and administrative information to be released by the laboratory staff.</li> </ul>	<p>The director is responsible for overall operation and administration of the clinical laboratory and must report results.<sup>14</sup> The director shall <u>specify in writing</u> the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, <u>test performance</u>, or <u>results reporting</u>, and <u>whether consultant, supervisor, or director review is required prior to the individual reporting patient test results</u>.<sup>15</sup> The laboratory director must be available to the laboratory for consultation when needed."<sup>16</sup></p> <p><b>42 CFR §493.1291(e):</b> "The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the <u>performance specifications established or verified</u> as specified in §493.1253. In addition, <u>information that may affect the interpretation of test results, for example test interferences, must be provided</u> upon request. Pertinent <u>updates on testing information</u> must be provided to clients whenever changes occur that affect the test results or interpretation of test results."</p>
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**5. 17 CCR §1050(e)(2) – Equipment and Test Materials**

As noted in the original justification, California incorporated CLIA regulations for quality control (subpart K) and quality assurance (subpart P).<sup>17</sup> Quality Control is widely known in CLIA as a system for verifying and maintaining a desired level of quality in an individual test or process. Quality control (subpart K) activities begin with specimen collection and ends when the physician receives the report. Quality assurance (subpart P) is widely known as the monitoring of quality control results and quality practice control parameters to ensure that all systems are functioning in a manner appropriate.

Subpart K and P expanded the requirements of equipment and test materials to ensure proper handling, preservation and supplies that far outnumber the few details outlined in this section of the CCR. There is more flexibility afforded to laboratories to establish and follow their own written policies and procedures regarding quality control and assurance to ensure the accuracy and safety of lab testing protocols such as labeling and

<sup>14</sup> See BPC §1209(b)(1).

<sup>15</sup> See BPC §1209(b)(1).

<sup>16</sup> See 42 CFR §493.1407(c).

<sup>17</sup> SB 75 (Chapter 18, Statutes of 2015) amended BPC §1220(d)(2), updating the incorporated version of Subpart K, as follows: "[a clinical laboratory performing non-waived tests must] establish and maintain a quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1200) of Title 42 of the Code of Federal Regulations *as in effect on January 1, 2015 . . .*" References to Subparts H, J, and P of CLIA continue to refer to the regulations in effect on January 1, 1994 which were incorporated into California by BPC §1220(d)(2).

specimen preparations.<sup>18</sup> Subpart K and P of CLIA are controlling law and conflict with 17 CCR 1050(e)(2). Thus, the department has no discretion but to repeal this provision because as noted in the chart below, when there is a conflict, the later adopted statute prevails because it is presumed that the legislators intended to change law when it passed later statutes. Leaving the CCR provisions would frustrate and confuse the regulated community.

17 CCR §1050(e)(2)	Subpart K CLIA as defined by 42 CFR commencing with Section 493.1200	Subpart K CLIA as defined by 42 CFR commencing with Section 493.1200
<p>"All reagents and stains shall be</p> <ul style="list-style-type: none"> <li>• dated at the time of preparation and</li> <li>• initialed by the person making the reagents or stains,</li> <li>• or the date received and date opened if commercially prepared reagents or stains are used. "</li> </ul>	<p><b>42 C.F.R. §493.1252(c) - Standard: Test systems, equipment, instruments, reagents, materials, and supplies</b>          "(b) The laboratory must define criteria for those conditions that are essential for <u>proper storage of reagents and specimens...</u>"</p> <p><b>42 C.F.R. §493.1256(e)</b> For <u>reagent</u>, media, and supply checks, the laboratory must do the following:</p> <p>(1) Check each batch (prepared in-house), lot number (<u>commercially prepared</u>) and shipment of <u>reagents</u>, disks, stains, antisera, (except those specifically referenced in § 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more <u>reagents</u>, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.</p> <p>(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate...</p> <p>(5) Follow the manufacturer's specifications for using <u>reagents</u>, media, and supplies and be responsible for results.</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.</p>	<p><b>42 CFR § 493.1242 - Specimen submission, handling, and referral</b>          "(a) <u>The laboratory must establish and follow written policies and procedures</u> for each of the following, if applicable:</p> <ol style="list-style-type: none"> <li>(1) Patient preparation.</li> <li>(2) Specimen collection.</li> <li>(3) <u>Specimen labeling</u>, including patient name or unique patient identifier and, when appropriate, <u>specimen source</u>.</li> <li>(4) Specimen storage and preservation.</li> <li>(5) Conditions for specimen transportation.</li> <li>(6) Specimen processing.</li> <li>(7) Specimen acceptability and rejection.</li> <li>(8) Specimen referral.</li> </ol> <p>(b) The laboratory must document the date and time it receives a specimen."</p> <p><b>42 CFR § 493.1251 – Procedure Manual</b>          "(a) A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel...</p> <p>(b) The procedure manual must include the following when applicable to the test procedure:</p> <ol style="list-style-type: none"> <li>(1) Requirements for patient preparation; <u>specimen collection</u>, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in § 493.1242.</li> <li>(2) Microscopic examination, including the detection of inadequately prepared slides.</li> <li>(3) Step-by-step performance of the procedure, including test calculations and interpretation of results.</li> <li>(4) <u>Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.</u></li> </ol>

<sup>18</sup> See 42 CFR §493.1242(a).

		<p>(5) Calibration and calibration verification procedures.                  (6) The reportable range for test results for the test system as established or verified in § 493.1253.                  (7) Control procedures.                  (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.                  (9) Limitations in the test methodology, including interfering substances.                  (10) Reference intervals (normal values).                  (11) Imminently life-threatening test results, or panic or alert values.                  (12) Pertinent literature references.                  (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values..."</p>
<p>"All reagents and stains shall be labeled to indicate identity, and titer, strength, or concentration."</p>	<p><b>42 C.F.R. §493.1252(c)</b> "<u>Reagents, solutions, culture media</u>, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:                  (1) <u>Identity</u> and when significant, <u>titer, strength or concentration</u>.                  (1) Identity and when significant, titer, strength or concentration."</p>	
<p>"Recommended storage temperature and expiration date . . ."</p>	<p><b>42 C.F.R. §493.1252(c)</b> "(2) Storage requirements.                  (3) Preparation and expiration dates."</p>	
<p>"and other pertinent information necessary for quality control must be on the label."</p>	<p><b>42 C.F.R. §493.1252(c)</b> "(4) Other pertinent information required for proper use."                  (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.                  (e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer."</p>	

**6. 17 CCR §1050(f) – Records - Cytology Specimen Documents.**

Cytology is the study of the function and structure of cells. As noted in the original justification, the later enacted statute of BPC 1220 which incorporates subpart K of CLIA was adopted and allows for a custom approach for laboratories to establish their own written policies and procedures to maintain specimen

identification and to reduce the risk of errors when examining cytological slides.<sup>19</sup> Since 1978 when this provision of the CCR was promulgated, many changes to laboratory practices have made this provision outdated. Computerized systems replaced many record keeping systems which negated the need for manual cross-filing of patient testing.<sup>20</sup> Legislation has updated the use of online access to patient records which negates the need to maintain detailed personal history by the laboratory.<sup>21</sup> Improved scientific techniques and technology has changed the practice of cytology. Recent changes such as AB 599 (Bonilla, 2015) modified BPC 1270, so that cytologists' scope of practice is expanded from only performing microscopic analysis on slides for cell screening to utilizing newer non-microscopic methodologies such as polymerase chain reaction testing (also known as PCR) that utilize molecular and genetic methodologies to identify infectious disease or assist with cancer diagnosis. Therefore, as noted in the language of the below chart, the department has no discretion but to repeal section 1050 subdivision (c) because when there is a conflict, the later adopted statute prevails because it is presumed that the legislators intended to change law when it passed later statutes.

<p>17 CCR §1050(f) <b>17 CCR §1050(f)(2)</b> "The laboratory shall maintain cytology records indicating the daily accession of specimens, each of which is numbered, and an appropriate cross-filing system according to patient's name."</p>	<p>Subpart K CLIA 42 as defined by 42 CFR commencing with Section 493.1200 <b>42 CFR § 493.1232</b> "The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results."  <b>42 CFR § 493.1291(a) – Test report</b> "The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (1) Results reported from calculated data. (2) Results and patient-specific data electronically reported to network or interfaced systems. (3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p>
<p><b>17 CCR §1050(f)(2)(A)(4)</b> "Minimum information provided shall include: <u>source of specimen</u> (anatomic site), <u>age</u> of patient, <u>previous therapy</u> (endocrine, surgical, radiation, birth control, etc.), <u>gynecologic history</u> on cervical-vaginal specimens, including date and normalcy of patient's last menstrual period, duration of patient's current pregnancy, if any,</p>	<p><b>42 CFR § 493.1241</b> (c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The <u>sex</u> and <u>age</u> or date of birth of the patient.</p>

<sup>19</sup> See 42 CFR §493.1232.

<sup>20</sup> See Federal Register, Vol. 79, No. 25, February 6, 2014 (<https://www.gpo.gov/fdsys/pkg/FR-2014-02-06/pdf/2014-02280.pdf#page=2>)

<sup>21</sup> See California Health and Safety Code §123100 which state, "The Legislature finds and declares that..persons having responsibility for decisions respecting the health care of others should, in general, have access to information on the patient's condition and care. It is, therefore, the intent of the Legislature in enacting this chapter to establish procedures for providing access to health care records or summaries of those records by patients and by those persons having responsibility for decisions respecting the health care of others (Stats. 1995, Ch. 415, Sec. 8, effective January 1, 1996).

<p>and patient's menopausal status or essential history on non-gynecologic specimen."</p>	<p>(4) The test(s) to be performed.          (5) The <u>source of the specimen</u>, when appropriate.          (6) The date and, if appropriate, time of specimen collection.          (7) For <u>Pap smears</u>, the <u>patient's last menstrual period</u>, and <u>indication of whether the patient had a previous abnormal report, treatment, or biopsy</u>.          (8) <u>Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable</u>.          (d) The <u>patient's chart or medical record may be used as the test requisition or authorization</u> but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.          (e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p><b>42 CFR § 493.1274(c)(2)</b>  <u>"Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies."</u></p> <p><b>42 CFR § 493.1291(b), (c), (l)</b>  <u>"(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</u>  <u>(c) The test report must indicate the following:</u>          (1) For <u>positive patient identification</u>, either the patient's name and identification number, or a unique patient identifier and identification number.          (2) The name and address of the laboratory location where the test was performed.          (3) The test report date.          (4) The test performed.          (5) Specimen source, when appropriate.          (6) The test result and, if applicable, the units of measurement or interpretation, or both.          (7) <u>Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</u>  <u>(l) Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient."</u></p>
<p><b>17 CCR §1050(f)(3)(C) – Cytology Laboratory Records</b>  <u>"Laboratories shall utilize reporting systems that are as explicit as is cytologically feasible and must include acceptable morphologic terminology<sup>22</sup>."</u></p>	<p><b>42 CFR § 493.1241(e)(5) - Cytology</b> <u>"The report contains narrative descriptive nomenclature for all results."</u></p>

<sup>22</sup> Morphologic terminology uses scientific terms to describe the form and structure of organisms.

**7. 17 CCR §1050(g) – Quality Control**

Quality control is defined above. This provision only requires limited protocols of labeling patient identification and the vague requirement of “appropriately prepared” by the submitter. The later enacted statute of subpart K of the CFR is more specific regarding the submission, handling and referral of specimen as noted in the language of the below chart. The department has no discretion but to repeal section 1050 subdivision (c) because when there is a conflict, the later adopted statute prevails because it is presumed that the legislators intended to change law when it passed later statutes.

