Division of State and Local Readiness (DSLR) Program Review

A Report from the Board of Scientific Counselors (BSC)

Office of Public Health Preparedness and Response (OPHPR)

Centers for Disease Control and Prevention (CDC)

Department of Health and Human Services (DHHS)

- **Barbara Ellis, PhD, DFO**

Approved by Vote of the BSC: April 26, 2010

Respectfully Submitted: March 19, 2012

Division of State and Local Readiness (DSLR) Program Review
Office of Public Health Preparedness and Response (OPHPR)
Ad Hoc Board of Scientific Counselors (BSC) Workgroup Report

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1.0 REVIEW OBJECTIVES AND PROCESS

Background

External peer review is a highly regarded mechanism for critically evaluating the scientific and technical merit of research and scientific programs. This rigorous process identifies strengths, gaps, redundancy, and research or program effectiveness in order to inform decisions regarding scientific direction, scope, prioritization, and financial stewardship. External peer review will address program quality, approach, direction, capability, and integrity and will also be used to evaluate the program's public health impact and relevance to the missions of the Centers for Disease Control (CDC) and the Office of Public Health Preparedness and Response (OPHPR; previously known as the Coordinating Office for Terrorism Preparedness and Emergency Response, or COTPER[1]).

OPHPR has established standardized methods for peer review of intramural research and scientific programs in order to ensure consistent and high quality reviews. A more detailed description of CDC's and OPHPR's peer review policy is available on request.

CDC policy requires that all scientific programs[2] (including research and non-research) that are conducted or funded by CDC be subject to external peer review at least once every five years. The focus of the review should be on scientific and technical quality and may also include mission relevance and program impact. The OPHPR Board of Scientific Counselors (BSC) provides oversight functions for the research and scientific program reviews. The BSC primarily utilizes ad hoc workgroups or expert panels to conduct the reviews. It is anticipated that the BSC will be engaged in most of the reviews and they may elect to utilize workgroups, subcommittees or workgroups under subcommittees to assist in the review. The BSC will evaluate findings and make summary recommendations on all reviews, including those they engage in, as well as reviews performed by other external experts.

[1] CDC began undergoing an organizational realignment of some offices and centers in the fall, 2009. Since this review was conducted prior to the change in name from COTPER to OPHPR, some of the documents in this report reference COTPER (not OPHPR).

[2] Scientific program is defined as the term "scientific program" includes, but is not necessarily limited to, intramural and extramural research and non-research (e.g., public health practice, core support services).

Review Objectives

The PHEP cooperative agreement was initially established in 1999 as a competitive grant program to provide funds to enhance the ability to plan and respond to public health emergencies, with particular focus on bioterrorism events. In 2002, Congress appropriated funds to CDC to expand the program to 62 entities, to move from competitive funding to formula funding based upon population density and other factors, and to provide guidance to awardees in seven critical "focus areas:" planning and assessments; surveillance and epidemiology capacity; biologic laboratory capacity; chemical laboratory capacity; health alerting, communications, and information technology; risk communication and information dissemination; and education and training.

The PHEP cooperative agreement has undergone annual shifts in the number and type of recommended activities, depending on the interests of various stakeholders, including state and local entities, national partner organizations, and other federal agencies. These stakeholder interests vary in complexity and content; therefore, a need to establish a more transparent, objective management process has been recognized by OPHPR senior leadership. The current Program Announcement ends in 2010 and a new Program Announcement (PA) is currently being developed for publication next year (project period length will be FY 2010-2015).

It is anticipated that the results of this review will inform the new PHEP Program Announcement by assisting DSLR to articulate roles and responsibilities of CDC in providing strategic direction for the PHEP content, prioritization of capabilities, and management of changes to the content going forward. In light of the absence of a finalized National Health Security Strategy, this review will focus on the prioritization process for the selection of capabilities underlying the PHEP cooperative agreement and be directed toward the following review objectives in order to evaluate priority capability-based priorities, and proposed strategic management practices:

1. Evaluate and provide recommendations to the DSLR's selection of PHEP cooperative agreement prioritized capabilities in context of existing priorities, framework, and limitations (legislative, departmental, and agency mandates, available funding, CDC preparedness goals and the mission, needs, and goals of OPHPR).
2. Evaluate and provide recommendations to DSLR's proposed approach to coordinate, organize, and manage the various CDC, HHS, and partner stakeholders' input in the development and management of future content for the PHEP Cooperative Agreement.

Review Process and Timeline:

The peer review will be conducted by a 6-member ad hoc workgroup with two members of the OPHPR Board of Scientific Counselors (BSC) serving as workgroup co-chairs and 4 invited expert reviewers external to the OPHPR BSC. Facilitation and logistical assistance is provided by the DSLR Associate Director for Science (ADS) and the OPHPR Office of Science and Public Health Practice (OSPHP).

1. Pre-meeting: OSPHP convened a pre-meeting web conference (webinar) with members of the workgroup on Monday, August 31, 2009 from 10:00 am to 12:00 pm. The webinar agenda included overview presentations on the history of the Division of State and Local Readiness and current Public Health Emergency Preparedness (PHEP) Cooperative Agreement priorities, the proposed process for determining 2010-2015 PHEP priority capabilities, and the proposed PHEP change management board. Reviewers were given the option of submitting written individual comments in response to the review questions. These comments and questions were intended to inform the co-chairs and assist OPHPR in providing the workgroup with the necessary information in advance of the in-person meeting.

2. Workgroup meeting: The workgroup met for two and one-half days from September 15, 2009 through September 17, 2009 in Atlanta, GA. On the first day and on the morning of the second day, there were presentations by DSLR staff as well as external stakeholders, discussions, and question and answer sessions. On the afternoon of the second day and the morning of the third day, the workgroup convened privately to deliberate, formulate findings, and write a draft workgroup report.

