Dated: July 2, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03118]

Cooperative Agreement for the Development and Evaluation of Medical Laboratory Quality Indicators and the Monitoring of Voluntary Practice Guidelines as a Model; Notice of Availability of Funds

Application Deadline: August 8, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317(k)(2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement for a program to develop and evaluate appropriate medical laboratory quality indicators and to evaluate the implementation of voluntary laboratory practice guidelines. This program addresses the ''Healthy People 2010'' focus area of Access to Quality Health Services.

The purpose of the program is twofold:

(1) Collaborate with a broad spectrum of laboratories (*e.g.*, hospital, public health, doctor's office, and local clinic), care providers and payers, and public health to develop and evaluate appropriate laboratory quality indicators and to develop a plan for collection and monitoring of the indicators.

(2) Recently collected data show that a significant number of laboratories do not follow professional practice guidelines in the areas of antimicrobial susceptibility testing and coagulation. The cooperative agreement recipient will further evaluate implementation of voluntary practice guidelines and assess the barriers to their implementation. This activity may be considered a subcomponent of the first activity and serve as a model for some of the quality indicators.

Measurable outcomes of the program will be in alignment with the following performance goal for the Public Health Practice Program Office: Increase the number of frontline public health workers at the state and local level that are competent and prepared to respond to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies, and prepare frontline state and local health departments and laboratories to respond to current and emerging public health threats.

C. Eligible Applicants

Applications may be submitted by:

- Public nonprofit organizations.
- Private nonprofit organizations.
- Faith-based organizations.
- State and local governments or their bona fide agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

Applications from the above entities are being solicited because they represent organizations that have sufficient background, experience, and current knowledge of laboratory testing. These entities include institutions or organizations with knowledge and experience in public health and medical laboratory testing who are also knowledgeable about current regulatory and voluntary laboratory standards, quality assurance, the use of quality indicators to measure performance and to identify areas in laboratory testing that are error-prone, and who can evaluate these findings in the broader context of the impact on patient health and safety. In addition, these entities will be able to collaborate and work with existing laboratory and health care networks, professional organizations, and others in the field of laboratory medicine to collect data and information on laboratory quality issues and implementation of laboratory standards.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

D. Funding

Availability of Funds: Approximately $125,000 is available in FY 2003 to fund one award ranging from $100,000 to $150,000. It is expected that the award will begin on or about September 15, 2003 and the project period will consist of one 12-month budget period. Funding estimates may change.

Recipient Financial Participation: No matching funds are required for this program.

Funding Preferences: Preference may be given to a State health department clinical laboratory quality assurance or evaluation program or other organization with existing laboratory networks (data collection networks comprised of clinical and public health laboratories that periodically monitor and report on issues related to the delivery of laboratory medicine and quality assurance programs associated with them).

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed in 1. Recipient Activities, and CDC will be responsible for the activities listed in 2. CDC Activities.

1. Recipient Activities:

a. Provide leadership in developing and evaluating laboratory quality indicators in collaboration with representatives from laboratories, care providers, payers, and public health.

b. Provide leadership in the development of an implementation plan for the use of quality indicators to collect and monitor data from a broad spectrum of laboratories (*e.g.*, hospitals, public health sites, doctors' offices and local clinics).

c. Test the plan developed in (b) above by collecting indicator measurement data from laboratories.

d. Evaluate the implementation of selected voluntary laboratory practice guidelines and identify and assess barriers to guideline implementation in various types of laboratories.

e. Collect, enter, analyze, and summarize the data in a manner that is statistically valid and, whenever necessary, ensures participant confidentiality.

f. Distribute reports to participants for self-evaluation and improvement, and make information available to other laboratories nationwide, as appropriate.

g. Develop recommendations for potential mechanisms to overcome barriers and improve the implementation of quality indicators and voluntary laboratory practice guidelines.

h. Prepare manuscripts for peer-review publications.

2. CDC Activities:

a. Assist in identifying quality indicators and voluntary laboratory practice guidelines for evaluation.

b. Facilitate collaboration with external partners who volunteer to work

with the recipient and CDC in developing laboratory quality indicators and identifying practice guidelines.

c. If requested, assist in the development of an implementation plan for the use of the quality indicators.

d. If requested, provide technical assistance with the development of data collection instruments.

e. Collaborate in analyzing the data and information collected and in preparing written summaries.

f. Work with the recipient to identify barriers to using laboratory practice guidelines and to develop recommendations for potential mechanisms to overcome these barriers.

g. Assist in the preparation of manuscripts for peer-reviewed publications.

F. Content

Applications: The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 20 pages, double-spaced, printed on one side, with one-inch margins and unreduced 12-point font, and on 8.5″ x 11″ paper.

The narrative should consist of goals and objectives, a plan of operation, project management and staffing, an evaluation plan, and proposed budget for carrying out the recipient activities in light of the evaluation criteria as described below.

G. Submission and Deadline

Application Forms: Submit the signed original and two copies of [PHS 5161–1 (OMB Number 0920–0428)]. Forms are available at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) at: 770–488–2700. Application forms can be mailed to you.

Submission Date, Time, and Address: The application must be received by 4 p.m. Eastern Time August 8, 2003. Submit the application to: Technical Information Management-PA#03118, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146.

Applications may not be submitted electronically.

