

Guidance for Fiscal Year 2001 Supplemental Funds for Epidemiology and Laboratory Capacity

for Infectious Diseases (ELC) Cooperative Agreement

[ELC Supplement A - NEDSS FY2001: New Activities]

National Electronic Disease Surveillance System (NEDSS) Activities

## 1. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for new competitive supplemental awards to current grantees of the Epidemiology and Laboratory Capacity (ELC) for Infectious Diseases cooperative agreement program. The purpose of these awards is to continue progress toward the implementation of the National Electronic Disease Surveillance System, which is intended to serve public health agencies at the local, state, and national levels. NEDSS implementation is also intended to foster the integration of CDC coordinated surveillance systems. This program addresses the Healthy People 2010 priority areas: Public Health Infrastructure; Immunization and Infectious Diseases; Food Safety; STDs; and TB.

The goals of NEDSS are to enhance public health surveillance through approaches that 1) emphasize, adopt, and promote national standards for electronic exchange of information; 2) foster integration of surveillance and health information systems; 3) support the development of surveillance systems according to a defined information systems architecture; 4) develop direct electronic communications between sources of data (such as health care providers or laboratories) and public health agencies; 5) facilitate ready exchange of data, as appropriate, between local and state health departments, among states, and between states and CDC; 6) ensure security and confidentiality of public health surveillance information in accordance with Health Insurance Portability and Accountability Act (HIPAA) and state regulations.

This competitive supplement describes a range of potential NEDSS activities. In addition, it describes eight NEDSS systems architecture elements, as modified since the FY2000 program announcement, and calls for their application in particular public health activities (See Attachment B for functional and technical descriptions of the elements of the NEDSS architecture). Depending on current capabilities, interests, and needs, applicants may request support under this supplement for one or more of the following NEDSS activities:

2. **Element Development** in the NEDSS architecture,
3. Development of a fully integrated model system in the NEDSS architecture as NEDSS **Charter sites**, and/or
4. Implementation of the NEDSS **Base System**.

**This program announcement is for new activities only - no continuation activities should be included in applications to this program announcement.** New activities include development and implementation of new/additional elements not previously approved and funded, becoming a

new Charter site, and implementation of the Base System. Grantees funded in FY2000 for Element Development or Charter sites will receive under separate cover a non-competitive continuation application solicitation under which they can separately apply for support to continue on-going development of specific elements approved and funded in FY2000 or to continue to act as a Charter site.

## **B. Eligible Applicants**

Eligibility for these competitive supplemental awards is limited to state, territorial, and local health departments that are current grantees under the CDC ELC cooperative agreement. No other applications will be accepted. Thus, the eligible state and local health departments are:

States: All 50

Territories: Puerto Rico

Locals: Chicago IL, Houston TX, Los Angeles County CA, New York City, Philadelphia, PA, Washington DC

Note: Title 2 of the United States Code, Chapter 26, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

## **C. Availability of Funds**

Approximately \$9,260,000 is available in FY 2001 to fund approximately 25-30 ELC grantees for new NEDSS activities as follows:

Approximately \$3,000,000 - \$4,500,000 is available for approximately 10-15 awards for NEDSS Element Development (awards up to approximately \$300,000 per grantee).

Approximately \$600,000 is available for approximately 2 awards for development of new NEDSS Charter sites (average \$300,000 per grantee).

Approximately \$3,750,000 - \$6,000,000 is available for up to 15-20 awards for implementation of the NEDSS Base System (approximate award range \$250,000-\$300,000 per grantee).

These amounts include direct costs, indirect costs, and Direct Assistance. Funding estimates and distribution of funds across the three above areas may change.

The awards will be made on or about September 30, 2001 and will be made within the recipient's current ELC budget period and project period. Continuation awards in subsequent ELC budget periods for on-going NEDSS activities will be made concurrent with recipient's existing annual renewal cycle/process and will be based on demonstrated need for continuation of the approved activities, satisfactory progress, and the availability of funds.

#### Direct Assistance

Applicants may request time-limited specialized technical consultation as direct assistance, *in lieu* of a portion of financial assistance. See additional guidance regarding Direct Assistance options under the CDC Activities and Application Content sections, below.

#### **D. Program Requirements**

To achieve NEDSS Program objectives, recipients will be responsible for the objectives defined under Recipient Activities, while CDC will carry out the responsibilities defined under CDC Activities.

#### Recipient Activities

5. Conduct one or a combination of the following activities:
  - a. NEDSS Element Development - Implement new NEDSS system elements (i.e., elements not previously approved and funded in your FY2000 award). See Attachment B for functional and technical descriptions of the elements. Comply with relevant HIPAA regulations (Health Insurance Portability and Accountability Act of 1996 - available at <http://aspe.os.dhhs.gov/admnsimp/index.htm>).
  - b. NEDSS Charter sites - Implement or demonstrate capacity for all of the systems architecture elements described in Attachment B and conduct activities to tie together these elements into a model of a fully integrated system as a NEDSS Charter site. (Support for the development of particular elements should be sought from activities described as NEDSS Element Development, or identified from other sources). Collaborate with CDC and other sites as a proving ground for and as a model of implementation of the NEDSS architecture. Collaborate with CDC and other sites to refine NEDSS standards and develop electronic public health messages (e.g., XML messages).

- c. Implementing the NEDSS Base System - Implement the NEDSS Base System as described in Attachment C and more in depth at the following CDC websites: [www.cdc.gov/od/hissb/docs/NEDSSBaseSysDescription.pdf](http://www.cdc.gov/od/hissb/docs/NEDSSBaseSysDescription.pdf) and [www.cdc.gov/od/hissb/docs/NEDSSBaseSysFactSheet.pdf](http://www.cdc.gov/od/hissb/docs/NEDSSBaseSysFactSheet.pdf) ). Work with CDC to evaluate the NEDSS Base System and provide input for improving it. Specifically, work with CDC and CDC representatives to discover new requirements and needs related to integration, workflow, and existing state architecture, among other things, and to test the NEDSS Base System in order to facilitate successful NEDSS Base System installation and operations. For grantees involved in other NEDSS implementation activities, coordinate these activities with NEDSS Base System implementation.
6. Support public health activities using NEDSS base system and/or elements implemented via this program. Identify and evaluate their impact on particular public health activities. The particular public health activities chosen for NEDSS implementation will depend on needs and interests of the recipients. The following are provided as examples:
  - a. Public health reporting involving the state health department and local health departments (In most jurisdictions, this would involve working first with selected rather than all local health departments). This activity could also involve messaging of appropriate information, e.g., notifiable diseases.
  - b. Public health reporting involving other current reporters. This could involve, for example, reporting from infection control practitioners or could also be used for reporting from laboratories which have relatively few cases to report and for which web browser-based reporting might be more appropriate than automated, message-based approach.
  - c. Electronic data exchange (e.g., from public health laboratories, private clinical laboratories, emergency departments, and health care provider organizations). Electronic reporting from one or more potential sources would be developed, using a standards-based approach. Potential sources of electronic reporting include the state public health laboratory, one or more clinical laboratories, emergency departments, and managed care organizations. For electronic reporting activities supported through these supplements that involve large laboratories that report to multiple jurisdictions, recipients would 1) work with CDC to coordinate communications with the laboratory and 2) develop with CDC and other participants the architecture for efficient and secure brokering of data reported from the large laboratories. If electronic reporting activities are already planned

or underway, they should be integrated with activities conducted through these supplements.

- d. Using NEDSS elements to enhance functioning of CDC-coordinated surveillance. For example, could potentially include implementation of CDC-coordinated surveillance information systems within the NEDSS systems architecture, e.g., surveillance systems for nationally notifiable diseases, vaccine preventable diseases, sexually transmitted diseases, Emerging Infections Programs, HIV/AIDS and TB.
7. Participate with CDC and its public health partners in overall NEDSS planning and development including further development and use of the Public Health Conceptual Data Model and data standards, and the future development of the NEDSS systems architecture. Participate, as appropriate, in efforts to brief key partners on their progress and on their assessment of NEDSS implementation, including representatives of ASTHO, CSTE, APHL, NACCHO, NAPHSIS, NAHDO and CDC. Collaborate with CDC in the planning, design, and execution of all phases of these projects.
8. Integrate the planning, execution, and management of activities under this NEDSS supplement with related efforts in categorical program areas, public health laboratories, and particularly in activities supported through FY2001 ELC NEDSS continuation funding and other CDC funding, such as those funded through the Bioterrorism Preparedness including the Health Alert Network (HAN), Sexually Transmitted Diseases (STD), HIV/AIDS, Epidemiology and Laboratory Capacity (ELC), Emerging Infections Programs (EIP), Tuberculosis Elimination, Vaccine Preventable Diseases, and other relevant cooperative agreements. NEDSS is consistent with and builds upon the Health Alert Network (HAN) in terms of purpose, technology infrastructure and technical architecture.
9. If a proposed project involves research on human participants, ensure appropriate Institutional Review Board (IRB) review.

#### CDC Activities

10. Provide technical assistance in the design and implementation of program activities.
11. Provide Direct Assistance through contracted, time-limited, technical consultation according to needs and interests of recipient as follows:
  - a. For NEDSS Element Development or Charter sites, direct assistance will consist of on-site technical consultation plus ongoing off site consultation during the first year, for a total value of approximately \$15,000 in each area per grantee and is available in the following areas:

- 1) Data modeling
  - 2) Messaging support (eXtensible Markup Language (XML), Health Level 7 (HL7), technical support)
  - 3) Security
  - 4) Lightweight Directory Access Protocol (LDAP) directory
  - 5) Software development methodology
- b. For implementation of the NEDSS Base System, direct assistance will consist of several days of on-site technical consultation as part of an integration team plus ongoing off- site consultation during the first year, for a total value of approximately \$25,000 per grantee.
12. Coordinate the implementation of NEDSS, including further development of the Public Health Conceptual Data Model (PHCDM) and data standards, development of a NEDSS technical architecture, and coordination of the activities funded in the various sites under these supplements.
  13. Coordinate an approach to electronic reporting from large laboratories by serving as a point of contact. Develop, in consultation with partners, a secure, efficient capacity for multi-jurisdictional data brokering for electronic reporting from large laboratories that report to multiple jurisdictions. Work with states to define requirements, and to explore the potential and challenges of a unified approach to reporting from large laboratories to public health.
  14. In collaboration with partners, develop, maintain and improve the NEDSS Base System.
  15. If during the project period, research involving human subjects is conducted and CDC scientists will be co-investigators in that research, assist in the development of a research protocol for IRB review by all institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

## **E. Application Content**

### General Instructions

**This program announcement is for new activities only - no continuation activities should be included** in applications to this program announcement. See Purpose, above, for further information.

Use the information in the applicable Program Requirements, Other Requirements, Evaluation Criteria sections, and below to develop the application content. Applications will be evaluated

on the criteria listed in Section G., below, so it is important that narratives follow the criteria in the order presented.

Applicants may apply for one or more of the three areas of NEDSS activities described in this supplemental program announcement: 1) new NEDSS Element Development; 2) new NEDSS Charter sites; and 3) implementation of the NEDSS Base System. **One application** should be submitted that addresses any/all of the three areas you choose to address. **If requesting funds for more than one of the three areas, the budget should be clearly separated by area.** See additional Budget instructions below.

The page limit for narratives (not including appendices for items such as curricula vitae, letters of support, and other similar supporting information) is up to a maximum of 15 single-spaced pages.

All pages of the applications must be single-spaced, printed on one side, with one-inch margins and a font size of 12 on white 8.5" x 11" standard weight paper.

All pages must be clearly numbered, and a complete Table of Contents for the application and its appendices must be included.

The required original application and two full copies must be submitted unstapled and unbound. Do not submit any bound or stapled materials (e.g., pamphlets, booklets, etc.). The entire application (including appendices) must be able to run through an automatic document feed copier.

### Specific Instructions

#### **Application Abstract:**

Begin the application narrative with a brief abstract that clearly indicates which of the areas are being addressed. Also indicate what specific areas or Elements (if any) were funded in FY2000 and whether continuation funding for those activities is being requested under the separate FY2001 non-competitive continuation application process.

#### **Report on Assessment and Planning results to-date:**

For applicants who have previously received funding for (e.g., via the ELC or CSTE cooperative agreements in FY2000 or early FY2001) or have independently engaged in NEDSS Assessment and Planning activities, clearly describe the status and results of these efforts.



### **Applications for new NEDSS Element Development:**

NOTE: This FY2001 NEDSS Element Development guidance recognizes that elements can be in various stages of implementation and that resources for element development may come from multiple sources (e.g., state resources, or resources, as appropriate, from other CDC cooperative agreements). It does not require “all or none” proposals for elements, nor does it specify a limit on the number of elements that may be proposed. However, it does require descriptions of the particular aspects of element development that are being proposed.

In addressing the Evaluation Criteria, applicants for new NEDSS Element Development should provide a description by element for the activities proposed.