3. Post-meeting: The workgroup Chair(s) took the lead in completing the workgroup report. Workgroup members and OPHPR and DSLR program leadership have had the opportunity to review and comment on the contents of the workgroup report before it was finalized. DSLR will have the opportunity to provide program responses to any findings and individual recommendations in the report at the BSC meeting. The full BSC will deliberate on the final panel report during the next meeting, reach a consensus on recommendations, and present these recommendations as summary determinations to OPHPR management. DSLR will respond to the BSC recommendations in writing and present their response and implementation plan at the next BSC meeting.

2.0 SCOPE OF THE REVIEW

Objective

This program review will evaluate the prioritization process for the determination of core Public Health Emergency Preparedness (PHEP) capabilities that will be used to develop the content of the PHEP Program Announcement in the context of current legislative, departmental, and agency mandates and priorities. It will also provide recommendations regarding a proposed strategic approach to managing the content of the PHEP Program Announcement, including the management of requested changes by PHEP stakeholders that may occur in the future.

Background

The Office of Public Health Preparedness and Response (OPHPR), Division of State and Local Readiness (DSLR), administers the PHEP Program Announcement that funds state and local efforts to build and strengthen their preparedness and infrastructure to respond to all hazards (infectious diseases, natural disasters and biological, chemical and radiological threats). The PHEP Program Announcement is a cooperative agreement requires that awardees achieve specific, targeted capabilities to meet all-hazard preparedness. This non-competitive cooperative agreement is to be used only for non-research activities. Approximately $6.3 billion in PHEP cooperative agreement funding has been awarded since 1999 to 62 awardees, which include 50 states, four U.S. territories, four Freely Associated States of the Pacific, and four metropolitan

areas (Washington, D.C., Chicago, Los Angeles County and New York City). The PHEP also has a unique history of being strongly influenced by legislative mandates (e.g., the Pandemic and All Hazards Preparedness Act) and significant oversight by the Department of Health and Human Services (HHS).

The PHEP cooperative agreement was initially established in 1999 as a competitive grant program to provide funds to enhance the ability to plan and respond to public health emergencies, with particular focus on bioterrorism events. The program was housed in the National Center for Infectious Diseases, and much of the content associated with the cooperative agreement was related to the core public health services (e.g., epidemiology, laboratory science and service, or health monitoring and other assessments). In addition, several public health generalists provided expertise in grants management support functions.

In 2002, Congress appropriated funds to CDC to expand the program to 62 entities, to move from competitive funding to formula funding based upon population density and other factors, and to provide guidance to awardees in seven critical "focus areas:" planning and assessments; surveillance and epidemiology capacity; biologic laboratory capacity; chemical laboratory capacity; health alerting, communications, and information technology; risk communication and information dissemination; and education and training. The program was also moved from the National Center for Infectious Diseases to DSLR and was renamed the Public Health Emergency Preparedness (PHEP) Program.

In Fiscal Year (FY)[3] 1999, PHEP funding was $40,717, 240. After the events of September 11, 2001 and the October 2001 anthrax attacks, funding rose to a peak level of $999,635,509 (FY 2001, 2002). Funding steadily decreased to $849,596,000 by FY 2004; this amount included $809,956,000 for PHEP projects and an additional $39 million of funding to support specialized projects such as Early Warning Infectious Disease Surveillance, Chemical Laboratory Capacity, and mass medication prophylaxis (Cities Readiness Initiative). In FY 2006 funding increased to $991,440,000 to include an additional $225 million in supplemental funding targeted at

[3] Fiscal Year (also known as financial year, or sometimes budget year) is a period used for calculating annual ("yearly") financial statements in businesses and other organizations. For the U.S. government the FY period includes 1 September to 31 August.

pandemic influenza preparedness. Current funding (FY 2008) is $704,867,418 and directs awardees to address PHEP projects, the above mentioned specialized projects, as well as pandemic influenza preparedness projects.

With the establishment of the Department of Homeland Security in 2004, program priorities for PHEP awardees became more focused on the achievement of targeted capabilities and all-hazard preparedness. The priorities include activities mandated by Presidential Directives, requests from the White House Homeland Security Council (HSC), authorizing legislative mandates (e.g., Pandemic and All-Hazards Preparedness Act (PAHPA)), policy interests from HHS, and various CDC programmatic interests external to DSLR. In October 2007, Homeland Security Presidential Directive 21 (HSPD-21) established a "National Strategy for Public Health and Medical Preparedness." HSPD-21 has a strategic focus on four areas (biosurveillance, countermeasure distribution, mass casualty care, and community resilience), with an acknowledgment of other critical areas of preparedness including: animal health systems, food and agriculture defense, global partnerships in public health, health threat intelligence activities, domestic and international biosecurity, and basic and applied research in threat diseases and countermeasures. HSPD-21 also directs the Secretary of Health and Human Services to submit in 2009, and quadrennially afterward, a National Health Security Strategy (NHSS) to the Congress; however, to date this "National Strategy" has not yet been articulated. It is unclear how the NHSS may influence the priorities that will be set forth in future PHEP Program Announcements.

The PHEP cooperative agreement has undergone annual shifts in the number and type of recommended activities, depending on the interests of various stakeholders, including state and local entities, national partner organizations, and other federal agencies. These stakeholder interests vary in complexity and content; therefore, a need to establish a more transparent, objective management process has been recognized by OPHPR senior leadership. DSLR leadership recognizes that there needs to be a comprehensive evaluation of the utility and suitability of the content and activities that the various stakeholders have included in the PHEP cooperative agreement, particularly in light of decreasing federal funding for the PHEP. Despite the influx of funding for this program, a comprehensive program evaluation has not yet occurred

due to a lack of clarity in program priorities, shifting program strategy, and a lack of defined performance measures for preparedness. The current Program Announcement ends in 2010 and a new Program Announcement (PA) is currently being developed for publication next year (project period length will be FY 2010-2015).