CDC Acknowledgement of Application Receipt: A postcard will be mailed by PGO–TIM, notifying you that CDC has received your application.

Deadline: Applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Application: Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

An independent review group appointed by CDC will evaluate each application against the following criteria:

1. Plan of Operation (30 Points):

a. The extent to which the applicant describes the steps to be taken in the planning and implementation of the proposed cooperative agreement.

b. The extent to which the applicant describes the methods to be used to carry out the responsibilities of the proposed cooperative agreement, including the ability to provide the representative participants in the laboratory groups with which they will collaborate.

2. Project Management and Staffing (30 Points):

a. The extent to which the applicant describes their ability to provide staff, knowledge, expertise, and other resources required to perform the responsibilities in this project.

b. The extent to which the applicant describes their qualifications, time allocations of key personnel to be assigned to this project, facilities and equipment, and other resources available for performance of this project.

3. Goals and Objectives (20 Points):

a. The extent to which the applicant describes its understanding of the objectives of this project, the relevance of its proposal to the stated objectives, and any unique characteristics of populations to be studied.

b. The extent to which the applicant's goals and objectives are time-phased, measurable, specific, and achievable.

4. Evaluation Plan (20 Points):

The extent to which the applicant describes their schedule for accomplishing the activities to be carried out in this project and methods for evaluating the accomplishments.

5. Proposed Budget (reviewed but not scored): The extent to which the proposed budget is reasonable, clearly justified, and consistent with the intended use of funds.

6. Performance Goals (reviewed but not scored): The extent to which the application is consistent with the performance goals stated in the purpose section of this announcement.

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

I. Other Requirements

Technical Reporting Requirements: Provide CDC with original plus two copies of:

1. Semiannual progress reports, which will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Additional Requirements: The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement, as posted on the CDC web site.

AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–15 Proof of Non-Profit Status

Executive Order 12372 does not apply to this program.

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements''.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For business management and budget assistance, contact: Deborah Workman, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: (770) 488–2085, E-mail address: *atl7@cdc.gov.*

For program technical assistance, contact: Devery Howerton, Ph.D., Chief, Laboratory Practice Evaluation and Genomics Branch, Division of Laboratory Systems, CDC Public Health Practice Program Office, 4770 Buford Highway, NE., Mailstop G–23, Atlanta, GA 30341–3717, *Telephone:* (770) 488–8126, E-mail: *dhowerton@cdc.gov.*

Dated: July 1, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03119]

Enhancing Testing Practices in the Clinical Laboratory by Developing Specific Training Activities for Medical Technologists, Medical Laboratory Technicians, and Pathologists; Notice of Availability of Funds

Application Deadline: August 8, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317(k)(2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year FY 2003 funds for a cooperative agreement program for Enhancing Testing Practices in the Clinical Laboratory by Developing Specific Training Activities for Medical Technologists (MT), Medical Laboratory Technicians (MLT), and Pathologists. This program addresses the ''Healthy People 2010'' focus areas of: Access to Quality Health Services, and Public Health Infrastructure.

The purpose of the program is to enhance laboratory testing practices and the quality of laboratory testing in the United States. These enhancements in testing practices and the quality of laboratory testing will be related to areas of public health significance such as, antimicrobial susceptibility testing, human immunodeficiency virus (HIV) rapid testing, testing for genetic disorders, chemical terrorism events, other diseases of public health importance, and the regulations, (*i.e.*, Clinical Laboratory Improvement Amendments of 1988 (CLIA)) governing laboratory testing. In addition to enhancing the quality of laboratory testing, the cooperative agreement will also evaluate the training received by laboratory MTs, MLTs, and pathologists to ensure appropriate training efforts are being developed and targeted effectively to the work force of laboratorians located in clinical laboratories across the United States.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the Public Health Practice Program Office: ''Increase the number of frontline public health workers at the state and local level that are competent and prepared to respond to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies and prepare frontline state and local health departments and laboratories to respond to current and emerging public health threats.

C. Eligible Applicants

Applications may be submitted by:

- Public nonprofit organizations.
- Private nonprofit organizations.
- Faith-based organizations.

Applications from the above referenced entities are being solicited because they represent organizations that have sufficient background, experience, and current knowledge of testing in the nation's clinical laboratories, already have in place an established training system for laboratorians that will reach laboratorians across the nation, have an established network of laboratories that provide unique opportunities for continued learning to constituents in all 50 states, have an established training system to enhance laboratory infrastructure with regard to testing, identifying, and reporting potential disease threats, and have a broad outreach to the medical laboratory professionals. These organizations are being solicited because they have a variety of established methods for delivery of laboratory training even in remote areas.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

D. Funding

Availability of Funds

Approximately $150,000 is available in FY 2003 to fund approximately one award. It is expected that the award will be $150,000, ranging from $125,000 to $175,000. It is expected that the award will begin on or about September 15, 2003 and will be made for a 12-month budget period within a project period of up to three budget years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Recipient Financial Participation

Matching funds are not required for this program.

Funding Preferences

Preference may be given to organizations having established medical laboratory training systems that offer a variety of methods to conduct training related to a large variety of subject matter, consistent with those disease threats of public health significance, and that would have a broad outreach to the medical laboratory community that would provide an end result of enhancing laboratory infrastructure.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient