California Code of Regulations, Title 17
Division 1
Chapter 2. Laboratories
Subchapter 1. Service Laboratories
Group 2. Clinical Laboratory Regulations
Article 5. Issuance of License
PROPOSED REGULATION TEXT

(1) Adopt Section 1053 to read:

Section 1053. Clinical Laboratory Improvement Amendments (CLIA) Record Retention Regulations Determined to be Less Stringent than California Law.

(a) All clinical laboratories licensed or registered by the Department shall comply with those federal regulations adopted under the CLIA of 1988 (42 C.F.R. § 493 et seq.), effective January 24, 2003, and published in the California Regulatory Notice Register 2016, Number 41-Z, pages 1825-26, which became effective by operation of law as a state regulation adopted under Division 2, Chapter 3 of the Business and Professions Code on January 5, 2017, in accordance with Business and Professions Code section 1208(c).

(b) In accordance with Business and Professions Code section 1208(b), the department, in consultation with the Clinical Laboratory Technology Advisory Committee, has determined that the following subparts of the federal regulations adopted under the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. § 493 et seq.), and effective January 24, 2003, are less stringent than California law. All clinical laboratories licensed or registered by the Department shall comply with applicable state law regarding retention of records and shall not comply with the following subparts of the above-referenced federal regulations, as indicated in Table 1: *Comparison of California and Federal Clinical Laboratory Record Retention Requirements*:

(1) 42 C.F.R. § 493.1105(a)(1)
(2) 42 C.F.R. § 493.1105(a)(2)
(3) 42 C.F.R. § 493.1105(a)(3)
(4) 42 C.F.R. § 493.1105(a)(3)(i)
(5) 42 C.F.R. § 493.1105(a)(5)
(6) 42 C.F.R. § 493.1105(a)(6)

TABLE 1

Comparison of California and Federal Clinical Laboratory Record Retention Requirements

RECORD TYPE	CA REQUIREMENT	CA LAW	FEDERAL REQUIREMENT	FEDERAL LAW 42 CFR § 493.1105(a)	COMPLY WITH
Test requisition and authorization records	3 years	CBPC § 1265(j)(2)	2 years	Subdivision (1)	State Law
Test procedure records	3 years	CBPC § 1265(j)(2)	2 years	Subdivision (2)	State Law
Quality control and patient test records	3 years	CBPC § 1265(j)(2)	2 years	Subdivision (3)	State Law
Test system performance specifications	3 years	CBPC § 1265(j)(2)	2 years	Subdivision (3)(i)	State Law
Immunohematology, blood, blood product, and transfusion records	10 years	CLIA 2003	10 years	Subdivision (3)(ii)	CLIA 2003
Proficiency testing records	2 years	CLIA 2003	2 years	Subdivision (4)	CLIA 2003
Quality systems assessment records	3 years	CBPC § 1265(j)(2)	2 years	Subdivision (5)	State Law
Test reports	3 years	CBPC § 1265(j)(2)	2 years	Subdivision (6)	State Law
Immunohematology test reports	10 years	CLIA 2003	10 years	Subdivision (6)(i)	CLIA 2003
Pathology test reports	10 years	CLIA 2003	10 years	Subdivision (6)(ii)	CLIA 2003
Cytology slides and blocks	5 years	CLIA 2003	5 years	Subdivision (7)(i)(A)	CLIA 2003
Histopathology slides	10 years	CLIA 2003	10 years	Subdivision (7)(i)(B)	CLIA 2003
Pathology specimen blocks	2 years	CLIA 2003	2 years	Subdivision (7)(ii)	CLIA 2003
Tissue	Until diagnosed	CLIA 2003	Until diagnosed	Subdivision (7)(iii)	CLIA 2003

NOTE: Authority: Business and Professions Code Sections 1208 and 1224, Health and Safety Code Section 131200. Reference: Business and Professions Code Sections 1220 and 1265.