The current PHEP cooperative agreement program announcement was published in July 2005 for a project period length of five years (http://emergency.cdc.gov/planning/guidance05/pdf/annoucement.pdf) and a budget period length of one year. Historically, the process for development of a new PA for the PHEP cooperative agreement has included: (1) DSLR and the CDC Procurement and Grants Office (PGO) create a draft document; (2) DSLR engages CDC subject matter experts that represent preparedness programs across CDC, as well as partner organizations (e.g., Association of State and Territorial Health Officials, Association of Public Health Laboratories) to collect their recommendations regarding activities that should be included in the PHEP PA; (3) CDC leadership (OPHPR, contributing CDC Centers, CDC Office of the Director) reviews and approves the draft announcement; (4) the HHS Assistant Secretary for Preparedness and Response (ASPR) reviews the draft announcement, and recommends the announcement for approval and publication by PGO. Revisions, usually additions, to the CDC-created draft are made as a result of ASPR priorities or other interests; (5) after receiving HHS concurrence, the document is approved by PGO and released. DSLR is responsible for the PHEP program administration, budget, and activity management, regardless of whether the activities and content originate from DSLR or from other subject matter experts or agencies external to DSLR.

It is anticipated that the results of this review will inform the new PHEP Program Announcement by assisting DSLR to articulate roles and responsibilities of CDC in providing strategic direction for the PHEP content, prioritization of capabilities, and management of changes to the content going forward. In light of the absence of a finalized National Health Security Strategy, this review will focus on the prioritization process for the selection of capabilities underlying the PHEP cooperative agreement and be directed toward the following review objectives in order to evaluate priority capability-based priorities, and proposed strategic management practices.

Review Objectives

1. Evaluate and provide recommendations to the DSLR's process to select PHEP cooperative agreement priority capabilities in context of existing priorities (legislative, departmental, and agency mandates, available funding, CDC preparedness goals and the mission, needs, and goals of OPHPR).
2. Evaluate and provide recommendations to DSLR's proposed approach to coordinate, organize, and manage the various CDC, HHS, and partner stakeholders' input in the development and management of future content for the PHEP Program Announcement.

3.0 WORKGROUP FINDINGS

3.1 Review of Proposed Prioritization Process

Context

The workgroup recognized that an ideal, well integrated public health preparedness system identifies and enables federal, state, and local roles and responsibilities in the collaborative enterprise. At the state and local level (and to a lesser extent, the federal level) public health preparedness and response for emergencies/issues of scale will be operationalized within the overall emergency management response system of the governmental jurisdiction rather than by the public health authority alone. Public health preparedness and response at these levels, therefore, must be understood and measured within the overall preparedness framework.

Unlike other governmental emergency response systems (i.e., fire, law enforcement, EMS, etc.) public health response to emergencies is predicated for the most part on the ability to redirect and mobilize the existing public health workforce away from their normal assignments to different duties and responsibilities related to emergency response. Given their different threats and capabilities and capacities developed to date, states and local jurisdictions need flexibility within the PHEP process to address those areas of greatest vulnerability and gap. The PHEP process must ensure the awardees' (states) plans and applications reflect the needs and priorities of the local public health jurisdictions within the state as well as those of the state itself. The workgroup recognized that the PHEP program should be strategically consistent with other federal funding programs and with federal guidance expressed in law, presidential directive, and

doctrine. Basing the cooperative agreement on the DHS Target Capabilities List (TCL) provides this strategic consistency.

The workgroup supports the continuing effort to create an empirical basis for allocation and evaluation of PHEP funding. The workgroup did not believe, however, that the proposed prioritization of these target capabilities on the basis of the strength of legislative and executive mandate is supported by need or by empirical evidence.

Prioritization Process Conclusions/Findings

The committee concluded that:

1. The development of a capabilities based framework for the cooperative agreement is a major accomplishment, but the attempt to prioritize these capabilities based on the strength of their legislative and executive mandates is a top down approach that does not encourage local and regional flexibility based on differences in vulnerabilities, needs, strategy, and existing capabilities and capacities.
2. The proposed prioritization methodology, although logically sound, was based on an inherently subjective system of assigning priorities based upon two sets of weights, (a) the perceived strength of match of the capability to referenced policy documents, and (b) the relative importance of the basic policy documents to the PHEP based on the type of document (law, Presidential Directive, other). These ratings are multiplied together to produce a final ranking. A prioritization methodology ideally should be outcome based and therefore should start with defining the emergency preparedness goals and the attributes of those goals. Capabilities could then be evaluated by estimating their contribution to each attribute of the desired end state. This process should be evidenced based wherever possible. If empirical evidence is not available, external expert judgment may be elicited and used in structured, theoretically sound ways using methodologies such as multi-attribute utility analysis or the analytic hierarchy process.
3. The efforts by DSLR to establish goals and metrics for target capabilities will enhance the ability to manage the PHEP program and will enhance national preparedness if these goals and metrics are established and monitored collaboratively with grantees.

Prioritization Process Recommendations

The workgroup makes the following individual recommendations:

1. PHEP funding should be based on the 20 targeted capabilities identified as having central public health relevance. However, all 37 targeted capabilities should be listed in the Cooperative Agreement for informational purposes to preserve the continuum of overall community preparedness. The public health capacity created by funding the 20 public health related targeted capabilities may support one or more of the remaining 17 capabilities.

2. The short form of the Targeted Capabilities List (TCL) should be provided as an appendix to the Cooperative Agreement. The DSLR should be prepared to provide interpretation and clarification of the targeted capabilities.

3. The 20 public health related targeted capabilities should *not* be divided into 3 prioritized tiers or rank-ordered at least not until strong evidence is available to support the establishment of priorities.

4. CDC/DSLR efforts to define a limited number of performance and outcome measures for each of the public health related targeted capabilities should be continued. Special priority should be given to developing a comprehensive set of metrics for assessing the outcomes from exercises, drills, and actual emergency incidents. The measures should be consistent and useful across federal, state and local levels. These measures will provide the basis for establishing an evidence-based prioritization of public health preparedness goals. Consistent reporting of these measures should be required as a condition of continued PHEP funding.