16. Development and support of NEDSS architecture elements as well as information systems generally, can be described in terms of three stages:

- a. Acquisition (through purchase or development);
- b. Deployment/Implementation; or
- c. Providing ongoing support.

Use these stages to describe the proposed activities for Element Development. In addition, address the functionality, technology, and public health activities (evaluation criteria #3 and #4 below) for the proposed Element Development activities. (An optional template for organizing this information is included in Attachment E).

17. For proposals involving the development of element C, Integrated Data Repository (IDR), the application should indicate which program area data will be integrated into the IDR initially and describe a plan for subsequent integration of additional program area data.

### **Applications for new NEDSS Charter sites:**

In addressing the Evaluation Criteria, applicants for new NEDSS Charter sites should:

18. Note that support for implementation of particular NEDSS architectural elements should be sought in the NEDSS Element Development section or through other means available to a site (e.g., State health department resources or funding, as appropriate, from other CDC cooperative agreements). The purpose of NEDSS Charter sites awards is to provide additional resources for developing a fully integrated system according to the NEDSS architecture. Accordingly, NEDSS Charter sites applicants who require additional support for development of particular elements would also be expected to apply under the NEDSS Element Development category.

19. Demonstrate in the narrative that the elements of the NEDSS architecture are or will be in place to form the basis for a NEDSS Charter site. Development and support of NEDSS architecture elements as well as information systems generally, can be described in terms

of three stages: 1) Acquisition (through purchase or development); 2) Deployment/Implementation; or 3) Providing ongoing support. Use these stages to describe the elements. (An optional template for organizing this information is included in Attachment E).

20. Describe an operational plan and activities to integrate NEDSS elements to form a NEDSS Charter site consistent with the Recipient Activities section above.

### **Applications for NEDSS Base System:**

Applicants for implementation of the NEDSS Base System should address the Evaluation criteria in section G. See Attachment C - a description of the NEDSS Base System Package - which should guide proposed activities for the implementation of the NEDSS Base System.

### **Budget:**

Budgets submitted should be annualized 12-month budgets. Note that actual awards made will only include costs for activities that occur during the remainder of recipient's current budget period (i.e., that expires either March 30 or June 30, 2002). Annualized budgets are requested to facilitate planning and projections for subsequent year continuations.

If requesting funds for more than one of the three areas, the budget should be clearly separated by area.

Budgets should also clearly identify whether individual items are one-time costs or expected to be on-going (i.e., for continuation in subsequent years). For applicants requesting new NEDSS Element Development funding, organize that segment of the budget by element.

### **Direct Assistance:**

As indicated in CDC Activities #2, above, Direct Assistance is available in certain areas. Applicants requesting DA should clearly include it in their budget as a separate line-item. Amounts requested should be consistent with the amounts indicated in CDC Activities.

## **F. Submission and Deadline**

**Letter of Intent (LOI):** The Letter of Intent (LOI) should be submitted on or before **June 25, 2001**, and can be provided by facsimile, postal mail, or E-mail to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement. Your letter of intent should include: (1) name and address of the applicant organization, (2) name, address, and telephone number of the contact person, and (3) a simple list of the activities/areas that will be addressed in the application.

**Application:** Submit the original and two copies of CDC Form 0.1246. Forms are in the application kit. On or before **July 20, 2001**, submit the application to the Grants Management Specialist identified in the “Where to Obtain Additional Information” section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

- (a) Received on or before the deadline date; or
- (b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications that do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

#### **G. Evaluation Criteria**

An independent review group appointed by CDC will evaluate each application individually against corresponding criteria below.

- 21. Understanding the Purpose and Commitment to the development of the National Electronic Disease Surveillance System. (20 points)  
Extent to which applicant demonstrates a clear understanding of the subject area, purpose and objectives of this cooperative agreement supplement, and a commitment to work towards NEDSS implementation as described in the Recipient Activities, including implementation of the NEDSS architecture (see Attachment B). Extent to which the applicant plans for interoperability and convergence with design level specifications as they evolve through the development of the NEDSS Base System and deliberations of the NEDSS Workgroups. Extent to which proposed activities overall match applicant's needs and capabilities for implementation.
- 22. Management (20 points)
  - a. Recognizing that the implementation of NEDSS may affect a variety of program areas, public health laboratories, and information technology units, extent to which the application demonstrates that, for the purposes of NEDSS implementation, a mechanism is in place or planned for effective decision making across the relevant units of the health department.