	<b>Subpart K CLIA</b>	<b>Subpart K CLIA</b>
<p><b><u>17 CCR §1050(g)(2)(A) - Additional Cytology</u></b>            “Specimen Identification. All smears and other specimens shall be <u>labelled</u> for patient <u>identification</u> and <u>appropriately prepared</u> by the submitter.”</p>	<p><b>42 CFR §493.1242 Specimen submission, handling, and referral</b>            (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable:            (1) Patient preparation.            (2) Specimen collection.            (3) Specimen labeling, including <u>patient name</u> or <u>unique patient identifier</u> and, when appropriate, specimen source.            (4) Specimen <u>storage</u> and preservation.            (5) Conditions for specimen <u>transportation</u>.            (6) Specimen <u>processing</u>.            (7) Specimen <u>acceptability</u> and rejection.            (8) Specimen referral.            (b) The laboratory must document the date and time it receives a specimen.            (c) The laboratory must refer a specimen for testing only to a CLIA–certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.            (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p>	<p><b>42 CFR §493.1276 – Clinical cytogenetics</b> “(a) The laboratory must have policies and procedures for <u>ensuring accurate and reliable patient specimen identification</u> during the process of accessioning, cell preparation...”</p>
<p><b><u>17 CCR §1050(g)(2)(B)(2) - Additional Cytology</u></b>            “<u>Staining</u> quality of cytologic specimens shall be <u>checked at least once daily</u>, with suboptimal results corrected immediately.”</p>	<p><b>42 CFR §493.1256 – Control procedures</b>            (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.            (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable,</p>	

	<p>the performance specifications verified or established by the laboratory as specified in § 493.1253(b)(3).                  (c) <u>The control procedures must—</u>                  (1) <u>Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.</u>                  (2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.                  - (e)(2): "[For reagent, media, and supply checks, the laboratory must do the following:] (2) <u>Each day of use</u> (unless otherwise specified in this subpart), <u>test staining</u> materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate."</p>	
<p><b><u>17 CCR §1050(g)(2)(B)(3) - Additional Cytology</u></b>                  "Gynecologic specimens shall be processed totally separately from non-gynecologic specimens."</p>	<p><b><u>42 CFR §1274 Cytology</u></b>                  "(b) "The laboratory <u>must have available</u> and follow written policies and procedures for each of the following...                  (2) <u>Effective measures to prevent cross-contamination</u> between gynecologic and nongynecologic specimens during the staining process must be used."                  "(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining."</p>	

**8. 17 CCR §1050(h) – Clinical Laboratory Test Results**

This provision conflicts with later adopted BPC section 1209.5, added by AB 2156 (Stats. 2006, ch. 319), which allows for an automated review process called "autoverification." Autoverification was used in almost all states and is considered "state of the art" practice.<sup>23</sup> It is supposed to improve efficiency and accuracy in the reporting of laboratory results.<sup>24</sup> Clearly, the legislators intended to change the verification of lab results when it enacted BPC section 1209.5 to reflect updated laboratory technology. As noted in the language of the below chart, the

<sup>23</sup> Assembly Bill 2156, August 23, 2006 Assembly Floor Analysis

<sup>24</sup> Id.

department has no discretion but to repeal section 1050 subdivision (c) because when there is a conflict, the later adopted statute prevails because it is presumed that the legislators intended to change law when it passed later statutes.

<p><b>17 CCR §1050(h)</b>          "Clinical laboratory test results <u>shall not be reported</u> from the laboratory until "</p>	<p><b>BPC §1209.5</b>          (e) A person licensed to perform the applicable type and complexity of testing pursuant to Section 1206.5 shall be physically present onsite in the clinical laboratory and shall have documented competency pursuant to <b>Section 1209</b> in all tests being autoverified, and shall be responsible for the accuracy and reliability of the results of the clinical laboratory test or examination when the results are autoverified <u>and reported</u>.</p> <p><b>BPC §1209</b>          (d)(1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory...          (f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:          (3) <u>Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.</u></p>
<p>- "these results have been <u>critically reviewed</u> and <u>verified for accuracy, reliability, and validity</u> by a licensed physician and surgeon or a person, other than a trainee, duly licensed under Chapter 3, Division 2, Business and Professions Code (commencing with Section 1200)."</p>	<p><b>BPC §1209.5</b>          (a) "Autoverification" means the use of a computer algorithm in conjunction with automated clinical laboratory instrumentation to <u>review and verify</u> the results of a clinical laboratory test or examination for <u>accuracy and reliability</u>.          (b) The <u>laboratory director or authorized designee shall establish, validate, and document explicit criteria</u> by which the clinical laboratory test or examination results are autoverified.          (c) The laboratory director or authorized designee shall annually revalidate the explicit criteria by which the clinical laboratory test or examination results are autoverified. The laboratory director shall approve and annually reapprove the computer algorithm.          (d) An authorized designee may be appointed by the laboratory director for the purposes of this section. The authorized designee shall be licensed to engage in clinical laboratory practice pursuant to this chapter and shall be qualified as a clinical consultant, technical supervisor, general supervisor, or technical consultant pursuant to regulations adopted by the department.</p>

**California Code of Regulations  
Title 17. Public Health  
Division 1. Department of Health Services  
Chapter 2. Laboratories  
Subchapter 1. Service Laboratories  
Group 2 Clinical Laboratory Regulations  
Article 5. Issuance of License**

**Sections Affected: 1050**

<b>Subdivision (a):</b> Repeal section 1050, subdivision (a).....	3
<b>Subdivision (b):</b> Repeal section 1050, subdivision (b). ....	4
<b>Subdivision (c):</b> Repeal section 1050, subdivision (c).....	6
<b>Subdivision (d):</b> Renumber section 1050, subdivision (d). ....	13
<b>Subdivision (e):</b> Repeal section 1050, subdivision (e). ....	13
<b>Subdivision (f):</b> Repeal section 1050, subdivision (f). ....	14
<b>Subdivision (g):</b> Repeal section 1050, subdivision (g). ....	19
<b>Subdivision (h):</b> Repeal section 1050, subdivision (h). ....	23
<b>Section 1050 Authority and Reference:</b> Eliminate Business and Professions Code section 1245 from the Authority and Reference. ....	24
<b>Appendix: 1050 Comparison Chart/Crosswalk</b> .....	25

**Justification for Changes Without Regulatory Effect:**

The California Department of Public Health (Department) proposes to amend California Code of Regulations, title 17, section 1050, by repealing subdivisions (a), (b), (c), (e), (f), (g), and (h). Subdivision (d), which is not repealed by this action, is renumbered for clarity. This repeal would make the Department's regulations consistent with revisions to the Business and Professions Code, sections 1206.5, 1208, 1209, 1209.5, 1220, 1228, 1265, 1269, and 1271 as amended by Senate Bill (SB) 113 (Maddy, Stats. 1995, ch. 510) and SB 75 (Stats. 2015, ch. 18).

Division 2, chapter 3 of the Business and Professions Code provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the Department. The Department promulgated regulations concerning proficiency testing, director requirements, facilities administration, equipment and test materials, retention of records, quality control, and reporting of test results in California Code of

Regulations, title 17, section 1050. Section 1050 was last amended in 1978 (Cal. Reg. Notice Register 78, No. 41).

In 1988, the federal government significantly expanded its oversight of clinical laboratories by enacting the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (Pub.L. No. 100-578 (Oct. 31, 1988); 42 U.S.C. § 263a). Federal regulations implementing CLIA were first published in 1992 under 42 Code of Federal Regulations part 493. The CLIA regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease.

In 1995, the California legislature enacted SB 113, revising significant portions of division 2, chapter 3 of the Business and Professions Code. The uncodified language of SB 113 indicates the intent of the bill, which was to enact state laws consistent with CLIA and the federal scheme.<sup>1</sup> Under SB 113, Business and Professions Code section 1220 was amended to require that a clinical laboratory performing non-waived tests<sup>2</sup> meet the standards of the CLIA regulations under the following subparts: participation in a proficiency testing program under Subpart H; establishment of a patient test management system under Subpart J; establishment of a quality control program under Subpart K; and establishment of a comprehensive quality assurance program under Subpart P.<sup>3</sup>

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<sup>1</sup> SB 113 (Stats. 1995, ch. 510, § 1, subd. (a)) "It is the intent of the Legislature in enacting this act to accomplish all of the following: (1) To enact state laws regulating clinical laboratories and clinical laboratory personnel that are consistent with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a). (2) To enact state laws that are at least as stringent as the requirements of CLIA . . . (5) To enact state laws that ensure that the State of California has enforcement authority and administrative structures adequate to enforce the requirements of CLIA and the state laws regulating clinical laboratories and clinical laboratory personnel."

<sup>2</sup> All clinical laboratory test systems, assays, or examinations are classified according to their complexity by the U.S. Food and Drug Administration, which fall broadly into two categories: a waived test, which is a simple laboratory examination or procedure that has an insignificant risk of an erroneous result and meets the statutory criteria specified under section 353(d)(3) of the Public Health Service Act (42 U.S.C. § 263a(d)(3)); and a non-waived test, which includes a moderate or high complexity test that does not meet the statutory criteria for a waived test.

<sup>3</sup> Unless explicitly stated otherwise, the incorporated "CLIA" provisions in division 2, chapter 3 of the Business and Professions Code means the version of the federal regulations *in effect on January 1, 1994*. See Bus. & Prof. Code § 1202.5, subd. (a) "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."

SB 75 (Chapter 18, Statutes of 2015) amended Bus. & Prof. Code § 1220, subd. (d)(2), updating the incorporated version of Subpart K, as follows: "[a clinical laboratory performing non-waived tests must] establish and maintain a quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1200) of Title 42 of the Code of Federal Regulations as *in effect on*

This action qualifies as a California Code of Regulations, title 1, section 100 because it does not materially alter any requirement, right, responsibility, condition, prescription, or other regulatory element of any California Code of Regulations provision.

California Code of Regulations, title 17, section 1050, subdivisions (a)-(c) and (e)-(h), is superseded by the amended Business and Professions Code sections and the incorporated CLIA regulations under SB 113 and SB 75. The Department has no discretion to adopt a change in substance other than to repeal section 1050 as to the specified subdivisions, as the later adopted revisions to the Business and Professions Code and the incorporated CLIA regulations constitute the controlling standard.<sup>4</sup>

## **Chapter 2. Laboratories**

### **Section 1050, Clinical Laboratory Standards**

**Subdivision (a):** Repeal section 1050, subdivision (a).

California Code of Regulations, title 17, section 1050, subdivision (a), states that “all licensed clinical laboratories be conducted, maintained, and operated without injury to the public health and shall maintain records, equipment, and facilities which are adequate and appropriate for the services rendered and demonstrate satisfactory performance in a proficiency program approved by the department.”

Subdivision (a) comprises three distinct requirements. First, the requirement that a laboratory maintain records, equipment, and facilities which are adequate and appropriate for the services rendered is duplicated in Business and Professions Code section 1220, subdivision (a)(1) (identical language).<sup>5</sup> Second, the requirement that a laboratory be maintained without injury to the public health is duplicated in Business and Professions Code section 1220, subdivision (b) (identical language). Because the regulation is textually identical to the statute, the repeal of this subdivision will not materially alter any requirement.