5. The Cooperative Agreement should require that a hazards vulnerability and gap analysis be completed in Year 1. These analyses should drive the development of a 5 year strategic plan that addresses how the awardee will attend to the 20 public health related targeted capabilities. These analyses should be viewed as living documents, updated as needed to maintain currency, and used to support future funding needs. Technical

assistance and guidance documents should be available to awardees to help them with these tasks.

6. Guidance materials should be provided by CDC. These materials should include standards for performing and reporting the results of the hazards vulnerability assessments and gap analysis.

Discussion

Although the workgroup did not endorse the proposed prioritization methodology, it strongly supported the capabilities based approach and the attention to performance measures initiated by DSLR. The workgroup's recommendations are intended to strengthen the Performance Measures Guidance section of the PHEP Cooperative Agreement in two ways. First, the guidance establishing performance targets and metrics can be improved through the careful review and mining of the 'diversity preparedness literature'. The workgroup provided recommended references from this literature that could assist DSLR to identify context, nuance and content that should inform readiness capability performance targets and related metrics. Examples include 'Voices of the Storm Health Experiences of low income Katrina Survivors', the GAO report on Voluntary Organizations', and Deloitte's "Road Map to Preparedness". For example, 'The Ready or Not' documents suggest criteria that would add effective value to specifying performance targets and metrics. These documents could greatly assist in the specification of criteria that would drive performance to desired responsiveness for vulnerable populations for most of the recommended priorities (including but not limited to Planning, Communications, Intelligence and Informing sharing, Risk Management, and Environmental Health, etc.). This literature addresses inadequate preparedness responses to low income population, including: 'lack of information about resources available', 'difficulties with uninsured' survivors', 'particular vulnerabilities of Populations with Limited English Proficiency'.

The second way in which the development and use of performance metrics can improve the PHEP program is the development, use, and tracking of outcome measures for drills, exercises and actual incidents. Such events appear to provide the major opportunity for CDC, and each

grantee, to evaluate the state of preparedness in a meaningful way. Because of the importance of this information, data collection and data quality control procedures for checking the information from at least a sample of these events from the grantee will be required. We note that CDC already is attempting to improve the information coming from these events.

The workgroup commends DSLR for using the Cooperative Agreement process to foster state and local hazard and vulnerability assessments, risk based strategic planning and the development of performance metrics. The performance metrics for grantees can reinforce the objective of ensuring equal public health response for all segments of the population. For example, the Cooperative Agreement could clearly state the expectation that grantees will measure and evaluate how well response is delivered in an equally effective manner to all segments of targeted populations. The CA could also include performance targets and measurement specification for Incident Management, Crisis and Emergency Risk Communication with the Public and Laboratory performance measures for all the aforementioned that drives the equal protection for all segments of the population performance criterion.

Progress in attaining pre identified strategic goals in compliance with the 'equal protection for all segments of the population performance for each of the 'Priority Capabilities' can be reviewed as part of the grant renewal process. The review criteria (measurement specification) should be informed by the 'diversity preparedness' literature.

3.2 Review of Proposed Change Management Process

Context

The Public Health Emergency Preparedness (PHEP) program was initially established in 1999 as a competitive grant program to provide funds to enhance the ability of state, local, territorial and tribal public health departments to develop their capacity to respond effectively to terrorism-related public health emergencies. Since then, the PHEP program has undergone many modifications in size and scope, including a change in 2002 from a competitive grant to a noncompetitive cooperative agreement, and reorganization of the cooperative agreement in 2005.

Initial Program Guidance was released in 2005 with each subsequent year between 2005-2010 deemed a continuation year for awardees. In a continuation year, awardees were expected to continue unfinished activities from the prior year and/or initiate new activities, all within the scope of the original cooperative agreement. However, each year, activities, tasks or requirements were added, deleted or modified by either internal (CDC) or external (e.g., White House, DHHS) stakeholders or both. These changes were made without a well defined vetting process or consideration of the potential impact of the change on awardees or DSLR staff. Just as one example, the initial smallpox directives erroneously presumed PHEP resources could be redirected, turned on a dime, to meet a totally new, and in many ways, very different target than PHEP resources were then directed toward.

As a result of these changes being made in an ad hoc manner, the PHEP program has suffered from a lack of clarity in program priorities by stakeholders, shifting program strategy, and lack of defined performance measures for preparedness. Since PHEP stakeholder interests vary in complexity and content, there is a need to develop a more objective process to manage change requests made once the program announcement guidance is officially approved and implemented. A defined process for considering changes would greatly improve transparency and requires consideration of consequences, both short and long term that have not characterized the PHEP to date.

The DSLR is proposing the creation of a PHEP program announcement Change Management Board (CMB) to meet this need. The workgroup fully supports the establishment of such a CMB.

Change Management Conclusions /Findings

The workgroup concluded that:

1. There is clearly a need to develop a more transparent, objective process to manage change requests made once PHEP program announcement guidance is officially approved and implemented. The goals and anticipated benefits of the proposed Change Management Process are well described in the DSLR proposal.

2. In principle, the establishment of a Change Management Board (CMB) should bring

stability to PHEP operations and address awardees' confusion over shifting priorities and activities. The establishment of a CMB would reduce the possibility that changes are introduced into PHEP without full consideration of the impact of such changes on all stakeholders.

3. We agree with the 'Critical Success Factors' outlined in the proposal. In particular, it will be important that all stakeholders (at the highest level of their respective agencies) conform to the change management process. Safeguards must be in place to prevent "end-runs" around the CMB.

4. Transparency of the change management process is critically important. As usually is the case, the importance of a proposed change is in the eyes of the 'requestor'. They want to know that they are taken seriously and that every reasonable effort will be made to accommodate their proposed change. The criteria for determining the 'significance' of the change must be clearly understood and accepted by all 'requestors.'

5. Change requests must clearly address awardees' capacity to perform the requested change and the resources required to implement the change.

