

**State of California**  
**Department of Health Services**

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# **Clinical Laboratory Technology Advisory Committee**

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Subcommittee to Advise  
The Department on Issues  
Related to  
Accreditation Organizations

**June 4, 1997**

*Thank you for being here!*

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Lee H. Hilborne, MD, MPH  
Director, Quality Management Services

TO: Clinical Laboratory Technology Advisory Committee

FROM: Accreditation Subcommittee

RE: Subcommittee Report

The Accreditation Subcommittee met several times by conference call and culminated our discussions with an in person meeting on May 23, 1997. We are pleased to attach our recommendations to the entire CLTAC for consideration. Upon approval or modification, these recommendations will be forward to the Department to assist them as they develop regulations to describe how deeming authority will be given to Accreditation Organizations when California becomes CLIA exempt.

Representatives from the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the College of American Pathologists (CAP), and the Commission on Office Laboratory Accreditation (COLA) participated in our discussions and provided input to our final recommendations.

The Subcommittee began with Subpart E of CLIA, recognizing that our regulations needed to be consistent with those specified in CLIA. We then added sections to address California specific requirements. The final product is attached. A version that contains ~~strikeout~~ and underline type with additions and deletions from CLIA language is available on request.

In addition to the items contained in the proposed language, the Subcommittee discussed the following additional concerns and hope the Department will consider these as they write and implement the regulations.

1. There was some concern expressed by the Accreditation Organizations regarding their desire to be the responsible party for proficiency testing evaluation for accredited laboratories. The Department should consider this request but not in lieu of the Department actually receiving proficiency testing data from accredited laboratories. The concern is that follow up of problems with proficiency testing problems should be addressed by one organization. To the extent that an accreditation organization follows up on problems and provides the resolution to the Department, this will eliminate the need for laboratories to respond to multiple entities for the same issue.
2. Accreditation Organizations are concerned about the extent to which they will be responsible for assuring compliance with California Laws and Regulations. They would, and the Subcommittee agrees, like some guidance from the Department as they develop tools to assess compliance with California laws and regulations. For example, to what extent should the Accreditation Organizations look beyond Chapter 3 and what specific areas of the law need to be explicitly addressed. We recommend that the Department prepare an "orientation" program to educate Accreditation Organizations with California requirements and how they might meet them. We believe this program will also be valuable to non-accredited (i.e., LFS licensed) laboratories as it will outline the most important California laws relating to laboratory services. This does not imply that it is acceptable to be out of compliance with any of the laws; however, how compliance is assessed and monitored will be helpful.
3. Concerns were raised about the ability of Accreditation Organizations to assess and assure compliance with fraud and abuse problems given they are not governmental agencies. While we believed it acceptable for there to be guidelines to determine if fraud or abuse might be present, the actual investigation for serious allegations is probably best handled by the Department.
4. The Committee was concerned about the Department's ability to cover HCFA overhead fees from

Accredited Laboratories because statute allows them only to collect \$100 per year after the first year as an administrative fee. The approximate overhead cost to the Department is about \$40/year. Options to address this concern include going back to the legislature to increase the allowable fee and passing on the overhead fees to the Accreditation Organizations who may assess an additional fee from their laboratories wishing California accreditation. The latter solution was considered problematic from the standpoint of the Accreditation Organizations present because they do not want to be seen as increasing fees charged to their laboratories. The Department will need to address this issue fairly soon if the solvency of the exemption program is to be continued.

5. There will be increased challenges to Accreditation Organizations wishing to accredit out-of-state laboratories receiving specimens from California.

The Subcommittee appreciates the support and guidance from the Department and from the CLTAC. We hope that this report meets the needs of both the Committee and the Department.

1 Subpart E -- Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an  
2 Approved State Laboratory Program

3  
4 §493.501 General requirements for accredited laboratories.

5 (a) *Deemed status.* The Department may deem a laboratory to meet all the applicable California Clinical  
6 Laboratory program requirements of this Section if the laboratory is accredited by a private, nonprofit  
7 accreditation organization for laboratories that-

8 (1) Provides reasonable assurance to the Department that it requires the laboratories it accredits to meet all  
9 California Clinical Laboratory condition level requirements specified in this section and would, therefore,  
10 meet condition level requirements if those laboratories had not been granted deemed status and had  
11 been inspected the Department against condition level requirements; and

12 (2) Meets the requirements of §493.506 (substitute California Statute) of this section.

13 (b) *Laboratory requirements.* To be deemed to meet the applicable California Clinical Laboratory licensing  
14 requirements, a laboratory accredited by a private, nonprofit accreditation organization must-

15 (1) Authorize its accreditation organization to release to the Department all records and information required  
16 by the Department;

17 (2) Permit inspections as required by these regulations;

18 (3) Obtain a California Clinical Laboratory license and Certificate of Accreditation as required by §1265(A)(1)  
19 §1300 (h) and (i) and of Chapter 3 of the California Business and Professions code; and

20 (4) Pay the applicable fees as required by §1300 (h) and (i) of Chapter 3 of the California Business and  
21 Professions Code

22 (c) *Application and reapplication process for accreditation organizations.* In applying or reapplying to the  
23 Department for deeming authority, a private nonprofit accreditation organization must provide the following  
24 information to the Department--

25 (1) Evidence that the organization has received and maintains deeming authority from HCFA;

26 (2) The specialty(ies) or subspecialty(ies) for which the organization is requesting "deeming authority": each  
27 laboratory subspecialty must be identified by the same numbering system as is used by HCFA.

28 (3) A detailed comparison of individual accreditation organization requirements with the comparable HCFA,  
29 CLIA and California condition level requirements; i.e., a crosswalk that incorporates, in addition to those  
30 requirements by HCFA, evidence that the organization inspection process verifies compliance with  
31 applicable California laws and regulations;

32 (4) A detailed description of the inspection process, including the frequency of inspections, copies of  
33 inspection forms, instructions, and guidelines, a description of the review and decision-making process of  
34 accreditation inspections and a description of the steps taken to monitor the correction of deficiencies;  
35 instruments designed to specifically satisfy California requirements must be included;

36 (5) A description of the process for monitoring proficiency testing (PT) performance, including action to be  
37 taken in response to unsuccessful participation in an approved PT program must be included;

38 (6) A description of the accreditation organization's data management and analysis system with respect to its  
39 inspection and accreditation decisions including the kinds of routine reports and tables generated by the  
40 system;

41 (7) Detailed information concerning the personnel who perform accreditation inspections, including but not  
42 limited to training in California Clinical Laboratory laws and regulations, the size and composition of  
43 individual accreditation inspection teams, education and experience requirements that those inspectors  
44 must meet and the content and frequency of the training provided to inspection personnel;

45 (8) Procedures to investigate and respond to complaints against accredited laboratories according to the  
46 requirements established by the accreditation organization and approved by the Department, including  
47 procedures for reporting complaints to the Department;

48 (9) A list of any currently accredited laboratories in California or performing services on specimens originating  
49 in California and the expiration date of each laboratory's accreditation;

50 (10) Procedures for removal or withdrawal of accreditation status for laboratories that fail to meet the  
51 organization's standards;

52 (11) A proposed agreement between the accreditation organization and the Department with respect to the  
53 notification requirements specified in §493.506(b)(3) (substitute California Statute) of this subpart; and

54 (12) A statement explaining whether routine inspections are conducted on an announced or unannounced  
55 basis, and a statement that the accrediting body will conduct unannounced inspections when the nature of  
56 the complaint is of the severity to warrant an on-site survey.

57 (13) Accrediting agencies will be responsible for paying an application and quality validation fee to the  
58 Department to cover the costs associated with carrying out the requirements of this section.