Third, the requirement that a laboratory must “demonstrate satisfactory performance in a proficiency testing program approved by the department” is less specific and inconsistent with Business and Professions Code section 1220, subdivision (a)(2)(A).

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*January 1, 2015 . . .*” References to Subparts H, J, and P of CLIA continue to refer to the regulations in effect on January 1, 1994.

<sup>4</sup> Cal. Code Regs., tit. 1, § 100, subd. (6).

<sup>5</sup> For each provision, please refer to the attached “Appendix: 1050 Comparison Chart/Crosswalk” for the full text of Cal. Code Regs., tit. 17, section 1050, and its corresponding statutes and incorporated CLIA regulations that are the basis of this action.

Section 1220, subdivision (a)(2)(A), alternatively permits participation in proficiency testing as approved by the Health Care Financing Administration (HCFA), which is not included in the regulation.<sup>6</sup> Section 1220, subdivision (a)(2)(A), further specifies that proficiency testing is to be conducted to the extent required under CLIA in Subpart H, which is also absent from the regulation. The repeal of this regulation, which misstates the modern proficiency testing statutory requirements, will not materially alter any requirement.

**Subdivision (b):** Repeal section 1050, subdivision (b).

California Code of Regulations, title 17, section 1050, subdivision (b), set standards for an approved proficiency testing program; however, it predates the adoption of SB 113. SB 113 amended Business and Professions Code section 1220, subdivision (a)(2)(A), to require instead that a proficiency testing program meet the requirements of CLIA in Subpart H (commencing with 42 C.F.R. § 493.801). The provisions of subdivision (b) are superseded by the later adopted statute and the incorporated CLIA regulations in Subpart H, as set out below.

Subdivision (b)(1), requiring participation in a state approved proficiency testing program for the specialties of microbiology, serology, clinical chemistry, hematology, and immunohematology, is duplicated in Business and Professions Code section 1272 (identical language). Because the regulation is identical to the statute, the repeal of this provision will not materially alter any requirement.

Subdivision (b)(2) states that "[t]he participating laboratory must test applicable materials each time they are distributed by the approved proficiency testing service according to a schedule approved by the department." This regulation is inaccurate, as the testing schedule is now provided for in statute and in the incorporated CLIA regulation. Under amended Business and Professions Code section 1220, subdivision (a)(2)(A), a proficiency testing program must instead meet the requirements of CLIA in Subpart H, which shall supply the testing schedule. Under the incorporated CLIA regulation, all approved proficiency testing programs require 5 samples (i.e. challenges) per testing event, and three testing events per year.<sup>7</sup> Because the state regulation conflicts with Business and Professions Code section 1220, subdivision (a)(2)(A) and

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<sup>6</sup> CMS is the successor agency of the HCFA.

<sup>7</sup> Each subspecialty of the specified disciplines has the same material requirement for program content and frequency of challenge. See, e.g., 42 C.F.R. § 493.911(b) "Program content and frequency of challenge. To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year"; 42 C.F.R. § 493.913(b) Mycobacteriology; same requirement; 42 C.F.R. § 493.915(b) Mycology; same requirement; 42 C.F.R. § 493.917(b) Parasitology; same requirement; 42 CFR § 493.919(b) Virology; same requirement.

the incorporated CLIA regulation, a repeal of this provision will not materially alter any requirement.

Subdivision (b)(3) requires that a laboratory perform a proficiency test each time test materials are received by an approved proficiency testing service. This requirement is duplicated in 42 C.F.R. § 493.801(b), which, in relevant part, also requires that that a laboratory must test each sample it receives from an approved testing service. The repeal of this provision, which is duplicated in the incorporated CLIA regulation, will not materially alter any requirement.

Subdivision (b)(4) states that “[t]he participating laboratory must authorize the approved proficiency testing service to report proficiency test results to the department.” This requirement is duplicated and extended by Business and Professions Code section 1220, subdivision (2)(B), which adds that reported results shall be “in an electronic format that is compatible with the department's proficiency testing data monitoring system and shall authorize the release of proficiency tests results to the public to the same extent required by CLIA.” Because the regulation is subsumed within the statute, the repeal of this provision will not materially alter any requirement.

Subdivision (b)(5) states that “[t]he participating laboratory must test applicable materials only in the laboratory to which the license and the proficiency testing requirement applies using personnel and equipment used in that facility in providing services.” This provision comprises two distinct requirements. First, the requirement that a laboratory shall only test materials in the participating laboratory is duplicated in 42 C.F.R. § 493.801(b)(4), prohibiting the sharing of proficiency testing samples with another laboratory “[t]he laboratory must not send PT samples or portions of samples to another laboratory for any analysis . . . . Second, the requirement that a laboratory shall use personnel and equipment of that facility is duplicated in by 42 C.F.R. § 493.801(b)(1), stating that “[t]he samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.” Because the state regulation is substantively duplicated in all material parts by the incorporated CLIA standards, the repeal of this provision will not materially alter any requirement.

Subdivision (b)(6) states that a laboratory may be required to discontinue providing a service in a procedure or category it does not achieve satisfactory performance on required proficiency testing for “three consecutive quarters.” Because the testing schedule no longer follows the quarter system, this regulation directly conflicts with the CLIA standard, incorporated by Business and Professions Code section 1220, subdivision (a)(2)(A). Under CLIA, a laboratory may be sanctioned for failure to achieve an overall testing event score of satisfactory performance for “two consecutive testing

events" or "two out of three consecutive testing events."<sup>8</sup> Because proficiency testing no longer follows the quarter system, and the incorporated CLIA regulation defines failure more strictly (i.e., two out of three unsatisfactory performances, rather than three consecutive quarters), a repeal of this conflicting provision will not materially alter any requirement.

Subdivision (b)(7) states that a laboratory whose services have been disapproved may apply for reapproval after "demonstrating satisfactory performance during two consecutive quarters or testing periods immediately prior to requesting reapproval." This subdivision conflicts with the incorporated CLIA regulation because proficiency testing does not follow the quarter system, and because the incorporated CLIA regulation stipulates that one of the proficiency testing events may be monitored on site. 42 C.F.R. § 493.807(a) states that after disapproval for a procedure or category of procedures, "a laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site," before reinstatement will be considered. Because the incorporated CLIA provision requires satisfactory performance on two consecutive proficiency testing events, one of which may be on site, rather than satisfactory performance during two consecutive quarters or testing periods, the repeal of this provision will not materially alter any requirement.

**Subdivision (c):** Repeal section 1050, subdivision (c).

California Code of Regulations, title 17, section 1050, subdivision (c), uniformly set the required duties for all laboratory directors irrespective of test complexity. This regulation predates the adoption of SB 113.<sup>9</sup> Under SB 113, the legislature amended Business and Professions Code section 1209 ("Laboratory director" defined; responsibilities; qualifications") to stratify duties based on the classification of the clinical laboratory

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<sup>8</sup> See 42 C.F.R. §493.803(b) "If the laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, sanctions will be taken as defined in subpart R of this part." Failure is identically defined for each subspecialty in Subpart H. See, e.g., 42 C.F.R. § 493.823(e) (Bacteriology; "Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.").

<sup>9</sup> The text of subdivision (c) states that "the person or persons directing a licensed clinical laboratory shall assume the following responsibilities . . .," which would imply that the director of a registered laboratory need not meet those provisions. Counterintuitively, Cal. Code Regs., title 17, § 1029.108 defines "license" for the purpose of the regulations to mean "license, certificate, registration or other means to engage in a business or profession regulated by Chapter 3." Consequently, subdivision (c), though it is directed at a "licensed" laboratory, applies to the director of a licensed laboratory and the director of a registered laboratory.

(i.e., the director's duties vary as to whether the laboratory is "registered" or "licensed").<sup>10</sup> The provisions of subdivision (c) do not capture the specificity and complexity of the two-tiered duty scheme, and must be repealed, as below.<sup>11</sup>

Subdivision (c)(1) states that a director of a clinical laboratory shall assume the responsibility to "[d]etermine what laboratory procedures will be performed, the techniques that will be followed, and the equipment and reagents that will be used." This requirement is subsumed within Business and Professions Code section 1209, subdivision (b)(1), stating that "[t]he laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA . . . ." Because the requirement is materially duplicated in the statutory provision, the repeal of this provision will not materially alter any requirement.

Subdivision (c)(2) states that the laboratory director must "[d]etermine the scope and nature of procedures to control the reliability of test performance and personally monitor these control programs." Subdivision (c)(2) comprises two distinct parts. First, the requirement to determine the scope and nature of procedures to control reliability is duplicated in Business and Professions Code section 1209, subdivision (b)(1) "The laboratory director is responsible for . . . the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures . . . ."; section 1209, subdivision (c) as to a registered laboratory, documenting the adequacy of personnel performing or supervising tests; and section 1209, subdivisions (d) and (e) as to a licensed laboratory, ensuring the competency of staff and establishing policies and

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<sup>10</sup> California maintains two license categories based on the complexity of tests performed by the clinical laboratory. A laboratory that performs tests or examinations classified as moderate or high complexity under CLIA must obtain "a clinical laboratory license," whereas a clinical laboratory that performs tests or examinations subject to a certificate of waiver or a certificate of provider-performed microscopy under CLIA must "register" with the department. See Bus. & Prof Code § 1265, subd. (a).

California imposes stricter requirements on "licensed," as compared to "registered," laboratories because of the complexity of tests performed. See, e.g., Bus. & Prof. Code § 1220, subd. (c) (licensed clinical laboratories are subject to routine inspection, whereas registered clinical laboratories are explicitly exempt); Bus. & Prof. Code § 1220, subd. (d)(2) (the patient test management and the quality control program of CLIA does not apply to a laboratory which only performs waived tests); Bus. & Prof. Code § 1220, subd. (a)(2)(a) (no proficiency testing for waived testing). A "registered" laboratory is subject to the condition that all clinical laboratory tests or examinations classified as waived under CLIA must be performed in conformity with the manufacturer's instruction. Bus. & Prof. Code § 1220, subd. (d)(1).

<sup>11</sup> Apart from CLIA, each laboratory director must meet the general requirements of Bus. & Prof. Code § 1209, subd. (b). Additionally, a director of a registered laboratory must meet the requirements of Bus. & Prof. Code § 1209, subd. (c); and a director of a licensed laboratory must meet the requirements of Bus. & Prof. Code § 1209, subd. (d) & (e).

procedures for monitoring individuals for testing. Second, personal monitoring is duplicated in Business and Professions Code section 1209, subdivision (b)(1) " active participation in its operations to the extent necessary to ensure compliance with this act and CLIA", and section 1209, subdivision (e) as to a licensed laboratory, the director or other specified staff must evaluate staff performance, including " direct observation of routine patient test performance . . . ." Because all material requirements of the regulation are duplicated in statute, the repeal of this regulation will not materially alter any requirement.