- b. Extent to which applicant clearly demonstrates technical and management capability to execute proposed activities, whether through existing capacity, outside collaboration, contracting, requests for Direct Assistance, or other means.
  - c. Extent to which applicant presents a sound operational plan for initiating and conducting the project, which clearly and appropriately addresses all Recipient Activities proposed in the application.
  - d. Extent to which applicant clearly identifies specific assigned responsibilities of all key professional personnel.
  - e. Extent to which applicant demonstrates a workable plan to procure standards-based hardware and software products in a timely manner as they become needed.
  - f. Extent to which activities proposed under these supplements are integrated with related activities conducted through other CDC-sponsored programs.
23. Functionality and Technology (30 points)
- a. Quality of the functional and technical descriptions for proposed NEDSS activities. Extent to which they meet the functional requirements described in Recipient Activities and in the description of the NEDSS Systems architecture (Attachment B). Extent to which proposed activities interoperate or converge with the NEDSS architecture design level specifications as they evolve through deliberations of the NEDSS Workgroups and the development of the NEDSS Base System (i.e., Logical Data Model, data base design, messages, services).
  - b. Extent to which application focuses on the users of the proposed NEDSS activities and their information needs, the process for identifying and prioritizing functional requirements, and evidence that user needs are being met.
  - c. Description of existing functional and technical capacity in terms of the systems architecture presented in Recipient Activities, and evaluation of the degree to which they are consistent with this architecture.
  - d. Extent to which proposed functions and technologies are integrated or planned to be integrated with existing capacities and with any on-going NEDSS continuation activities.
24. Impact on Public Health Work (30 points)
- a. Extent to which applicant focuses on well-defined, important public health activities.
  - b. Quality of application with respect to impact of the proposed activities on public health work, particularly access to needed information for public health decision-making.

- c. Extent to which functional and technical aspects of the project are integrated with the proposed public health surveillance activities.
  - d. If proposed activities involve human subject research, the degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:
    - 1. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.
    - 2) The proposed justification when representation is limited or absent.
      - 3) A statement as to whether the design of the study is adequate to measure differences when warranted.
      - 4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.
25. Human Subjects (not scored)  
Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?
26. Budget (not scored)  
The extent to which the proposed budget is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds.

## **H. Other Requirements**

Technical Reporting Requirements:

Technical reporting requirements are the same as those under grantee's existing ELC cooperative agreement award.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I.

AR-1 Human Subjects Requirements

AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-7 Executive Order 12372 Review

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

Additionally, DHHS is licensing SAS software from Logicon. “Authorized Users” under the license shall also include grantees of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) who receive grants related to the development, deployment, and operation of national systems for the identification, reporting, tracking, and analysis of diseases, health conditions, and health determinants. Recipients under this ELC-NEDSS program announcement that receive or use SAS software under the DHHS license shall abide by all terms of the license. DHHS shall only permit Grantees to use the software to perform DHHS funded Program activities as specified above.

Use by a Grantee of the SAS software or any other provided commercial software for any purpose other than the funded Program activities is not permitted. In the event a Grantee completes or ends the funded Program activity prior to the expiration of the license of the software, the Grantee shall destroy or return the licensed software to CDC.

Authority and Catalog of Federal Domestic Assistance Number:

This program is authorized under the Public Health Service Act Sections 301(a)[42 U.S.C. 241(a)], 317(k)(1)[42 U.S.C. 247b(k)(1)], and 317(k)(2)[42 U.S.C. 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

#### **I. Where to Obtain Additional Information**

This and other CDC announcements can be found on the CDC home page Internet address - <http://www.cdc.gov> Click on Funding then Grants and Cooperative Agreements.

To obtain additional information:

Business management technical assistance may be obtained from:

Gladys Gissentanna, Grants Management Specialist  
Grants Management Branch, Procurement and Grants Office  
Centers for Disease Control and Prevention (CDC)  
2920 Brandywine Road, Room 3000  
Atlanta, Georgia 30341-4146  
Telephone: (770) 488-2753  
E-mail address: [gcg4@cdc.gov](mailto:gcg4@cdc.gov)

Programmatic technical assistance may be obtained from:

Deborah Deppe, M.P.A., Office of the Director  
National Center for Infectious Diseases

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road, N.E., MS C12

Atlanta, Georgia 30333

Telephone: (404) 639-4668

E-mail Address: [dad1@cdc.gov](mailto:dad1@cdc.gov)