6. Change requests must address and provide a solution for DSLR staffing support to implement the proposed new priority.

7. As is true in establishing any new process, attention to detail is critical. The workgroup recognized that DSLR wanted the initial concept of the CMB vetted and approved before moving forward with specifying the sub-processes, activities, roles and metrics of the process. We encourage them to proceed in doing so, being mindful of the need to develop an *efficient* process. Precautions must be in place to ensure the change management process is nimble enough to be responsive to real needs in a timely manner without becoming a major planning body itself. If anything, the process may stifle the motivation to propose changes given the strict process for submitting, assessing, reviewing, and approving changes. This is always a balancing act.

8. Ongoing monitoring of the process is critical. A tracking system is needed to ensure requests are being handled in an effective and efficient manner. DSLR should be open to changes in the process to achieve these goals.

Change Management Recommendations

The workgroup makes the following individual recommendations:

1. The workgroup recommends to the OPHPR Director that in order to help preserve the integrity of the process, the Chair of the Change Management Board should directly report to the Director of CDC.

2. Explicit criteria should be developed to assist in categorizing a proposed change as an administrative revision/update not requiring full review by the CMB.

3. Explicit criteria should be developed for review of all proposed change requests brought to the CMB. These criteria should include: consideration of the cost and burden of a proposed change on awardees; the impact of the proposed change on currently funded programs; and the overall feasibility of implementation, including technical and timeliness considerations. Both short and long-term effects should be considered.

4. Requests must be forwarded to NACCHO and ASTHO for their comments on the request and its potential impact on awardees. These comments should be routinely included in the materials made available for review by the CMB.

5. To ensure timely and consistent review, careful consideration should be given to the frequency of the scheduled meetings of the CMB. Meetings should be frequent enough to prevent backlogs and unnecessary emergency meetings and assure that requests are not put on hold for an extended period of time.

6. All change requests should be resolved within a reasonable, pre-defined time limit.

7. An appeal process should be defined to preserve the integrity of the process.

8. A Program Change Request Tracking System should be designed and implemented. This could considerably ease the manual tracking of change requests, provide a considerably more efficient process, and provide a clear record of events. The system would automatically undertake such activities as: (a) identify who needs to review each category of request (such as whether emergency or not, changes relating to particular hazards, those that are purely administrative change requests, etc.; (b) track the status of those reviews and needed sign offs for each category of request; (c) keep track of the time periods and give warnings for behind-schedule reviews; and (d) summarize overall progress of the changes for the year. CDC would likely need to assign a staff member to be the "Program Change Administrator," if only part time.

9. After 1 year of implementation, the process should be internally reviewed and changes made accordingly.

Discussion

The workgroup commends DSLR for developing a more objective process to manage change requests made to the PHEP program announcement (once it is officially approved and implemented). A defined process for considering changes will greatly improve transparency, bring stability to the PHEP operations, and address awardees' confusion over shifting priorities and activities. The establishment of a CMB will also reduce the possibility that changes are introduced into PHEP without full consideration of the impact of such changes on all stakeholders, including the staff of DSLR and the state and local awardees. It will be important to ensure that sufficient input is obtained from state and local health officers and that this input is carefully considered in reviewing each request.

3.3 Report Conclusions

The workgroup expresses its appreciation to the DSLR staff for its professional support of the workgroup's process and wishes to recognize the value of the briefings and materials provided to the workgroup. The workgroup encourages DSLR to:

- continue its emphasis on establishing performance based goals for state and local preparedness

- continue to seek stability and consistency in program objectives and funding through well managed cooperative agreements and change management processes,

- strongly advise and assist state and local awardees to strategically base preparedness efforts on vulnerability and risk assessments.

- ensure that state and local awardees needs and priorities are recognized in the cooperative agreement process.

4.0 APPENDICES

Appendix A
Workgroup Member Biographies

John (Jack) Harrald, Ph.D. (*Workgroup Co-Chair*) Research Professor, Center for Technology, Security, and Public Policy at Virginia Tech, Director Emeritus, Institute for Crisis, Disaster, and Risk Management at George Washington University (GWU)

Dr. Harrald is a Research Professor at the Virginia Tech Center for Technology, Security and Public Policy. He is the Co-Director Emeritus of GWU Institute for Crisis, Disaster, and Risk Management and a Professor Emeritus of Engineering Management and Systems Engineering in the GWU School of Engineering and Applied Science. Dr. Harrald is a member of CDC's Board of Scientific Counselors, a member and Chairman of the National Research Council Disasters Roundtable Steering Committee and the National Research Council Committee on Aviation Emergency Management. He is the Executive Editor of the electronic *Journal of Homeland Security and Emergency Management.* He is the Immediate Past President of The International Emergency Management Society (TIEMS) and is the former Associate Director of the National Ports and Waterways Institute. Dr. Harrald has been actively engaged in the fields of emergency and crisis management and maritime safety and security and as a researcher in his academic career and as a practitioner during his 22 year career as a U.S. Coast Guard officer, retiring in the grade of Captain. He has written and published in the fields of crisis management, emergency management, management science, risk and vulnerability analysis, and maritime safety. Dr. Harrald was the Principal Investigator for maritime risk and crisis management studies in Prince William Sound, Alaska, the Port of New Orleans, San Francisco Bay, and Washington State. He has studied the response to the Exxon Valdez oil spill, the Loma Prieta Earthquake, Hurricane Hugo, Hurricane Andrew, the Northridge Earthquake, the 1999 Turkey earthquakes, the September 11 terrorist attacks on the World Trade Center and the Pentagon, and Hurricane Katrina.

Dr. Harrald received his B.S. in Engineering from the U.S. Coast Guard Academy, a M.A.L.S. from Wesleyan University; an M.S. from the Massachusetts Institute of Technology where he was an Alfred P. Sloan Fellow; and an MBA and Ph.D. from Rensselaer Polytechnic Institute.