Subdivision (c)(3) requires that the laboratory director "[r]egularly assess the activities of the laboratory by personal observation, evaluation, and review of reports of laboratory findings." The requirement of regular assessment by personal observation, evaluation, and review of findings is superseded by later adopted statutes, as follows:

Subdivision (c)(3)	Superseding Requirements	Explanation
<p>"[r]egularly assess the activities of the laboratory by personal observation . . . ."</p>	<p>Bus. &amp; Prof. Code § 1209, subd. (b)(1):            "The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including . . . the selection and supervision of procedures . . . and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA . . . ."</p> <p>Bus. &amp; Prof. Code § 1209, subd. (d): "As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following: [¶] . . . ¶] (2) Ensure that policies and procedures are established for monitoring individuals . . . ."</p> <p>Bus. &amp; Prof. Code § 1209, subd. (e):            "The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory. (1) The procedures for evaluating the competency of the staff shall include, but</p>	<p>In the later adopted statute, the director is responsible for the operation and administration of the clinical laboratory, including, without limitation, "supervision" of procedures and "active participation."</p> <p>The director of a licensed laboratory (or designated technical consultant or supervisor) must also make "direct observation" of clinical laboratory functions, which is equivalent to the regulation's mandate of "personal observation."</p>

	<p>are not limited to, all of the following: (A) Direct observations of routine patient test performance . . . .”</p>	
<p>“[r]egularly assess the activities of the laboratory by . . . evaluation, . . .”</p>	<p>Bus. &amp; Prof. Code § 1209, subd. (b)(1):              “The laboratory director is responsible for . . . the selection and supervision of procedures . . . .”</p> <p>Bus. &amp; Prof. Code § 1209, subd. (e):              “The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory. (1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following: [¶] . . . [¶] (2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens.”</p>	<p>In the later adopted statute, the director of a licensed laboratory (or designated technical consultant or supervisor) is required to assess the laboratory through “evaluation” of the staff, which must occur at least semiannually during the first year an individual tests biological specimens.</p>
<p>“[r]egularly assess the activities of the laboratory by . . . review of reports of laboratory findings.”</p>	<p>Bus. &amp; Prof. Code § 1209, subd. (e):              “The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory. (1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following: [¶] . . . [¶] (B) Monitoring the recording and reporting of test results. (C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. (D) Direct observation of performance of</p>	<p>In the later adopted statute, the director of a licensed laboratory (or designated technical consultant or supervisor) must review reports of laboratory findings (“[m]onitoring the recording and reporting of test results”), but must also review intermediate test results, quality control records, proficiency testing results, maintenance records, and maintenance and function checks,</p>

	instrument maintenance and function checks. (E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.”	among other activities.
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The repeal of subdivision (c)(3) will not materially alter any requirement.

Subdivision (c)(4) states that the laboratory director must “[e]stablish qualification criteria of laboratory personnel.” The requirement to establish qualification criteria is duplicated in statute, but the regulation does not include the requirement to use CLIA as a basis for establishing the qualification criteria as mandated in statute. Business and Professions Code section 1209, subdivision (c), requires that director of a registered laboratory must “document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations.” Business and Professions Code section 1209, subdivision (d), requires that a director of a licensed laboratory “[e]nsure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered . . .” and consider in determining the adequacy of qualifications “any CLIA requirements relative to the education or training of personnel.” Because the regulation is materially duplicated in statute, and because it does not contain the statutory criteria for setting personnel qualifications, the repeal of this regulation will not materially alter any requirement.

Subdivision (c)(5) states that the laboratory director must “[d]etermine the format of laboratory report forms and decide what information is to be contained on these report forms.” This regulation conflicts with the statutorily incorporated CLIA regulation, which, rather than leaving it to the discretion of the laboratory director, requires certain minimum information be included on a report form. 42 C.F.R. § 493.1291(c) (Standard: Test report) requires that a test report include the following: “(1) [f]or positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (2) The name and address of the laboratory location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.” Since subdivision (c)(5) conflicts with the incorporated CLIA regulation, which mandates certain information on report forms, the repeal of this provision will not materially alter any requirement.

Subdivision (c)(6) states that the laboratory director “[r]egularly consult with supervisors and other staff members.” The requirement to regularly consult with supervisors and

staff is superseded by the incorporated CLIA provision, 42 C.F.R. § 493.1407(c), which mandates that “[t]he laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.” Both provisions functionally require that the director is available to laboratory personnel. The repeal of subdivision (c)(6) will not materially alter any requirement.

Subdivision (c)(7) states that the laboratory director must “[c]onfer with those served by the laboratory on matters that relate to test performance and determine the nature and scope of technical and administrative information to be released by the laboratory staff.” This regulation comprises two distinct requirements. First, the requirement to confer with those served by the laboratory concerning test performance is superseded by the statutorily incorporated CLIA regulations. 42 C.F.R. § 493.1291(e) states that the laboratory must, upon request, make available to clients a list of test methods and performance specifications, and to provide to clients any pertinent updates on testing information that would affect test results or the interpretation thereof (i.e., “matters that relate to test performance”). Further, under 42 C.F.R. § 493.1291(g), the laboratory must “immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.”

Second, the requirement to determine the nature and scope of information to be released by staff is superseded by later adopted statute. Business and Professions Code section 1209, subdivision (d)(3), states that the director of a licensed laboratory shall “[s]pecify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases . . . and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.” Accordingly, under statute, the director must specify what information is shared (i.e., performance of the postanalytic phase, which includes reporting) and whether higher-level review is required before that information is shared. Because both material requirements of subdivision (c)(7) are functionally duplicated in statute and the incorporated CLIA regulation, the repeal of this subdivision will not materially alter any requirement.

Subdivision (c)(8) states that a laboratory director must “[b]e available daily in any laboratory performing cytology and serve as director of no more than three (3) laboratories.” Subdivision(c)(8) comprises two distinct requirements. First, the requirement for a director to be available daily in a laboratory performing cytology is functionally duplicated in statute and the incorporated CLIA regulations; however, the incorporated CLIA regulation permits the director to assume the day-to-day supervisory role, or to delegate that responsibility to another qualified person functioning as a cytology general supervisor. SB 75 amended Business and Professions Code section 1220, subdivision (d)(2)(B), to require that a clinical laboratory establish and maintain a quality control program under CLIA in Subpart K (commencing with part 493.1200). 42 C.F.R.

§ 493.1274(c) (Standard: Cytology) requires that a person serve as a cytology general supervisor qualified under part 493.1469. A cytology general supervisor is the person “responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results” (part 493.1471). Business and Professions Code section 1209, subdivision (a), permits the laboratory director to serve as the general supervisor or technical supervisor,<sup>12</sup> if qualified under CLIA, signifying that the director may serve as the cytology general supervisor and perform the task of daily supervision. If the director does not serve in this capacity, 42 C.F.R. § 493.1445(e)(10) mandates that the laboratory director must “[e]nsure that a general supervisor provides on-site supervision of high complexity test performance . . . .” Because the director or other general supervisor responsible to the director must be available daily under the incorporated CLIA regulations, the repeal of this provision will not materially alter any requirement.

As to the second component of Subdivision (c)(8), the specified three (3) laboratory supervision limit is superseded by Business and Professions Code section 1209, subdivision (h), which alternatively states that “[a] laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.” CLIA permits a laboratory director of a moderate complexity or high complexity laboratory to serve as the director in “no more than five laboratories” under 42 C.F.R. part 493.1407(d) and part 493.1445(d). Accordingly, because the regulation is superseded by statute, which through the incorporated CLIA regulation allows for the supervision of up to five (5) laboratories, the repeal of this subdivision will not materially alter any requirement.

Subdivision (c)(9) states that a laboratory director must “[c]ause a licensed physician or dentist, qualified in cytopathology, to personally examine and report findings on abnormal or questionable gynecologic and all non-gynecologic specimens.”<sup>13</sup> The requirement to have abnormal gynecologic and all non-gynecologic specimens examined by a licensed doctor or dentist is superseded by the statutorily incorporated CLIA regulation, which instead delegates that duty to a “technical supervisor” under 42 C.F.R. § 1274(e)(1) (abnormal gynecologic slides) and 42 C.F.R. § 1274(e)(3) (all nongynecologic slides). A technical supervisor may be a doctor of medicine, doctor of osteopathy, a pathologist, or other technical degree with qualifying laboratory training or experience under 42 C.F.R. §§ 1449(b) and (k). Because subdivision (c)(9) is superseded by the statutorily incorporated CLIA regulation, the repeal of this subdivision will not materially alter any requirement.

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<sup>12</sup> Under CLIA, a technical supervisor “[m]ay perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§ 493.1471 and 493.1485, respectively.” See 42 C.F.R. § 493.1451(c)(1).

<sup>13</sup> Although not specified in this outdated regulation, a cytotechnologist license is required to examine cytological slides unless the person holds a valid, physician’s or surgeon’s certificate. See Bus. & Prof. Code § 1270.

**Subdivision (d):** Renumber section 1050, subdivision (d).

As a result of this action, California Code of Regulations, title 17, section 1050, subdivision (d) is the sole remaining subdivision. To maintain the organization and structure of the regulation, the subdivision marker "(d)" is deleted, and the numbers (1) through (5) are renumbered (a) through (e).<sup>14</sup>

**Subdivision (e):** Repeal section 1050, subdivision (e).

California Code of Regulations, title 17, section 1050, subdivision (e), set standards for equipment and test material; however, the subdivision predates the adoption of SB 75. Business and Professions Code section 1220, subdivision (d)(2)(B), amended by SB 75, requires that a clinical laboratory performing non-waived tests must establish and maintain a quality control system that meets the requirements of CLIA in Subpart K (commencing with part 493.1200). The quality control standards of the statutorily incorporated CLIA regulations supersede the outdated regulation, as set out below.

Subdivision (e)(1) states that "[t]he laboratory must provide for and assure that equipment, instruments, glassware, and reagents are maintained in proper working order by periodic inspection, testing, or calibration in a manner acceptable to the department." The general requirement to assure that equipment is maintained in a manner acceptable to the department is superseded by the statutorily incorporated CLIA regulation, 42 C.F.R. § 493.1254 (Standard: Maintenance and function checks), which specifies two distinct sets of criteria for equipment checks, categorized by whether the equipment is "unmodified manufacturer's equipment, instruments, or test systems" or "[e]quipment, 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 manufacturers." Because subdivision (e)(1) is superseded by the more specific provisions of the statutorily incorporated standard, the repeal of this subdivision will not materially alter any requirement.

Subdivision (e)(2) sets the labeling requirement for reagents and stains. The labeling requirement is duplicated in 42 C.F.R. § 493.1252(c) "Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: . . . ."

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<sup>14</sup> Cal. Code of Regs., tit. 1, § 100, subd. (a)(1).

Subdivision (e)(2)	42 C.F.R. § 493.1252(c)
"[a]ll reagents and stains shall be dated at the time of preparation and initialed by the person making the reagents or stains, or the date received and date opened if commercially prepared reagents or stains are used."	"(3) Preparation and expiration dates."
"All reagents and stains shall be labeled to indicate identity, and titer, strength, or concentration."	"(1) Identity and when significant, titer, strength or concentration."
"Recommended storage temperature and expiration date . . . ."	"(2) Storage requirements. (3) Preparation and expiration dates."
"and other pertinent information necessary for quality control must be on the label."	"(4) Other pertinent information required for proper use."

Because all material provisions of subdivision (e)(2) are duplicated in the incorporated CLIA regulation, the repeal of this provision will not materially alter any requirement.