59 (14) Accrediting agencies with deeming authority under HCFA as of the effective date of these regulations  
60 must apply to the Department for California deeming authority within 90 days of notification of  
61 promulgation of these regulations by the Department to accrediting organizations. Federal deeming  
62 authority will no longer be recognized by California beyond this time if application has not been submitted.  
63 Federal deeming authority will no longer be recognized in California when the Department has denied an

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- 1 application.  
 2 (15) Accrediting agencies with deeming authority under HCFA as of the effective date of these regulations  
 3 must --  
 4 (a) If the laboratory's accreditation is to be renewed between the time the accrediting agency receives  
 5 deeming authority and within one year of the effective date of these regulations, the accrediting  
 6 agency must complete an on-site inspection of each accredited laboratory to ensure compliance with  
 7 requirements specified in §493.506(b)(2) (substitute California regulation) within that year; or  
 8 (b) If the laboratory's regular inspection cycle does not fall with the period specified in (a) above, the  
 9 accrediting agency must require accredited laboratories to complete a self-inspection and provide  
 10 the agency with written documentation that each accredited laboratory is in compliance with  
 11 California statute and regulation.  
 12 (c) Include compliance with §493.506(b)(2) (substitute California regulation) as part of each subsequent  
 13 inspection performed for laboratories receiving specimens originating in California.  
 14 (d) *Application review process.* Once the Department receives an application for deeming authority from a private  
 15 non-profit accreditation organization--  
 16 (1) Within 90 days, the Department will determine if additional information is necessary to make a  
 17 determination for approval of the accreditation organization's application for deeming authority and will so  
 18 notify the organization and give it an opportunity to provide the additional information.  
 19 (2) The Department may visit the organization's offices to verify representations made by the organization in  
 20 its application, including, but not limited to, review of documents and interviews with the organization's  
 21 staff.  
 22 (3) Within 30 days from when the Department determines the application is complete, the accreditation  
 23 organization will receive a formal notice from the Department stating whether the request for deeming  
 24 authority has been approved or denied and the rationale for any denial.  
 25 (4) The Department may approve an accreditation organization for a period not to exceed six years.  
 26 (5) An accreditation organization may withdraw its application for approval of deeming authority at any time  
 27 prior to the official notification specified in paragraph (d)(3) of this section.  
 28 (6) Except as provided in paragraph (d)(8) of this section, any accreditation organization whose request for  
 29 approval of deeming authority is denied may request, within 60 days of the notification of the denial, that  
 30 its original application be reconsidered.  
 31 (7) Except as provided in paragraph (d)(8) of this section, any accreditation organization whose request for  
 32 approval of deeming authority has been denied may resubmit its application if the organization--  
 33 (i) Has revised its accreditation program to address the rationale for denial of its previous request;  
 34 (ii) Can demonstrate that it can provide reasonable assurance that its accredited facilities meet CLIA,  
 35 HCFA and California condition level requirements; and  
 36 (iii) Resubmits the application in its entirety.  
 37 (8) If an accreditation organization has requested, in accordance with part 488, subpart D (substitute  
 38 California Statute) of this chapter, a reconsideration of the Department's determination that its request for  
 39 deeming approval is denied, it may not submit a new application for deeming authority until a final  
 40 reconsideration determination is issued.  
 41 (e) *Publication of names of approved accreditation organizations.* The Department publishes a notice in the  
 42 California Regulatory Notice Register when it grants deeming authority to an accreditation organization under  
 43 paragraph (a) of this section. The notice--  
 44 (1) Names the accreditation organization;  
 45 (2) Describes the basis for granting deeming authority to the accreditation organization;  
 46 (3) Describes how the accreditation organization provides reasonable assurance to the Department that  
 47 laboratories accredited by the organization meet California Clinical Laboratory requirements equivalent to  
 48 those specified in this part and would, therefore, meet California Clinical Laboratory requirements if those  
 49 laboratories had not been granted deemed status, but had been inspected against HCFA, CLIA and  
 50 California condition level requirements; and  
 51 (4) Specifies a term of approval not to exceed six years.  
 52 §493.504 *Revocation or extinction of accreditation.*  
 53 (a) After a private, nonprofit accreditation organization withdraws or revokes its accreditation of a laboratory, the  
 54 certificate of accreditation required by this part will continue in effect until the earlier of--  
 55 (1) 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or  
 56 (2) The effective date of any action taken by the Department.  
 57 (b) If a laboratory is approved by a California approved agency that will no longer accredit California Clinical  
 58 laboratories, the accredited laboratory must, within 45 days of notification--  
 59 (1) Seek accreditation from another, California approved, accreditation agency; or  
 60 (2) Apply for regular licensure through the Department.  
 61 (c) If a laboratory is approved by a HCFA approved agency prior to California exemption, if that agency fails to  
 62 achieve California deeming authority by 180 days, the accredited laboratory must, within 30 days of notification--  
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- (1) Seek accreditation from another, California approved, accreditation agency; or
  - (2) Apply for regular licensure through the Department.
- (d) A laboratory's certificate of accreditation shall be considered valid during all periods in which the accrediting organization that issued the certificate of accreditation is participating in deeming authority review, deeming authority reconsideration, or appeal processes.