Ellen MacKenzie, Ph.D. (*Workgroup Co-Chair*) Chair, Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Dr. Ellen MacKenzie is the Fred and Julie Soper Professor and Chair of the Department of Health Policy and Management of the Johns Hopkins Bloomberg School of Public Health. She is a graduate of the School of Public Health where she earned Master of Science and doctoral degrees in biostatistics. She joined the Hopkins faculty in 1980 and holds joint appointments in the School's Department of Biostatistics and with the departments of Emergency Medicine and Physical Medicine and Rehabilitation at the Johns Hopkins University School of Medicine. In addition to her faculty appointments, Dr. MacKenzie served as Senior Associate Dean at the School from 1996 to 2000 and Director of the Center for Injury Research and Policy from 1995-2005. Dr. MacKenzie completed a term as chair of the National Advisory Committee for Injury Prevention and Control and is Immediate Past President of the American Trauma Society.

Dr. MacKenzie's research focuses on the impact of health services and policies on the short- and long-term consequences of traumatic injury. She has contributed to the development and evaluation of tools for measuring both the severity and outcome of injury, which have been used to evaluate the organization, financing and performance of trauma care and rehabilitation. Of particular interest to Dr. MacKenzie is the delineation of factors (both medical and non-medical) that explain variations in functional outcome. Her research has advanced the knowledge of the economic and social impact of injuries and our understanding of how personal and environmental factors influence recovery and return to work. Dr. MacKenzie's ongoing research includes a national evaluation of the cost and effectiveness of trauma care, the evaluation of amputation versus limb salvage in the military, the development and evaluation of self management programs following trauma and limb loss, and efforts to facilitate the development and exchange of information among trauma and EMS providers.

Dr. MacKenzie’s awards include the A.J. Mirkin Service Award from the Association for the Advancement of Automotive Medicine, the Ann Doner Vaughan Kappa Delta Award from the American Academy of Orthopaedic Surgeons, the Distinguished Career Award from the American Public Health Association (Injury Control and Emergency Health Services Section), the American Trauma Society's Distinguished Achievement Award and the Trauma Leadership

Award from the Society of Trauma Nurses. She is also an honorary fellow of the American Association for the Surgery of Trauma.

Bonnie Arquilla, D.O., FACEP - Assistant Professor of Emergency Medicine and the Director of Disaster Preparedness for the State University of New York at Downstate/Kings County Medical Center

Dr. Arquilla completed her internship at Methodist Hospital and completed her residency in Emergency Medicine at Lincoln Medical and Mental Health Center in the Bronx, New York. In her role of Director of Disaster Preparedness she provides consultation to The New York City Police Department, the New York City Department of Health and Mental Hygiene, New York City's Health and Hospitals Corporation, the American Red Cross of Greater New York, the New York City Department of Education, and the Metropolitan Transit Authority Centers for Disease Control.

Dr. Arquilla is the Co-chair of the Pediatric Task Force for the New York City Department of Health and Mental Hygiene. She is the founder of the Disaster Preparedness Fellowship Program at SUNY Downstate. Along with Dr. Michael Augenbraun at SUNY DOWNSTATE she developed the New York Institute, All Hazards Preparedness (NYIAHP); a unique program in its approach to community based preparation and planning for disasters. NYIAHP is responsible, under Dr. Arquilla's leadership, for creating and implementing some of the largest and most complicated disaster exercises in the United States.

Since 2006, Dr. Arquilla is a faculty member of INDUS-EM, a collaborative United States - India effort to bring the specialty of Emergency Medicine to India. She is the academic chairperson for the INDUS-EM conference for 2009 – 2010. Dr. Arquilla received her D.O. from New York College of Osteopathic Medicine and is Diplomat of the American Board of Emergency Medicine.

Harry P. Hatry, M.S. – Distinguished Fellow and Director, Public Management Program, The Urban Institute

Harry P. Hatry is a Principal Research Associate and Director of the Public Management Program for The Urban Institute. He has worked on public sector issues in performance measurement, program evaluation, strategic planning, alternative service delivery systems, and motivational programs for public employees (including elementary and secondary education) - both monetary and non-monetary approaches, for many years.

Mr. Hatry has been a national leader in developing performance measurement procedures for public agencies -- federal, state, and local government -- since 1970. These services include transportation, social services, corrections, police and fire, education, HIV-prevention, mental health, economic development, sanitation, parks and recreation, and environmental protection. In recent years, he has also been working with private nonprofit organizations to help them improve outcome management in their organizations.

He has provided assistance to the U.S. Departments of Education, Health and Human Services, and Justice, the Environmental Protection agency, and the National Institute for Literacy -- to help them improve their performance measurement and performance management procedures. A significant part of this effort was to work with program working groups in each agency to help them develop on-going performance measurement procedures/systems for their programs.

He led a team that conducted a 2008 evaluability assessment for the Robert Wood Johnson Foundation of its Trust for America's Health program. Also for RWJF, he is currently completing an assessment of its "Finding Answers" program aimed at reducing health care disparities for disadvantaged populations.

He led the work, involving a number of city and county governments that led to the joint Urban Institute-International City/County Management report *How Effective Are Your Community Services? Procedures for Measuring Their Quality*, now in its third edition. That work was developed from experiences with a number of city and county governments. It covered a number of basic municipal services, including police, fire, solid waste management services, and road maintenance. The first edition was one of the first documents that addressed the need for performance measurement, particularly of service quality and outcomes, by public agencies.

In 1999 the Center for Accountability and Performance of the American Society of Public Administration presented him with a lifetime achievement award for his work in performance measurement and established the "Harry Hatry Award for Distinguished Practice in Performance Measurement." In 2000, he was a recipient of the "50th Anniversary Einhorn-Gary" award from the Association of Government Accountants for outstanding service to government financial professionals and sustained commitment to advancing government accountability." In 2005, The Urban Institute named him a Distinguished Fellow. He has been, or is currently, on the editorial boards of *Evaluation Review, National Civic Review, Public Productivity and Management Review, Public Budgeting and Financial Management, The Public Manager, State and Local Government Review, New Directions for Program Evaluation, Operations Research,* and *Local Government Studies*.