**Subdivision (f):** Repeal section 1050, subdivision (f).

California Code of Regulations, title 17, section 1050, subdivision (f), titled "Records," set requirements for (1) "Retention of Records," (2) "Cytology Specimen Documents," and (3) "Cytology Laboratory Records." Subdivision (f) predates the adoption of SB 113, which incorporated the patient test management system from CLIA in Subpart J in Business and Professions Code section 1220, subdivision (d)(2)(A); SB 75, which incorporated the quality system requirements from CLIA in Subpart K in Business and Professions Code section 1220, subdivision (d)(2)(B); and AB 1098 (Romero, Stats. 2000, ch. 322), which amended the retention requirements in Business and Professions Code section 1265, subdivision (j). Subdivision (f) is superseded by the foregoing statutes and the incorporated CLIA regulations, as set out below.

Subdivision (f)(1)(A)-(D) states that "[t]he laboratory must maintain for a period of at least two years documentation of the following: (A) Records of specimens received and tested . . . (B) Records of inspection . . . (C) Manuals, card files, or flow charts for each procedure performed in the laboratory . . . (D) Records of quality control procedures . . . ." The two year retention requirement conflicts with Business and Professions Code section 1265, subdivision (j)(2)(A), which requires a minimum three year retention period for medical and laboratory records ("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.”<sup>15</sup> Because the regulation (requiring a two year retention period) conflicts with the statute (minimum three year retention), the repeal of subdivision (f)(1)(A)-(D) will not materially alter any requirement.

Subdivision (f)(1)(E) states that “[t]he laboratory shall retain all cytology slides and cell blocks for a minimum of five (5) years and all cytology reports for a minimum of ten (10) years.” This requirement is duplicated in Business and Professions Code section 1271, subdivision (g) (identical language). Because the regulation is identical to the statute, the repeal of subdivision (f)(1)(E) will not materially alter any requirement.

Subdivision (f)(2), first paragraph, states that the “[t]he laboratory shall maintain cytology records indicating the daily accession of specimens, each of which is numbered, and an appropriate cross-filing system according to patient's name.” The cytology filing system specified in subdivision (f)(2) is superseded by the statutorily incorporated CLIA regulation, which requires written policies and procedures to maintain specimen identification and integrity from collection to reporting. Under 42 C.F.R. § 493.1221 (Condition: Cytology), a laboratory providing services in cytology must meet the requirements in sections 493.1230 through 493.1256. The integrity language is contained in 42 C.F.R. section 493.1232 (Standard: Specimen identification and integrity), stating that “[t]he laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.” Positive identification of a patient specimen under the incorporated CLIA standard involves the same processes as described in subdivision (f)(2); however, under the incorporated CLIA regulation, the laboratory may be sanctioned for failure to maintain written policies and procedures. Because subdivision (f)(2) is superseded by the statutorily incorporated CLIA regulation, which further requires written policies and procedures, the repeal of subdivision (f)(2) will not materially alter any requirement.

Subdivision (f)(2)(A) concerns test requests (i.e., test requisition records) for cytology, specifying the information that must be included in the request. All material provisions of subdivision (f)(2)(A) are superseded by the incorporated CLIA regulation, 42 C.F.R. § 493.1241 (Standard: Test request), as below.

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<sup>15</sup> Medical records and laboratory records comprises all the documents described in subdivision (f)(1)(A)-(D). Bus. & Prof. Code § 1265, subd. (j)(2)(B), defines “medical records” to mean “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.” Section 1265, subdivision (j)(2)(C), defines “laboratory records” to mean “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.”

1050, subdivision (f)(2)(A)	42 C.F.R. § 493.1241
"1. The laboratory accession number when assigned by the laboratory."	"(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately."
"2. The name of the person from whom the specimen was taken."	"(2) The patient's name or unique patient identifier."
"3. The name of the licensed physician or other authorized person or clinical laboratory who submitted the specimen."	"(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.
"4. Minimum information provided shall include: source of specimen (anatomic site), age of patient, previous therapy (endocrine, surgical, radiation, birth control, etc.), gynecologic history on cervical-vaginal specimens, including date and normalcy of patient's last menstrual period, duration of patient's current pregnancy, if any, and patient's menopausal status or essential history on non-gynecologic specimen."	(3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. (d) 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.
"5. The date the specimen was collected."	"(6) The date and, if appropriate, time of specimen collection."

Because all substantive requirements of subdivision (f)(2)(A) are duplicated in the statutorily incorporated CLIA regulation, the repeal of subdivision (f)(2)(A) will not materially alter any requirement.

Subdivision (f)(2)(B) indicates the minimum required information for a cytology test report. Subdivision (f)(2)(B) is superseded by the incorporated CLIA standard, 42 C.F.R. § 1291 (Standard: Test report), as below.

1050, subdivision (f)(2)(B)	42 C.F.R. § 493.1291
"1. The dates the specimen was collected, received in the laboratory and reported by the laboratory; and the accession number."	"(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (2) The name and address of the laboratory location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate."
"2. The result of the laboratory examination."	"(6) The test result and, if applicable, the units of measurement or interpretation, or both."

Because the statutorily incorporated CLIA regulation includes all elements of the subdivision (f)(2)(B), the repeal of the subdivision will not materially alter any requirement.

Subdivision (f)(3)(A), concerning cytology test records validation, is superseded by the incorporated CLIA regulation, 42 C.F.R. § 1274(e) ("Standard: Cytology") and 42 C.F.R. § 493.1283 ("Standard: Test records"), as set out below.

1050, subdivision (f)(3)(A)	42 C.F.R. § 1274(e)	42 C.F.R. § 493.1283
"The laboratory director shall be responsible for the final laboratory report and shall sign all abnormal and all non-gynecological reports. Each report, or a laboratory copy, shall be signed or initialed by the cytopathologist and/or cytotechnologist who examined the preparation and evaluated the final	"(2) The report of gynecologic slide preparations with conditions specified in paragraph (e)(1) [gynecologic slide preparation interpreted to exhibit reactive or reparative changes or specified epithelial cell abnormalities]of this section must be signed to reflect the technical supervisory review	N/A

report.”	or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review. (3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review. “	
The names of all persons who examined the specimen and their evaluation, if inconsistent with the final report, shall be indicated on the laboratory work sheet or report copy.	N/A	“(a) The laboratory must maintain an information or record system that includes the following: . . . (4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).”

Because the statutorily incorporated CLIA regulations duplicate all substantive requirements of subdivision (f)(3)(A), the repeal of the subdivision will not materially alter any requirement.<sup>16</sup>

Subdivision (f)(3)(B) “[d]uplicate copies of laboratory reports are filed in a manner which permits ready identification and accessibility.” is superseded by the statutorily incorporated CLIA regulation, 42 C.F.R. § 1291 (i) “Standard: Test report”; “If a laboratory refers patient specimens for testing— . . . (2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory’s report . . . .” and part 1291 (k)

<sup>16</sup> Note that a director may serve as a technical supervisor. See Bus. & Prof. Code § 1209 “. . . . The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA.”

“When errors in the reported patient test results are detected, the laboratory must do the following: . . . (3) Maintain duplicates of the original report, as well as the corrected report.” Accordingly, the repeal of this subdivision will not materially alter any requirement.

Subdivision (f)(3)(C) states that “[l]aboratories shall utilize reporting systems that are as explicit as is cytologically feasible and must include acceptable morphologic terminology.” The requirement to use explicit and acceptable morphologic terminology is superseded by the incorporated CLIA regulation, 42 C.F.R. § 1274(e)(5) Standard: Cytology; “The report contains narrative descriptive nomenclature for all results.” As the federal guidance clarifies, there exists significant variation among the systems and terms a laboratory may use to report patient results on cytology reports. In practice, a laboratory must specify the descriptive nomenclature employed, to use the nomenclature in a clear and concise manner, and to ensure uniformity and consistency.<sup>17</sup> Accordingly, the repeal of this provision will not materially alter any requirement.

Subdivision (f)(3)(D) states that “[i]f a specimen is judged by the laboratory director or cytotechnologist to be suboptimal, an accompanying statement shall indicate the reason, e.g., samples of sparse cellularity, poor preservation, or exhibiting other factors interfering with the laboratory evaluation, such as, excessive blood, inflammatory cells, etc.” The requirement to issue a statement when a cytology specimen is suboptimal is duplicated in California statute and in the incorporated CLIA regulations. First, Business and Professions Code section 1271, subdivision (h), requires that the laboratory issue a “statement of inadequacy” to the referring physician if the presence of any factor would prohibit the proper examination of a cytologic slide. Second, 42 C.F.R. section 1274(e)(4) (Standard: Cytology) states a similar proposition, i.e., that “[u]nsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.” Because subdivision (f)(3)(D) is duplicated in statute and the statutorily incorporated CLIA regulation, the repeal of the subdivision will not materially alter any requirement.

**Subdivision (g):** Repeal section 1050, subdivision (g).

California Code of Regulations, title 17, section 1050, subdivision (g), titled “Quality Control,” requires that a clinical laboratory participate in (1) a quality control program acceptable to the department, with (2) “Additional Cytology” requirements, and (3) “Clinical Correlation” requirements. This set of regulations predates the adoption of SB 75, which amended Business and Professions Code section 1220, subdivision (d)(2)(B), to require that a laboratory maintain a quality system in accordance with Subpart K of CLIA as in effect on Jan. 1, 2015. Because the quality control standards are superseded

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<sup>17</sup> See CDC, State Operations Manual, Appendix C, Interpretative Guidelines §493.1274(e)(5), available at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap\\_c\\_lab.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf).

by the later adopted statute and the incorporated CLIA regulations, the repeal of this subdivision will not materially alter any requirement, as set out in additional detail below.

Subdivision (g)(1) states that “[t]he laboratory must conduct, maintain, and operate programs for controlling the quality of test performance in a manner acceptable to the department.” This subdivision is superseded by Business and Professions Code section 1220, subdivision (d)(2)(B), which requires that a laboratory establish and maintain a quality system in accordance with CLIA in Subpart K, not in the discretion of the Department. Accordingly, the repeal of subdivision (g)(1) will not materially alter any requirement.

Subdivision (g)(2)(A) states the following: “Additional Cytology. (A) Specimen Identification. All smears and other specimens shall be labelled for patient identification and appropriately prepared by the submitter.” The requirement to appropriately label and identify all smears and other specimen is duplicated by the incorporated CLIA regulation, 42 C.F.R. § 1242(a) Standard: Specimen submission, handling, and referral; “The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source . . . .” and 42 C.F.R. § 493.1232 Standard: Specimen Identification and Integrity; “The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.” Because the specimen identification requirements of subdivision (g)(2)(A) are duplicated in the statutorily incorporated CLIA regulations, the repeal of the subdivision will not materially alter any requirement.

Subdivision (g)(2)(B) sets the requirements for cytology specimen preparation, which is superseded by the incorporated CLIA regulations, 42 C.F.R. §§ 493.1274 (Standard: Cytology) and 493.1256 (Standard: Control procedures), as below.

1050, subdivision (g)(2)(B)	42 C.F.R. § 493
“1. The laboratory shall use the Papanicolaou staining technique or its equivalent as determined by the laboratory director.”	1274(b): “Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (1) All gynecologic slide preparations must be stained using a Papanicolaou or modified Papanicolaou staining method.”
“2. Staining quality of cytologic specimens shall be checked at least once daily, with suboptimal results corrected immediately.”	1256(e)(2): “[For reagent, media, and supply checks, the laboratory must do the following:] (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to

	ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate."
"3. Gynecologic specimens shall be processed totally separately from non-gynecologic specimens."	1274(b)(2): "[The laboratory must have available and follow written policies and procedures for each of the following, if applicable:] Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used."

Because all elements of subdivision (g)(2)(B) are duplicated in the statutorily incorporated CLIA regulations, the repeal of the subdivision will not materially alter any requirement.