8 **§493.506 California state review and approval of private, nonprofit accreditation organizations.**

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- (a) An accreditation organization may request and may be granted "deeming authority" for all specialties and subspecialties or for specific specialty or subspecialty areas. In the latter case, the accreditation organization will be accountable for the monitoring of compliance with all requirements equivalent to HCFA condition level requirements within the scope of the specialty or subspecialty.
  - (b) The Department's review of a private, non-profit accreditation organization includes, but is not necessarily limited to, an evaluation of the following--
    - (1) Whether the accreditation organization's requirements for laboratories are equal to or more stringent than the HCFA and CLIA condition level requirements for laboratories;
    - (2) All applicable California Clinical Laboratory and related laws and regulations, whether the laboratory is operating within or outside California using a validation mechanism acceptable to the Department
    - (3) The accreditation organization's inspection process to determine --
      - (i) The composition of the inspection team, qualifications of the inspectors (including their knowledge of applicable California statute and regulations), and the ability of the organization to provide continuing education and training to inspectors;
      - (ii) The comparability of the organization's full inspection and complaint inspection requirements to those of the Department, including but not limited to inspection frequency, and the ability to investigate and respond to complaints against accredited laboratories;
      - (iii) The organization's procedures for monitoring laboratories found to be out of compliance with its requirements. (These monitoring procedures are to be used only when the accreditation organization identifies noncompliance. If noncompliance is identified through validation inspections, the Department monitors corrections as authorized at §493.507(b)(4) of this subpart) (substitute California Statute);
      - (iv) The ability of the organization to provide the Department with electronic data and reports, including the crosswalk specified in §493.501(c)(2) (substitute California Statute), in ASCII-comparable code that are necessary for effective validation and assessment of the organization's inspection process;
      - (v) The ability of the organization to provide the Department with electronic data in ASCII-comparable code related to the adverse actions resulting from PT results constituting unsuccessful participation in PT programs as well as data related to the PT failures, within 30 days of the initiation of adverse action;
      - (vi) The ability of the organization to provide the Department with electronic data in ASCII-comparable code for all accredited laboratories, including the area of specialty or subspecialty;
      - (vii) The adequacy of numbers of staff and other resources;
      - (viii) The organization's ability to provide adequate funding for performing required inspections; and
      - (ix) How the accrediting organization will assure compliance with California statute and regulations if the accrediting organization wishes to accredit laboratories outside California that receive California specimens.
    - (4) The organization's agreement with the Department that requires it to:
      - (i) Notify the Department of any laboratory accredited by the organization that has had its accreditation denied, withdrawn, revoked or limited by the accreditation organization or that has had any other adverse action taken against it by the accreditation organization within 30 days of the action taken;
      - (ii) Notify the Department within 10 days of a deficiency identified in an accredited laboratory where the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public;
      - (iii) Notify the Department of all newly accredited laboratories (or laboratories whose areas of specialty or subspecialty are revised) within 30 days;
      - (iv) Notify each laboratory accredited by the organization within 10 days of the Department's withdrawal of recognition of the organization's deeming authority;
      - (v) Provide oversight of all areas performing tests under the accreditation certificate, identifying each specialty, subspecialty and each testing location included in the accreditation;
      - (vi) Provide oversight for any non-diagnostic general health assessment-like programs operated under the laboratory's license;
      - (vii) Provide the Department with inspection schedules, as requested, for the purpose of conducting onsite validation inspections;
      - (viii) Provide the Department with any facility-specific data to include, but not be limited to, the following (upon request):

