

All COLA accredited laboratories are currently required to meet these CLIA standards. We have, therefore, found the COLA personnel requirements to be equal to the CLIA personnel requirements.

Subpart P—Quality Assurance for Moderate or High Complexity Testing or Both

We have determined that COLA's requirements for immunohematology are equal to the CLIA requirements of this subpart. COLA also makes educational materials available to its accredited laboratories, which provide further information on quality assurance in the office laboratory.

Subpart Q—Inspections

The COLA inspection process, which is announced and performed on-site on a biennial basis, is equal to the applicable CLIA requirements at §§ 493.1777. Therefore, we have determined that COLA's requirements are equal to the requirements of this subpart.

Subpart R—Enforcement Procedures for Laboratories

COLA meets the requirements of subpart R to the extent it applies to accreditation organizations. COLA policy stipulates the action it takes when laboratories it accredits do not comply with its essential standards pertaining to immunohematology. When appropriate, COLA will deny accreditation to a laboratory and report the denial to HCFA within 30 days. COLA also provides an appeals process for laboratories that have had accreditation denied.

We have determined that COLA's laboratory enforcement and appeal policies are essentially equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of COLA accredited laboratories, as specified in § 493.507, may be conducted on a representative sample basis or in response to substantial allegations of noncompliance, "complaint inspections". The outcome of those validation inspections, performed by HCFA, the State survey agency, or a HCFA agent, will be HCFA's principal means for verifying that the laboratories accredited by COLA remain in compliance with CLIA requirements. This Federal monitoring is an on-going process.

V. Removal of Approval as an Accrediting Organization

Our regulations at § 493.511 provide that the approval of an accreditation organization, such as that of COLA, may be removed by HCFA for cause, prior to the end of the effective date of approval. If validation inspection outcomes and the comparability or validation review produce findings as described at § 493.509(a), HCFA will conduct a review of the accreditation organization's program. A review is also conducted when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2), indicate widespread or systematic problems in the organization's processes. These findings provide evidence that the organization's requirements are no longer equivalent to the CLIA requirements.

If it is determined that COLA has failed to adopt requirements that are equal to or more stringent than the CLIA requirements, or widespread systemic problems exist in its inspection process, a probationary period, not to exceed one year, may be given to allow COLA to adopt comparable requirements. Based on an evaluation of any of the items stipulated at § 493.511(d), a determination will be made as to whether or not COLA retains its approved status as an accreditation organization under CLIA. If approved status is denied, an accreditation organization such as COLA may resubmit its application when it: (1) Has revised its program to address the rationale for the denial; (2) demonstrated that it can reasonably assure that its accredited laboratories meet CLIA condition level requirements; and (3) resubmits its application for approval as an accreditation organization in its entirety. If, however, an accrediting organization requests reconsideration of an adverse determination in accordance with subpart D of part 488 of our regulations, it may not submit a new application until a final reconsideration determination is issued.

Should circumstances result in COLA having its approval withdrawn, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: March 16, 1997.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting of the Advisory Committee to the Director, NIH

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, June 5, 1997, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 8:30 a.m. to adjournment. The topics proposed for discussion may include (1) the future of research careers in biology and medicine; (2) clinical research; (3) further implementation of the recommendations of the Report of the NIH AIDS Research Program Evaluation Task Force, particularly in regard to the development of an HIV vaccine; (4) activities related to research misconduct; and (5) infectious diseases in Africa. Attendance by the public will be limited to space available.

Ms. Janice Ramsden, Program Specialist, Office of the Deputy Director, National Institutes of Health, 1 Center Drive MSC 0159, Bethesda, Maryland 20892-0159, telephone (301) 496-0959, fax (301) 496-7451, will furnish the meeting agenda, roster of committee members, and substantive program information upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Ramsden no later than May 30, 1997.

Dated: May 14, 1997.

LaVeen Ponds,
Acting Committee Management Officer, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute on Drug Abuse