Subdivision (g)(2)(C)(1) states that "[e]ach specimen shall be evaluated to determine whether the material is satisfactory and consistent with the patient source. For satisfactory specimens, a cytologic evaluation shall be rendered according to the reporting system, as outlined in Section 1050(f)(3)(C)." Subdivision (g)(2)(C)(1) comprises two distinct requirements. First, the requirement to evaluate cytologic specimens for adequacy is duplicated in Business and Professions Code section 1271, subdivision (h), which states that the inverse, "[t]he presence of any factor that would prohibit the proper examination of a cytologic slide, including, but not limited to, damaged slides or inadequate specimens, as determined by the director of the laboratory, shall result in the issuance of a statement of inadequacy to the referring physician and no report of cytologic findings shall be issued on that slide." Second, the requirement to utilize the reporting system in "Section 1050(f)(3)(C)" is superseded by the incorporated CLIA reporting system regulation, 42 C.F.R. § 1274(e)(5), as referenced in the repeal above. Because all substantive requirements of subdivision (g)(2)(C)(1) are superseded in the statutorily incorporated CLIA regulations, the repeal of the subdivision will not materially alter any requirement.

Subdivision (g)(2)(C)(2), in two parts, concerns the requirement to have a sufficient number of employed cytotechnologists, and their coordinate workload limits. First, it states that "[t]he laboratory shall have a sufficient number of certified cytotechnologists to handle, under general supervision, the volume and diversity of tests performed requiring the exercise of independent judgment." The requirement is duplicated in Business and Professions Code section 1209, subdivision (b)(1), requiring that the laboratory director "employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests . . . ." Thus, the repeal of this provision will not materially alter any requirement.

Second, as to cytotechnologists' workload limits, subdivision (g)(2)(C)(2) states that "[n]o cytotechnologist shall be required to examine more than 75 one-slide gynecologic cases or 50 two-slide gynecologic cases per day; not including aspiration cytology specimens, cell block specimens, and other not normally examined by a cytotechnologist. Work load ratios for cytotechnologists who also prepare and stain slides shall be based on time spent in examining cytologic preparations." This requirement is superseded by the later adopted statute, Business and Professions Code section 1271, subdivision (l), which instead requires that workload limits shall be established by the technical supervisor in accordance with the incorporated CLIA standard ("[t]he technical supervisor of an individual who performs primary screening shall establish the maximum workload limit for the individual, based on the individual's performance, in accordance with the criteria set forth in Section 493.1274(d)(1) of Title 42 of the Code of Federal Regulations.").<sup>18</sup> Because subdivision (g)(2)(C)(2)'s workload limits are superseded by the statute and incorporated CLIA regulation, the repeal of the subdivision will not materially alter any requirement.

Subdivision (g)(2)(C)(3) states that "[t]he director or a supervising cytotechnologist shall examine (to verify proper staining and correct interpretation) at least ten (10) percent of all gynecologic smears previously examined and classified as not abnormal or questionable, including smears initially examined by a supervising cytotechnologist." This requirement is duplicated in Business and Professions Code section 1271, subdivision (j) ("Ten percent of the negative or normal slides examined by each cytotechnologist employed by a clinical laboratory shall be rescreened at least weekly by a cytopathologist or supervising cytotechnologist other than the original examiner."). Since the regulation is substantively identical to the statute, the repeal of the regulation will not materially alter any requirement.

Subdivision (g)(3) states the following: "Clinical Correlation. The laboratory shall maintain records for a minimum of 10 years of histologic or clinical confirmation of cytologic findings on abnormal cases and false negative and false positive results for each category of specimens, when such results are made available to them." This requirement is functionally duplicated in Business and Professions Code section 1274, subdivision (d) ("A clinical laboratory shall maintain records of all false positive and false negative cases. When any errors in the reporting of a smear evaluation are discovered, a corrected report shall be immediately sent, when medically applicable. Copies of corrected reports shall be maintained in the laboratory records for a period of 10 years."). Because the requirement to maintain records for a minimum of 10 years for the specified cases is duplicated in statute, the repeal of this subdivision will not materially alter any requirement.

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<sup>18</sup> See Appendix A for the CLIA formula for calculating workload limits.

**Subdivision (h):** Repeal section 1050, subdivision (h).

California Code of Regulations, title 17, section 1050, subdivision (h) ("Clinical Laboratory Test Results"), requires that a person licensed under division 2, chapter 3 of the Business and Professions Code (other than a trainee) critically review and verify test results prior to release. Subdivision (h) may be repealed without materially altering any requirement for two reasons, as set out below.

First, to the extent that subdivision (h) requires critical review and verification of results by a licensed person in all instances, the regulation is incompatible and conflicts with later adopted Business and Professions Code section 1209.5, added by AB 2156 (Stats. 2006, ch. 319), which allows for an automated review process called "autoverification."<sup>19</sup> According to the procedures for autoverification, "[a] person licensed to perform the applicable type and complexity of testing pursuant to Section 1206.5 shall be physically present onsite in the clinical laboratory and shall have documented competency pursuant to Section 1209 in all tests being autoverified, and shall be responsible for the accuracy and reliability of the results of the clinical laboratory test or examination when the results are autoverified and reported,"<sup>20</sup> however, in conflict with the regulation, critical review and verification is accomplished by the computer algorithm in conjunction with the automated test instrumentation, not the licensed person. Because the regulation conflicts with the later adopted statute, the repeal of subdivision (h) will not materially alter any requirement.

Second, the substantive element of Subdivision (h), that review and verification of test results must be accomplished by a licensed person, is duplicated in Business and Professions Code section 1206.5 (specifying the professional license required to perform a test or examination by complexity), which ensures that licensed personnel perform tests in accordance with their qualifications; and Business and Professions Code section 1269, subdivision (d), which asserts the contrapositive requirement; that unlicensed personnel may not record test results or "[p]erform any test or part thereof that involves the quantitative measurement of the specimen or test reagent, or any mathematical calculation relative to determining the results or the validity of a test procedure."<sup>21</sup>

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<sup>19</sup> "Autoverification means the use of a computer algorithm in conjunction with automated clinical laboratory instrumentation to review and verify the results of a clinical laboratory test or examination for accuracy and reliability." Bus. & Prof. Code § 1209.5, subd. (a).

<sup>20</sup> Bus. & Prof. Code § 1209.5, subd. (e).

<sup>21</sup> See Bus. & Prof Code section 1269, subd. (d) "Unlicensed laboratory personnel shall not do any of the following:(1) Record test results, but he or she may transcribe results that have been previously recorded, either manually by a physician and surgeon or personnel licensed under this chapter, or automatically by a testing instrument.(2) Perform any test or part thereof that involves the quantitative measurement of the specimen or test reagent, or any mathematical calculation relative to determining the results or the validity of a test procedure."

Further, Business and Professions Code 1209, subdivision (b), makes it the director's responsibility to ensure that licensed personnel "report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter." As to a licensed laboratory, Business and Professions Code section 1209, subdivision (d)(3), requires that the director also specify in writing "whether consultant, supervisor, or director review is required prior to the individual reporting patient test results." Because the substantive requirement of critical review and verification by a licensed person prior to reporting is duplicated in statute, the repeal of subdivision (h) will not materially alter any requirement.

**Section 1050 Authority and Reference:** Eliminate Business and Professions Code section 1245 from the Authority and Reference.

Business and Profession Code section 1245 was amended by SB 113, now concerning personnel standards for blood gas analysis. This section is not an authority for section 1050; nor does the remaining section 1050, subdivision (d), interpret or reference that provision. Accordingly, Business and Professions Code section 1245 must be repealed from the authority and reference citation.<sup>22</sup>

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<sup>22</sup> California Code of Regulations, tit. 1, § 100, subd. (a)(5).

**Appendix: 1050 Comparison Chart/Crosswalk**  
See attached document.

Appendix: 1050 Comparison Chart/Crosswalk

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Subpart H	Sections 493.801 to 493.865	Jan. 1, 1994
Subpart I	Sections 493.901 to 493.959	Jan. 1, 1994
Subpart J	Sections 493.1101 to 493.1111	Jan. 1, 1994
Subpart K	Sections 493.1200 to 493.1299	Jan. 1, 2015 <sup>1</sup>

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<sup>1</sup> See Bus. & Prof. Code § 1220, subd. (d)(2)(B).

**California Code of Regulations, title 17, section 1050, and Superseding Law<sup>2</sup>**

**Subdivision (a)**

**Cal. Code Regs., tit. 17, section 1050, subd. (a): All licensed clinical laboratories shall be conducted, maintained, and operated without injury to the public health and shall maintain records, equipment, and facilities which are adequate and appropriate for the services rendered and demonstrate satisfactory performance in a proficiency program approved by the department.**

- Bus. & Prof. Code § 1220, subd. (a)(1): "Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered."
- Bus. & Prof. Code § 1220, subd. (b): "Each clinical laboratory shall be conducted, maintained, and operated without injury to the public health."
- Bus. & Prof. Code § 1220, subd. (a)(2)(A): "Except for tests or examinations classified as waived under CLIA, each clinical laboratory shall enroll, and demonstrate successful participation, as defined under CLIA, for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, in a proficiency testing program approved by the department or by HCFA, to the same extent as required by CLIA in Subpart H (commencing with Section 493.801) of Title 42 of the Code of Federal Regulations. This requirement shall not be interpreted to prohibit a clinical laboratory from performing clinical laboratory tests or examinations in a specialty or subspecialty for which there is no department or HCFA approved proficiency testing program."

**Subdivision (b)**

**Cal. Code Regs., tit. 17, section 1050, subd. (b), Proficiency Testing. (1) The laboratory must participate in a state approved proficiency testing program and demonstrate satisfactory performance in all of the laboratory specialties that include tests performed in the laboratory. Proficiency shall be tested in the following specialties: microbiology, serology, clinical chemistry, hematology, and immunohematology.**

- Bus. & Prof. Code § 1272. "A clinical laboratory shall participate in a state-approved proficiency testing program and demonstrate satisfactory performance in all of the laboratory specialties that include tests performed in the laboratory. Proficiency shall be tested in the following specialties: microbiology, serology, clinical chemistry, hematology, cytology, and immunohematology"

<sup>2</sup> Bolded text represents Cal. Code Regs, tit. 17, § 1050.

- Bus. & Prof. Code § 1220, subd. (a)(2)(A): "Except for tests or examinations classified as waived under CLIA, each clinical laboratory shall enroll, and demonstrate successful participation, as defined under CLIA, for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, in a proficiency testing program approved by the department or by HCFA, to the same extent as required by CLIA in Subpart H (commencing with Section 493.801) of Title 42 of the Code of Federal Regulations. This requirement shall not be interpreted to prohibit a clinical laboratory from performing clinical laboratory tests or examinations in a specialty or subspecialty for which there is no department or HCFA approved proficiency testing program."
- Bus. & Prof. Code § 1220, subd. (a)(2)(B): "Each clinical laboratory shall authorize its proficiency test results to be reported to the department in an electronic format that is compatible with the department's proficiency testing data monitoring system and shall authorize the release of proficiency tests results to the public to the same extent required by CLIA."