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- (A) PT results that constitute unsuccessful participation in an approved PT program; and  
 (B) Notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation;
- (ix) Provide the Department written notification at least 30 days in advance of the effective date of any proposed changes in its requirements; and
- (x) Disclose any laboratory's PT results upon the reasonable request by any person.

**§493.507 Validation inspections of laboratories with certificates of accreditation.**

- (a) **Basis for inspection.** The Department may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation. The results of these inspections will be used to validate the accreditation organization's accreditation process. These inspections may be conducted on a representative sample basis or in response to substantial allegations of noncompliance.
- (1) When conducted on a representative sample basis, the inspection is comprehensive, addressing all federal and state condition level requirements, or may be focused on a specific condition level requirement or requirements, and the number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of each accreditation organization. The Department may conduct validation inspections concurrently with the accreditation agency.
- (2) When conducted in response to a substantial allegation of noncompliance the Department inspects for any condition level requirement or requirements that the Department determines to be related to the allegation. If the Department substantiates a deficiency and determines that the laboratory is out of compliance with any condition level requirement, the Department will conduct a full California Clinical Laboratory inspection.
- (b) **Effect of selection for inspection.** A laboratory selected for inspection must:
- (1) Authorize its accreditation organization to release to the Department, on a confidential basis, a copy of the results of the laboratory's most recent full, and any subsequent partial, accreditation inspection(s).
- (2) Authorize the validation inspection to take place.
- (3) Provide the Department access to all facilities, equipment, materials, records and information that the Department determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit the Department to copy any such material or require it to be submitted; and
- (4) Authorize the Department to monitor the correction of any deficiencies found through the validation inspection.
- (c) **Refusal to cooperate with the inspection.**
- (1) If a laboratory selected for inspection fails to comply with the requirements specified in paragraph (b) of this section it--
- (i) Will be subject to full review by the Department in accordance with this part; and
- (ii) May be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.
- (2) An accredited laboratory will be once again deemed to meet the condition level requirements by virtue of its accreditation when--
- (i) It withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure;
- (ii) It withdraws any prior refusal to allow a validation inspection; and
- (iii) The Department finds that the laboratory meets all the condition level requirements.
- (d) **Consequences of a finding of noncompliance.** If a validation inspection results in a finding that the laboratory is out of compliance with one or more condition level requirements, the laboratory is subject to the same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following a State agency inspection under this part and to full review by the Department in accordance with this part, i.e., the laboratory will be subject to the principal and alternative sanctions specified in §493.1806 (substitute California Statute) of this part.
- (e) **Disclosure of accreditation and validation inspection results.** The accreditation inspection results are disclosable to the public only if they are related to an enforcement action taken by the Department. The results of all validation inspections conducted by the Department are disclosable.
- (f) **Onsite observation of accreditation organization operations.** As part of the validation review process, the Department may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. Such an onsite inspection may include, but is not limited to, the review of documents, the auditing of meetings concerning the accreditation process, the evaluation of accreditation inspection results or the accreditation decision-making process, and interviews with the organization's staff.

**§493.509 Continuing California oversight of private, nonprofit accreditation organizations.**

- (a) **Comparability review.** In addition to reviewing the equivalency of specified accreditation requirements to the

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comparable condition level requirements when an accreditation organization initially applies to the Department for "deeming authority", the Department reviews the equivalency of requirements--

- (1) When the Department promulgates new condition level requirements;
  - (2) When the Department identifies accreditation organizations whose requirements do not continue to be equal to or more stringent than federal or state condition level requirements;
  - (3) When an accreditation organization adopts new requirements;
  - (4) When an accreditation organization adopts changes to its inspection process as required by §493.511(b) (substitute California Statute), or
  - (5) Every six years or sooner if the Department determines the organization requires an earlier review.
- (b) *Validation review.* Following the end of a validation review period, the Department evaluates the validation inspection results for each approved accreditation organization.
- (c) *Reapplication procedures.*
- (1) Every six years, or sooner as determined by the Department, an approved accreditation organization must reapply for continued approval of deeming authority. The Department will notify the organization of the materials the organization must submit as part of the reapplication procedure.
  - (2) An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability or validation review, must furnish the Department, upon request and at any time, with the reapplication materials the Department requests. The Department will establish a deadline by which the materials are to be submitted.
- (d) *Notice.* The Department provides written notice to the accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that an accreditation organization is not meeting the requirements of this subpart and that a deeming authority review is being initiated. The notice contains the following information--
- (1) A statement of the discrepancies that were found as well as other related documentation;
  - (2) An explanation of the Department's review process on which the final determination will be based and a description of the possible actions as specified in §493.511 (substitute California Statute) that may be imposed by the Department based on the findings from the comparability or validation review;
  - (3) A description of the procedures available if the accreditation organization desires an opportunity to explain or justify the findings made during the comparability or validation review; and
  - (4) The reapplication materials the organization must submit and the deadline for that submission.

#### §493.511 Removal of deeming authority and final determination review.

- (a) *Deeming authority review.*
- (1) The Department reviews, as appropriate, the criteria described in §493.506 (substitute California Statute) to reevaluate whether the accreditation organization continues to meet all these criteria. The Department conducts a deeming authority review of an accreditation organization's program if the comparability or validation review produces findings as described at §493.509(a) (substitute California Statute) of this subpart.
  - (2) The Department conducts, at its discretion, a deeming authority review of an accreditation organization's program if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to California Clinical Laboratory requirements, taken as a whole.
  - (3) The Department conducts a deeming authority review whenever validation inspection results over a one-year period indicate a rate of disparity of 20 percent or more between the findings of the accreditation organization and the findings of the Department.
- (b) Following the deeming authority review, if the Department determines that the accreditation organization has failed to adopt requirements equal to or more stringent than California Clinical Laboratory requirements, the Department may give the accreditation organization a conditional approval effective 30 days following the date of the Department's determination of its deeming authority for a probationary period, not to exceed one year, to adopt comparable requirements.
- (c) Following the deeming authority review, if the Department determines that there are widespread systematic problems in the organization's inspection process, the Department may give the accreditation organization conditional approval of its deeming authority during a probationary period not to exceed one year that is effective 30 days following the date of the Department's determination.
- (d) Within 60 days after the end of any probationary period, the Department will make a final determination as to whether or not an accreditation organization continues to meet the criteria described at §493.506 (substitute California Statute) of this subpart and issues an appropriate notice (including reasons for the determination) to the accreditation organization. This determination is based on the evaluation of any of the following:
- (1) The most recent validation inspection and review findings as described at §493.509(b) (substitute California Statute) of this subpart. In order for the accreditation organization to continue to have deeming authority, it must continue to meet the criteria in §493.506 (substitute California Statute) of this subpart;
  - (2) Facility-specific data and other related information;

