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

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 evaluating the knowledge of clinical laboratory professionals regarding antimicrobial susceptibility testing.

b. Develop an evaluation protocol to determine gaps in knowledge associated with susceptibility testing.

c. Determine if laboratory professionals understand why susceptibility testing is necessary and the implications associated with not performing this type of testing. Develop training and education programs and related materials based on up-to-date laboratory procedures.

d. Implement training and education programs to resolve the knowledge gaps and apply evaluation model to ensure laboratory professionals have received appropriate training, knowledge gaps are resolved, and that knowledge is retained over a specific time period.

e. Provide leadership in developing, implementing, and evaluating training and education programs associated with HIV Rapid Testing.

f. Determine if laboratory professionals know how to perform HIV rapid testing, what algorithm should be applied to results obtained from rapid testing, *i.e.*, how does HIV Rapid Testing affect the current testing algorithm in the United States, as well as, how rapid testing performed in the international laboratory may affect rapid testing in the United States.

g. Provide leadership in developing, implementing, and evaluating training and education programs associated with performing tests to detect chemical terrorism events. Recipient would determine among the clinical laboratory professionals, how many professionals are knowledgeable in detecting chemical terrorism agents and, even if knowledgeable, does their laboratory have the capacity to perform testing.

h. Evaluate the knowledge of laboratory professionals concerning their understanding of DNA testing and the relationship to identification of genetic disorders.

i. Develop and implement training programs for laboratory professionals to increase the awareness of genetics testing in their laboratory and how the testing results assist the clinician in the diagnosis of genetic disorders in their patient, *i.e.*, inherited or mutated disorders.

j. Provide leadership in developing, implementing, and evaluating training and education programs related to CLIA. Ensure that laboratory professionals have received adequate information and are aware of the impact of CLIA regulations on the day-to-day operation of their laboratory.

k. Access information obtained from the CDC sponsored Quality Institute Conference to develop strategies that can be used to improve quality assurance activities, use of quality control materials, recognition of where most testing errors may be occurring, and issues related to point of care testing. It may be necessary for the recipient to form focus groups of experts to discuss the information from the conference associated with these issues to determine possible future recommendations. This may include developing a set of indicators for quality laboratory testing and testing services against which changes in the safety, effectiveness, timeliness, and adequacy of service can be measured.

2. CDC Activities

a. If requested, senior staff will provide consultation and technical assistance in the planning, implementation, and evaluation, of program activities.

b. Senior staff will provide the most up to date scientific information related to antimicrobial susceptibility testing that would assist grantee in developing the appropriate training and education programs.

c. Senior staff will provide consultation and technical assistance related to HIV Rapid Testing and any published reports or other scientific information related to rapid testing that would assist grantee in understanding the possible impact of rapid testing in the United States, and how rapid testing has been performed in international laboratories.

d. Senior staff in the division would provide any up to date genetics testing information, use of genetics quality assurance materials, or other information grantee would find useful in developing training and education programs related to genetics testing.

e. Senior divisional staff would assist the grantee in collaborating with other organizations, other CDC staff, and obtaining useful information regarding testing for chemical terrorism agents that could be useful in developing, implementing, and evaluating training and education programs for chemical terrorism agent testing.

f. Provide current information and experienced senior staff that could assist grantee in preparing training and education programs concerning CLIA regulations and the impact on laboratory testing.

g. Provide information from the CDC sponsored Quality Institute Conference. Senior staff would assist grantee in establishing any expert focus groups from whom strategies and recommendations could be developed, *e.g.*, assistance might be related to helping establish collaborations with world expert scientists who may participate on focus group panels.

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 50 pages, double-spaced, printed on one side, with one inch margins, and unreduced 12-point font.

The narrative should consist of goals and objectives, methods and technical approach, project management and staffing, evaluation plan, and proposed budget for carrying out the recipient activities consistent with the criteria listed in the evaluation criteria section of this announcement.

The plan and methods should address activities to be conducted over the entire three-year project period. Narrative should include a detailed plan for the first year and a brief plan for years two through three.

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#03119, 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. Methods and Technical Approach (30 Points)

a. The extent to which the applicant's proposal describes the approach 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.

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 associated with the 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 their understanding of the objectives of the project and the relevance of their proposal to the stated objectives, including specific outcomes.

b. The extent to which the applicant describes objectives that are specific, measurable, and achievable, including a reasonable schedule for implementation.

4. Evaluation Plan (20 Points)

The extent to which the applicant describes a schedule for accomplishing the activities related to this project and a plan for evaluating their accomplishments.

5. Budget (Reviewed, But Not Scored)

The extent to which the budget is appropriate, reasonable, justified, and consistent in relation to the activities proposed.

6. Performance Measures (Reviewed, But Not Scored)

The extent to which the proposed activities relate to the PHPPO performance goals listed in the purpose section of this announcement.

7. 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. Interim progress report, no less than 90 days before the end of the budget period. The progress report 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:

AR9 Paperwork Reduction Act Requirements

AR10 Smoke Free Workplace Requirements

AR11 Health People 2010

AR12 Lobbying Restrictions

AR15 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''.

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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: William O. Schalla, M.S., Associate Director for Program and Finance, Division of Laboratory Systems, Public Health Practice Program Office, 4770 Buford Hwy., NE., Atlanta, GA 30341–3717, Telephone: (770) 488–8098, E-mail: *wschalla@cdc.gov*.

Dated: July 1, 2003.

Edward Schultz,

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

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