**(2) The participating laboratory must test applicable materials each time they are distributed by the approved proficiency testing service according to a schedule approved by the department.**

- Bus. & Prof. Code § 1220, subd. (a)(2)(A): "Except for tests or examinations classified as waived under CLIA, each clinical laboratory shall enroll, and demonstrate successful participation, as defined under CLIA, for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, in a proficiency testing program approved by the department or by HCFA, to the same extent as required by CLIA in Subpart H (commencing with Section 493.801) of Title 42 of the Code of Federal Regulations. This requirement shall not be interpreted to prohibit a clinical laboratory from performing clinical laboratory tests or examinations in a specialty or subspecialty for which there is no department or HCFA approved proficiency testing program."
- 42 C.F.R. § 493.803(a): "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 certified under CLIA."
- 42 C.F.R. § 493.911(b) (bacteriology): "Program content and frequency of challenge. To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing

event. There must be at least three testing events at approximately equal intervals per year.”

- 42 C.F.R. § 493.913(b) (Mycobacteriology): [Same requirement.]
- 42 C.F.R. § 493.915(b) (Mycology): [Same requirement.]
- 42 C.F.R. § 493.917(b) (Parasitology): [Same requirement.]
- 42 C.F.R. § 493.919(b) (Virology): [Same requirement.]

**(3) Those procedures performed by the laboratory for which test materials are provided by the approved proficiency testing service and which have been designated by the department as a requirement for measuring test performance, must be proficiency tested by the participating laboratory each time test materials are received.**

- 42 C.F.R. § 493.801(b): “Standard; Testing of proficiency testing samples. The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.”

**(4) The participating laboratory must authorize the approved proficiency testing service to report proficiency test results to the department.**

- Bus. & Prof. Code § 1220, subd. (a)(2)(B): “Each clinical laboratory shall authorize its proficiency test results to be reported to the department in an electronic format that is compatible with the department's proficiency testing data monitoring system and shall authorize the release of proficiency tests results to the public to the same extent required by CLIA.”

**(5) The participating laboratory must test applicable materials only in the laboratory to which the license and the proficiency testing requirement applies using personnel and equipment used in that facility in providing services.**

- 42 C.F.R. § 493.801(b)(1): “The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.”

- 42 C.F.R. § 801(b)(4): "The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify HCFA of the receipt of those samples."

**(6) A laboratory may be required to discontinue providing a service in a procedure or category of procedures if:**

**(A) For three consecutive quarters the laboratory fails to report on test materials received for procedures for which the laboratory is required to be proficiency tested, or**

**(B) For three consecutive quarters the laboratory demonstrates unsatisfactory performance in a procedure or category of procedures. A determination of satisfactory performance for a procedure shall be based upon results being within acceptable limits established by the proficiency testing service for that procedure and approved by the department. A determination of satisfactory performance for a category of procedures shall be based upon an average of performance within the category over four consecutive quarters.**

- 42 C.F.R. § 493.803(b): "If the laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, sanctions will be taken as defined in subpart R of this part."
- 42 C.F.R. § 493.823(e) (Standard; Bacteriology): "Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance."
- 42 C.F.R. § 493.825(e) (Standard; Mycobacteriology): [Same requirement].
- 42 C.F.R. § 493.827(e) (Standard; Mycology): [Same requirement].
- 42 C.F.R. § 493.829(e) (Standard; Parasitology): [Same requirement].

**(7) A laboratory whose services have been disapproved because of unsatisfactory performance may apply to the department for reapproval to provide these services after demonstrating satisfactory performance**

**during the two consecutive quarters or testing periods immediately prior to requesting reapproval.**

- 42 C.F.R. § 493.807(a): "If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before HCFA will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test."

**Subdivision (c)**

**Cal. Code Regs., tit. 17, section 1050, subd. (c) Direction. The person or persons directing a licensed clinical laboratory shall assume the following responsibilities:**

**(1) Determine what laboratory procedures will be performed, the techniques that will be followed, and the equipment and reagents that will be used.**

- Bus. & Prof. Code § 1209, subd. (b)(1): "The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter."

**(2) Determine the scope and nature of procedures to control the reliability of test performance and personally monitor these control programs.**

- Bus. & Prof. Code § 1209, subd. (b)(1): "The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of

a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA . . . .”

- Bus. & Prof. Code § 1209, subd. (c): “As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations.”
  
- Bus. & Prof. Code § 1209, subd. (d): “As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following: (1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question. (2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.”
  
- Bus. & Prof. Code § 1209, subd. (e): “The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory. (1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following: (A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing. (B) Monitoring the recording and reporting of test results. (C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and

preventive maintenance records. (D) Direct observation of performance of instrument maintenance and function checks. (E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. (F) Assessment of problem solving skills. (2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation."

**(3) Regularly assess the activities of the laboratory by personal observation, evaluation, and review of reports of laboratory findings.**

- Bus. & Prof. Code § 1209, subd. (e): "The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory. (1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following: (A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing. (B) Monitoring the recording and reporting of test results. (C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. (D) Direct observation of performance of instrument maintenance and function checks. (E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. (F) Assessment of problem solving skills. (2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation."

**(4) Establish qualification criteria of laboratory personnel.**

- Bus. & Prof. Code § 1209, subd. (c): “As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations.”
  
- Bus. & Prof. Code § 1209, subd. (d): “As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following: (1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question. (2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.”
  
- Bus. & Prof. Code § 1209, subd. (e): “The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory. (1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following: (A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing. (B) Monitoring the recording and reporting of test results. (C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. (D) Direct observation of performance of

instrument maintenance and function checks. (E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. (F) Assessment of problem solving skills. (2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation."

**(5) Determine the format of laboratory report forms and decide what information is to be contained on these report forms.**

- Bus. & Prof. Code § 1209, subd. (b)(1): "The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter."
- 42 C.F.R. § 493.1291 (Standard: Test report): "(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (1) Results reported from calculated data. (2) Results and patient-specific data electronically reported to network or interfaced systems. (3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. (b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. (c) The test report must indicate the following: (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (2) The name and address of the laboratory location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen

source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability . . . .”

**(6) Regularly consult with supervisors and other staff members.**

- Bus. & Prof. Code § 1209, subd. (b)(1): “The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA . . . .”
- 42 C.F.R. § 493.1407(c): “The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.”

**(7) Confer with those served by the laboratory on matters that relate to test performance and determine the nature and scope of technical and administrative information to be released by the laboratory staff.**

- 42 C.F.R. § 493.1291(e): “The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in §493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.”
- 42 C.F.R. § 493.1291(g): “The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.”
- Bus. & Prof. Code § 1209, subd. (d)(3): “Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or

director review is required prior to the individual reporting patient test results.”

**(8) Be available daily in any laboratory performing cytology and serve as director of no more than three (3) laboratories.**

- Bus. & Prof. Code § 1209, subd. (h): “A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.”
- 42 C.F.R. § 493.1407(d) (laboratories performing moderate complexity testing; laboratory director): “Each individual may direct no more than five laboratories.”
- 42 C.F.R. § 493.1445(d) (laboratories performing high complexity testing; laboratory director): “Each individual may direct no more than five laboratories.”
- Bus. & Prof. Code § 1209, subd. (a): “The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapporitions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.”
- 42 C.F.R. § 493.1445(e)(10): “[The laboratory director must –] Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)(4).”
- 42 C.F.R. § 493.1463(a) (Standard: General supervisor responsibilities): “The general supervisor – (1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor. (2) Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under § 493.1489; (3) Except as specified in paragraph (c) of this section, must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under § 493.1489(b)(4); . . . .”
- 42 C.F.R. 493.1471 (Standard: Cytology general supervisor responsibilities): “The technical supervisor of cytology may perform the

duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under § 493.1469. (a) The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. (b) The cytology general supervisor must – (1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology; . . . .”

**(9) Cause a licensed physician or dentist, qualified in cytopathology, to personally examine and report findings on abnormal or questionable gynecologic and all non-gynecologic specimens.**

- Bus. & Prof. Code § 1209, subd. (d): “As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following: (1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question. (2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills. (3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.”

- Bus. & Prof. Code § 1220, subd. (d)(2)(B): “[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 quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1200) of Title 42 of the Code of Federal Regulations as in effect on January 1, 2015, and that may include the clinical laboratory's use of the following alternative quality control testing procedures recognized by the federal Centers for Medicare and Medicaid Services (CMS) . . . .”
- 42 C.F.R. § 1274(e)(1) (Standard: Cytology): “A technical supervisor confirms each gynecologic slide preparation interpreted to exhibit reactive or reparative changes or any of the following epithelial cell abnormalities: . . . .”
- 42 C.F.R. § 1274(e)(3): “All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.”

**Subdivision (e)**

**(e) Equipment and Test Materials.**

**(1) The laboratory must provide for and assure that equipment, instruments, glassware, and reagents are maintained in proper working order by periodic inspection, testing, or calibration in a manner acceptable to the department.**

- Bus. & Prof. Code § 1220, subd. (d)(2)(B): “[Except for those clinic all laboratories performing only tests or examinations classified as waived under CLIA, each clinical laboratory shall establish and maintain all of the following:] A quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1200) of Title 42 of the Code of Federal Regulations as in effect on January 1, 2015, and that may include the clinical laboratory's use of the following alternative quality control testing procedures recognized by the federal Centers for Medicare and Medicaid Services (CMS) . . . .”
- 42 C.F.R. § 493.1254 (Standard: Maintenance and function checks): “*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."

**(2) All reagents and stains shall be dated at the time of preparation and initialed by the person making the reagents or stains, or the date received and date opened if commercially prepared reagents or stains are used. All reagents and stains shall be labeled to indicate identity, and titer, strength, or concentration. Recommended storage temperature and expiration date, and other pertinent information necessary for quality control must be on the label.**

- 42 C.F.R. § 493.1252(c) (Standard: Test systems, equipment, instruments, reagents, materials, and supplies): "Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use."

**Subdivision (f)**

**(1) Retention of Records: The laboratory must maintain for a period of at least two years documentation of the following:**

**(A) Records of specimens received and tested, including identification of the patient, name of the submitter, dates of receipt and report, type of test performed, and test results.**

**(B) Records of inspection, validation, calibration, repair, and replacement to insure proper maintenance and operation of equipment and proper reactivity of test materials.**

**(C) Manuals, card files, or flow charts for each procedure performed in the laboratory which include:**

- 1. Name of procedure.**
- 2. Source or reference for the test method.**
- 3. Date the procedure was last reviewed or modified by the director or supervisor.**
- 4. Current specific instructions for test performance.**
- 5. The standards and controls required.**
- 6. Instructions for collecting and handling specimens to insure test reliability.**

**(D) Records of quality control procedures in use in the various technical areas of the laboratory, including results on standards and reference materials and action limits when appropriate.**

- 42 C.F.R. § 493.1283 (Standard: Test records): "The laboratory must maintain an information or record system that includes the following: (1) The positive identification of the specimen. (2) The date and time of specimen receipt into the laboratory. (3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). (b) Records of patient testing including, if applicable, instrument printouts, must be retained."
- Bus. & Prof. Code § 1265, subd. (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. (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. (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. (D) Information contained in medical records and laboratory records shall be confidential, and shall be disclosed only to authorized persons in accordance with federal, state, and local laws.

**(E) Additional requirements for cytology. The laboratory shall retain all cytology slides and cell blocks for a minimum of five (5) years and all cytology reports for a minimum of ten (10) years.**

- Bus. & Prof. Code § 1271, subd. (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."

**(2) Cytology Specimen Documents. The laboratory shall maintain cytology records indicating the daily accession of specimens, each of which is numbered, and an appropriate cross-filing system according to patient's name.**

- 42 C.F.R. § 493.1232 (Standard: Specimen identification and integrity): "The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results."

**(A) Requests shall contain at least the following information:**

- 1. The laboratory accession number when assigned by the laboratory.**
- 2. The name of the person from whom the specimen was taken.**
- 3. The name of the licensed physician or other authorized person or clinical laboratory who submitted the specimen.**
- 4. Minimum information provided shall include: source of specimen (anatomic site), age of patient, previous therapy (endocrine, surgical, radiation, birth control, etc.), gynecologic history on cervical-vaginal specimens, including date and normalcy of patient's last menstrual period, duration of patient's current pregnancy, if any, and patient's menopausal status or essential history on non-gynecologic specimen.**
- 5. The date the specimen was collected.**

- 42 C.F.R. § 493.1241 (Standard: Test request): "(a) The laboratory must have a written or electronic request for patient testing from an authorized person. (b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization. (c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient."

(4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. (d) 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. (e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately."

**(B) Reports shall contain at least the following information:**

- 1. The dates the specimen was collected, received in the laboratory and reported by the laboratory; and the accession number.**
- 2. The result of the laboratory examination.**

- 42 C.F.R. § 1291 (Standard: Test report): "The test report must indicate the following: (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (2) The name and address of the laboratory location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability."

**(3) Cytology Laboratory Records.**

**(A) The laboratory director shall be responsible for the final laboratory report and shall sign all abnormal and all non-gynecological reports. Each report, or a laboratory copy, shall be signed or initialed by the cytopathologist and/or cytotechnologist who examined the preparation and evaluated the final report. The names of all persons who examined the specimen and their evaluation, if inconsistent with the final report, shall be indicated on the laboratory work sheet or report copy.**

- Bus. & Prof. Code § 1220, subd. (d)(2)(B): "[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 quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1200) of Title 42 of the Code of Federal Regulations as in effect on January 1, 2015, and that may include the clinical laboratory's use of the following alternative quality control testing procedures

recognized by the federal Centers for Medicare and Medicaid Services (CMS)  
.....”

- 42 C.F.R. § 1274(e): “(2) The report of gynecologic slide preparations with conditions specified in paragraph (e)(1) of this section must be signed to reflect the technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review. (3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.”
- 42 C.F.R. § 493.1283 (Standard: Test records). “(a) The laboratory must maintain an information or record system that includes the following: (1) The positive identification of the specimen. (2) The date and time of specimen receipt into the laboratory. (3) The condition and disposition of specimens that do not meet the laboratory’s criteria for specimen acceptability. (4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). (b) Records of patient testing including, if applicable, instrument printouts, must be retained.”

**(B) Duplicate copies of laboratory reports are filed in a manner which permits ready identification and accessibility.**

- 42 C.F.R. § 1291(j) (Standard: Test report): “All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.”
- 42 C.F.R. § 1291(i): “If a laboratory refers patient specimens for testing— . . . (2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory’s report; . . . .”
- 42 C.F.R. § 1291(k): “When errors in the reported patient test results are detected, the laboratory must do the following: . . . (3) Maintain duplicates of the original report, as well as the corrected report.”

**(C) Laboratories shall utilize reporting systems that are as explicit as is cytologically feasible and must include acceptable morphologic terminology.**

- 42 C.F.R. § 1274(e)(5): “The report contains narrative descriptive nomenclature for all results.”

- CMS, State Operations Manual ([https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap\\_c\\_lab.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf)), Interpretative Guidelines §493.1274(e)(5): “In cytology, great variation exists among the systems and terms a laboratory may use to report patient results on cytology reports. The laboratory must specify the descriptive nomenclature used for reporting patient results. This nomenclature must define the criteria used to classify patient results in a particular category in a clear and concise manner to ensure that all employees report patient results in a uniform, consistent manner. Use of the Papanicolaou numerical system without narrative description is not acceptable. The Bethesda System is an example of a recognized system of narrative descriptive nomenclature for gynecologic cytology.”

**(D) If a specimen is judged by the laboratory director or cytotechnologist to be suboptimal, an accompanying statement shall indicate the reason, e.g., samples of sparse cellularity, poor preservation, or exhibiting other factors interfering with the laboratory evaluation, such as, excessive blood, inflammatory cells, etc.**

- 42 C.F.R. § 1274(e)(4): “Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.”

### **Subdivision (g)**

#### **(g) Quality Control.**

**(1) The laboratory must conduct, maintain, and operate programs for controlling the quality of test performance in a manner acceptable to the department.**

- Bus. & Prof. Code § 1220, subd. (d)(2)(B): “[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 quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1200) of Title 42 of the Code of Federal Regulations as in effect on January 1, 2015, and that may include the clinical laboratory's use of the following alternative quality control testing procedures recognized by the federal Centers for Medicare and Medicaid Services (CMS) . . . .”

#### **(2) Additional Cytology.**

**(A) Specimen Identification. All smears and other specimens shall be labelled for patient identification and appropriately prepared by the submitter.**

- 42 C.F.R. § 493.1242(a)(Standard: Specimen submission, handling, and referral): “(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation.

(2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source . . . .”

- 42 C.F.R. § 493.1232 (Standard: Specimen Identification and Integrity):  
“The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.”

**(B) Specimen Preparation.**

**1. The laboratory shall use the Papanicolaou staining technique or its equivalent as determined by the laboratory director.**

- 42 C.F.R. § 493.1274(b): “*Staining*. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (1) All gynecologic slide preparations must be stained using a Papanicolaou or modified Papanicolaou staining method.”

**2. Staining quality of cytologic specimens shall be checked at least once daily, with suboptimal results corrected immediately.**

- 42 C.F.R. § 493.1256(e)(2): “[For reagent, media, and supply checks, the laboratory must do the following:] (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.”
- 42 C.F.R. § 493.1274(c): “*Control procedures*. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: . . . .”

**3. Gynecologic specimens shall be processed totally separately from non-gynecologic specimens.**

- 42 C.F.R. § 493.1274(b)(2): “[The laboratory must have available and follow written policies and procedures for each of the following, if applicable:] Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.”

**(C) Microscopy.**

**1. Each specimen shall be evaluated to determine whether the material is satisfactory and consistent with the patient source. For satisfactory specimens, a cytologic evaluation shall be rendered according to the reporting system, as outlined in Section 1050(f)(3)(C).**

- Bus. & Prof. Code § 1271, subd. (h): "The presence of any factor that would prohibit the proper examination of a cytologic slide, including, but not limited to, damaged slides or inadequate specimens, as determined by the director of the laboratory, shall result in the issuance of a statement of inadequacy to the referring physician and no report of cytologic findings shall be issued on that slide."

**2. The laboratory shall have a sufficient number of certified cytotechnologists to handle, under general supervision, the volume and diversity of tests performed requiring the exercise of independent judgment. No cytotechnologist shall be required to examine more than 75 one-slide gynecologic cases or 50 two-slide gynecologic cases per day; not including aspiration cytology specimens, cell block specimens, and other not normally examined by a cytotechnologist. Work load ratios for cytotechnologists who also prepare and stain slides shall be based on time spent in examining cytologic preparations.**

- Bus. & Prof. Code § 1271, subd. (l): "The technical supervisor of an individual who performs primary screening shall establish the maximum workload limit for the individual, based on the individual's performance, in accordance with the criteria set forth in Section 493.1274(d)(1) of Title 42 of the Code of Federal Regulations."
- 42 C.F.R. § 493.1274(d): "*Workload limits.* The laboratory must establish and follow written policies and procedures that ensure the following: (1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. (i) The workload limit is based on the individual's performance using evaluations of the following: (A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section. (B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section. (ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. (2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition— (i) The maximum number of 100

slides is examined in no less than an 8-hour workday; (ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula—

$$\frac{\text{Number of hours examining slides} \times 100}{8}$$

is used to determine maximum slide volume to be examined; (iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and (iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit. (3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. (4) Records are available to document the workload limit for each individual."

**3. The director or a supervising cytotechnologist shall examine (to verify proper staining and correct interpretation) at least ten (10) percent of all gynecologic smears previously examined and classified as not abnormal or questionable, including smears initially examined by a supervising cytotechnologist.**

- Bus. & Prof. Code § 1271, subd. (j): "Ten percent of the negative or normal slides examined by each cytotechnologist employed by a clinical laboratory shall be rescreened at least weekly by a cytopathologist or supervising cytotechnologist other than the original examiner."

**(3) Clinical Correlation. The laboratory shall maintain records for a minimum of 10 years of histologic or clinical confirmation of cytologic findings on abnormal cases and false negative and false positive results for each category of specimens, when such results are made available to them.**

- Bus. & Prof. Code § 1274(d): "A clinical laboratory shall maintain records of all false positive and false negative cases. When any errors in the reporting of a smear evaluation are discovered, a corrected report shall be immediately sent, when medically applicable. Copies of corrected reports shall be maintained in the laboratory records for a period of 10 years."

**Subdivision (h)**

**(h) Clinical Laboratory Test Results. Clinical laboratory test results shall not be reported from the laboratory until these results have been critically reviewed and verified for accuracy, reliability, and validity by a licensed physician and surgeon or a person, other than a trainee, duly licensed under Chapter 3, Division 2, Business and Professions Code (commencing with Section 1200).**

- Bus. & Prof. Code § 1209.5 "Autoverification' means the use of a computer algorithm in conjunction with automated clinical laboratory instrumentation to review and verify the results of a clinical laboratory test or examination for accuracy and reliability. (b) The laboratory director or authorized designee shall establish, validate, and document explicit criteria by which the clinical laboratory test or examination results are autoverified. (c) The laboratory director or authorized designee shall annually revalidate the explicit criteria by which the clinical laboratory test or examination results are autoverified. The laboratory director shall approve and annually reapprove the computer algorithm. (d) An authorized designee may be appointed by the laboratory director for the purposes of this section. The authorized designee shall be licensed to engage in clinical laboratory practice pursuant to this chapter and shall be qualified as a clinical consultant, technical supervisor, general supervisor, or technical consultant pursuant to regulations adopted by the department. (e) A person licensed to perform the applicable type and complexity of testing pursuant to Section 1206.5 shall be physically present onsite in the clinical laboratory and shall have documented competency pursuant to Section 1209 in all tests being autoverified, and shall be responsible for the accuracy and reliability of the results of the clinical laboratory test or examination when the results are autoverified and reported."
- Bus. & Prof. Code § 1206.5: "(a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Sections 1206.6 and 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons: . . . (b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons: . . . (c) Notwithstanding subdivision (b) of Section 1206,

no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons: . . . .”

- Bus. & Prof. Code § 1269, subd. (d): “Unlicensed laboratory personnel shall not do any of the following:(1) Record test results, but he or she may transcribe results that have been previously recorded, either manually by a physician and surgeon or personnel licensed under this chapter, or automatically by a testing instrument.(2) Perform any test or part thereof that involves the quantitative measurement of the specimen or test reagent, or any mathematical calculation relative to determining the results or the validity of a test procedure.(3) Perform any phase of clinical laboratory tests or examinations in the specialty of immunohematology beyond initial collection and centrifugation.”
- Bus. & Prof. Code § 1209, subd. (b): “(1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter (2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.”
- Bus. & Prof. Code § 1209, subd. (c): “As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel . . . .”

- Bus. & Prof. Code § 1209, subd. (d)(3): “[As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:] Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.”