- 1 (3) The accreditation organization's surveyors in terms of qualifications, ongoing education and training, com-  
2 position of inspection team, etc.;
- 3 (4) The organization's inspection procedures; and
- 4 (5) The organization's accreditation requirements.
- 5 (e) The Department may remove recognition of deeming authority effective 30 days from the date that it provides  
6 written notice to the accreditation organization that its deeming authority will be removed if the accreditation  
7 organization has not made improvements acceptable to the Department during the probationary period.
- 8 (f) The existence of any validation review, deeming authority review, probationary status, or any other action by  
9 the Department with respect to an accreditation organization does not affect or limit the conduct of any  
10 validation inspection of its accredited laboratories.
- 11 (g) The Department will publish a notice in the California Regulatory Notice Register containing a justification of the  
12 basis for removing the deeming authority from an accreditation organization.
- 13 (h) After the Department withdraws approval of an accreditation organization's deeming authority, the certificates  
14 of accreditation of all affected laboratories continue in effect for 60 days after the laboratory receives notifica-  
15 tion of the withdrawal of approval. The Department may extend the period for an additional 60 days for a  
16 laboratory if it determines that the laboratory submitted an application for inspection to another approved  
17 accreditation organization for an application for a certificate, certificate for physician-performed microscopy  
18 procedures, or certificate of waiver to the Department before the initial 60 day period ends.
- 19 (i) If at any time the Department determines that the continued approval of deeming authority of any accreditation  
20 organization poses an immediate jeopardy to the patients of the laboratories accredited by that organization, or  
21 such continued approval otherwise constitutes a significant hazard to the public health, the Department may  
22 immediately withdraw the approval of deeming authority of that accreditation organization.
- 23 (j) Any accreditation organization that is dissatisfied with a determination to withdraw its deeming authority may  
24 request a reconsideration of that determination in accordance with subpart D of part 488 (substitute California  
25 Statute).
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## CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE

### ACCREDITATION SUBCOMMITTEE MEMBERS

Lee H. Hilborne, M.D. (CHAIR)  
UCLA Center for Health Sciences  
Department of Pathology and Laboratory Medicine  
(HOME) 11116 Montana Avenue  
Los Angeles, CA 90049  
PHONE: (310) 825-5656 FAX: (310) 794-9218

Kay Cassel, Ph.D.  
21977 Wakefield Court  
Santa Clarita, CA 91350  
PHONE (HOME): (805) 2975915 FAX: (805) 263-0426

Mr. Robert I. Footlik  
Department of Pathology and Laboratory Medicine  
Cedars-Sinai Medical Center  
8700 Beverly Boulevard, Room 3726  
Los Angeles, CA 90048  
PHONE: (310) 855-5335 FAX: (310) 659-0517

Mr. Lyle Rosser  
Kaiser Permanente Regional Office  
11668 Sherman Way  
North Hollywood, CA 91605  
PHONE: (818) 503-7036 FAX: (818) 503-6866

Karen L. Nickel, Ph.D.  
Laboratory Field Services  
2151 Berkeley Way, Annex 12  
Berkeley, CA 94704  
PHONE: (510) 873-6360 FAX: (510) 286-6731

Ms. Alice Brydon  
Laboratory Field Services  
2151 Berkeley Way, Annex 12  
Berkeley, CA 94704  
PHONE: (510) 873-6334 FAX: (510) 286-6731

Ms. Donna Nowakoski  
JCAHO  
1 Renaissance Blvd  
Oakbrook Terrace, IL 60181  
Phone (630) 916-5600

Fax: (630) 792-5636

Ms. Gloria Hopewell  
325 Waukegan Road  
Northfield, IL 60093  
Phone: 1-800-323-4040

Fax: (847)832-8171

Ms. Tammy Zinsmeister  
COLA  
~~119 S. Main Street, Suite 220~~<sup>240</sup>  
Seattle, WA 98104

Phone: (206) 343-1456

Fax: 206)624-2592

600 First Avenue, #240  
Seattle WA 98104