

FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons at the time of the Public Notice remains unchanged. As authorized by Government Code Section 11346.9(d), the California Department of Public Health (Department) incorporates by reference all contents of the Initial Statement of Reasons into the Final Statement of Reasons.

Local Mandate Determination

The Department has determined that the proposed regulation does not impose any mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code, nor are there any other nondiscretionary costs imposed.

Impact on Small Business

The Department has determination that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. Thus, there will be no significant adverse economic impact on California businesses.

Alternatives Determination

The Department has determined that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law regarding Clinical Laboratory Standards: Definitions intended to protect the public interest in maintaining high standards of regulating clinical laboratory personnel.

Summary and Response to Comments Received During the Initial Notice Period

The Department received one comment during the initial public notice period beginning February 7, 2020, through March 23, 2020, though due to the Department's response to the COVID-19 pandemic, the comment period was extended to April 6, 2020. No request for a public hearing was received and no hearing was held.

List of Commenters During Initial 59-day Notice Period (Written testimony)

- 1) Samir Aleryani, Redwood Toxicology Laboratory

Comment: Suggested the Department consider adding the words "national registry" and "registry" to the definition of Certifying Organization to read as follows: "Certifying organization" also called a national accreditation or accrediting board or national registry; means an organization; agency; or body that creates competency.

Response: The Department considered and rejected the alternative of adding the terms "national registry" and "registry" to the definition of "certifying organization." Registries, including national registries, do not create competency examinations. Registries list people who have successfully completed examinations. Adding these terms to the definition could create confusion about the role of registries.

Explanation for adopting language identical to state or federal statutory definitions.

This change was requested by stakeholder groups. The statutory definitions adopted in this regulations package are the subject of numerous inquiries, because the individual definitions are located in different sections of the BPC as well as federal codes and can be difficult to locate. For ease of reference, and to avoid requiring the reader to search through the BPC for these definitions, and to locate them in one place for ease of comparison, the Department is incorporating the exact federal statutory definitions as incorporated into various sections of the BPC.