Patrick M. Libbey – Consultant

Mr. Libbey is currently engaged as a consultant on several projects addressing issues of public health systems and structures. Most recently Mr. Libbey served as the Executive Director of the National Association of County and City Health Officials (NACCHO.) In that role Mr. Libbey represented our nation's local health departments and their staff who protect and promote health, prevent disease, and seek to establish the foundations for wellness in all communities across the United States. During his tenure NACCHO was increasingly recognized and engaged by a range of federal, national and other organizations as a critical resource and partner ensuring the perspective of local public health practice was considered in policy and program implementation and development.

Notable among his efforts while at NACCHO, Mr. Libbey initiated and led the organization's effort to create a uniform, nationally shared definition and standards for a functional local health development. This work, now known as the NACCHO Operational Definition, has gained national recognition and acceptance and serves as a key base for the emerging national voluntary public health accreditation effort. Mr. Libbey has been a national leader in the movement for accreditation of local and state health departments serving as a founder and incorporating board member of the Public Health Accreditation Board.

Prior to joining NACCHO in 2002, Mr. Libbey who has 28 years of local public health experience was the director of the Thurston County Public Health and Social Services Department in Olympia, WA. This Department has been recognized as an early leader in community involvement and population-based approaches to public health improvement.

In addition to being the NACCHO president prior to joining its staff, Mr. Libbey has provided leadership to a variety of professional organizations. He has served in leadership roles, including president, of both the Washington State Association of Local Public Health Officials and the Washington State Association of County Human Services. He was also actively involved in developing Washington State's approach to public health having served as a member of the Washington State Core Government Public Health Functions Task Force, member of the Public Health Improvement Plan Steering Committee, and the initial chair of the Performance Measures Technical Advisory Committee. He was a member of the Performance Management Collaborative with the Robert Wood Johnson Foundation sponsored Turning Point Initiative.

Mr. Libbey's published works include articles in the Journal of Public Health Management and Practice and as a co-contributor of chapters to several public health text books. He is a former Public Health Leadership Institute Scholar. Mr. Libbey has received several awards and recognitions over the years for his work in public health including most recently the Champion of Prevention award from the director of the Centers for Disease Control and Prevention and the President's Award from the Association of State and Territorial Health Officials. Current volunteer activities include serving as a board member basis for the Nurse-Family Partnership.

Ricardo A. Millett, M.P.P., Ph.D. – Principal, Millett & Associates

Dr. Millett is currently the principal of his company Millett & Associates providing program evaluation and strategic planning consultant services to foundations and non-profits. His most former employment was as the president of the Woods Fund of Chicago where he spent five successful five year developing and implementing a strategic grantmaking plan for the foundation that served it well in responding to the needs of Chicago least advantaged communities. He brings over forty years of experience in program evaluation, community and public policy planning and research to his role as a consultant. He brings to his consultant

practice a set of educational training and professional experiences that uniquely qualifies him as a leader with the experience and skills to help shape its grantmaking philosophy, strategies and realize its goals. During his tenure at the Woods Fund his success in working with his staff to strengthen the community by improving opportunities for people in Chicago has been widely acknowledged and acclaimed. He is particular proud of their accomplishments in working with grantees to shape programs and policies through strong community organizing and active participation of the least advantaged community residents. Building the capacity of non-profits and their community based constituents with well designed activities that include issue analysis, public policy development, advocacy, and citizen participation to improve functioning of the city and its neighborhood are areas where Dr. Millett has considerable experience and expertise.

Prior to the Woods Fund, Dr. Millett was Director of Program Evaluation for the W.K. Kellogg Foundation. Before joining the Kellogg Foundation, Dr. Millett served as senior vice president of planning and resource management for the United Way of Massachusetts Bay in Boston. He has also served as deputy associate commissioner of the Department of Social Services for Massachusetts, where he managed the Office of Planning and Evaluation. At ABT Associates, he was a senior analyst and worked on national research projects that helped to inform national policy in areas such as day care regulations and housing development in urban areas. He has served as director for Neighborhood Housing and Development for the Boston Redevelopment Authority, executive director of Roxbury Multi-service Center, associate professor of research and evaluation at Atlanta University, and director of the Martin Luther King Center at Boston University. He has been a leader in major collaboration initiatives that have brought community and corporate representatives and their respective institutions together to support program activities in housing, anti-drug and violence, and childcare. He has also published a book and several articles on the subject of citizen participation and community capacity building. Dr. Millett received his B.S. in Economics, M.S.W. in Social Policy, and Ph.D. in Social Policy Planning and Research from Brandeis University.

Appendix B

Pre-Meeting Teleconference Agenda

Division of State and Local Readiness (DSLR) Program Review:
Priorities, Grantee Capabilities, and Strategic Management of the Public Health Emergency Preparedness (PHEP) Cooperative Agreement

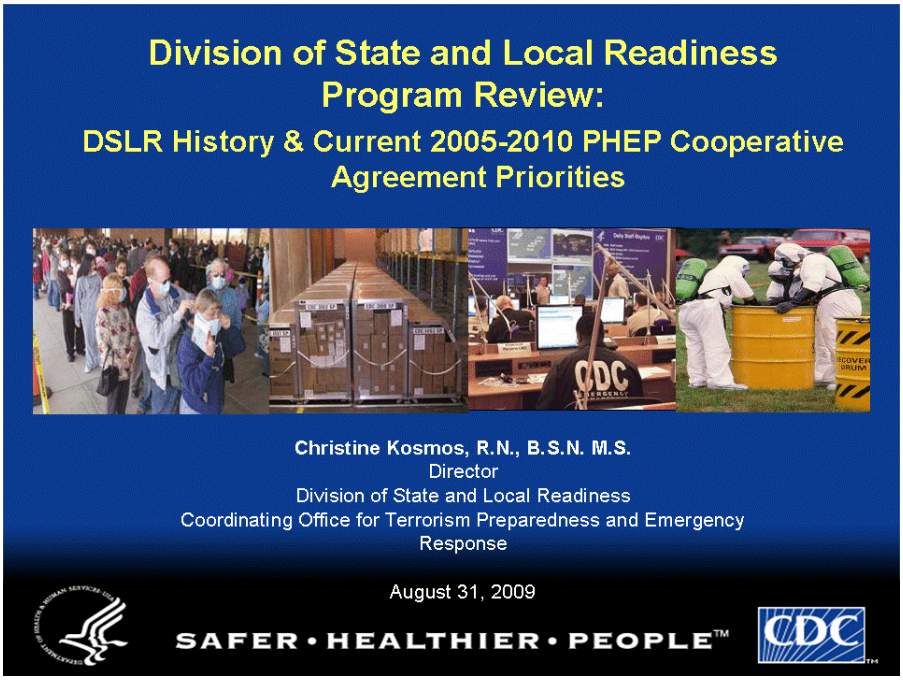
Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER)
Centers for Disease Control and Prevention (CDC)

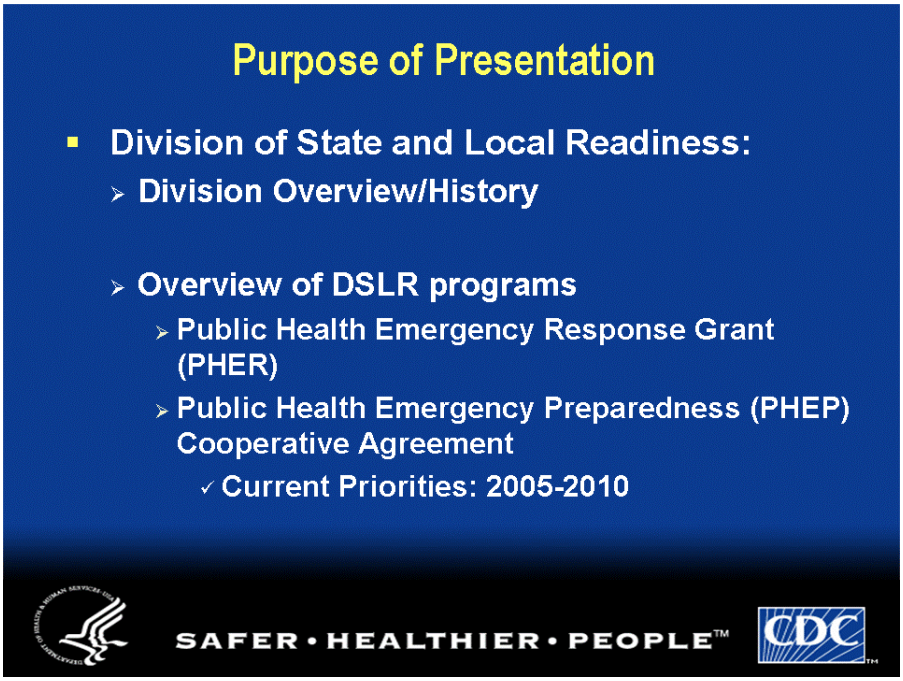
Roybal Campus, GCC Building 21, Room 6116
August 31, 2009, 10:00 a.m. - 12:00 p.m. (EDT)

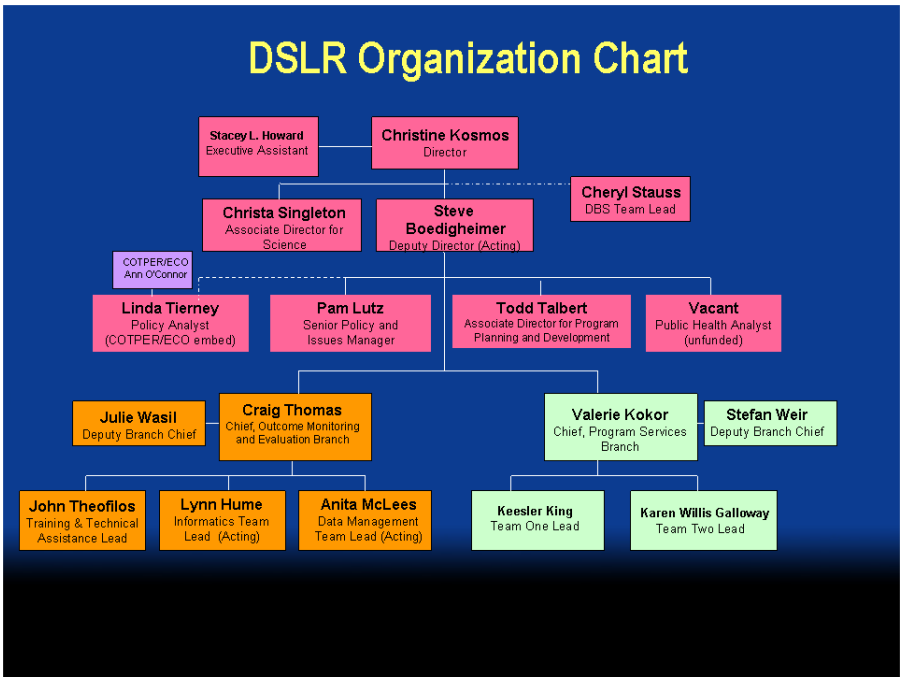
10:00 – 10:05 a.m.	**Welcome and Introductions** Dr. Ellen McKenzie, DSLR Workgroup Co-Chair; BSC, COTPER Dr. Jack Harrald, DSLR Workgroup Co-Chair; BSC, COTPER
10:05 – 10:10 a.m.	**Charge for Reviewers** Dr. Christa Singleton, Associate Director for Science, DSLR
10:10 – 10:35 a.m.	**DSLR History & Current 2005-2010 PHEP Cooperative Agreement Priorities** Christine Kosmos, Director, DSLR
10:35 – 10:55 a.m.	**Proposed Process for Determining 2010-2015 PHEP Priority Capabilities** Christine Kosmos, Director, DSLR
10:55 – 11:05 a.m.	**Questions**
11:05 – 11:20 a.m.	**Proposed PHEP Change Management Board** Christine Kosmos, Director, DSLR
11:20 – 11:55 a.m.	**Questions**
11:55 a.m. – 12:00 p.m.	**Next Steps and Adjourn** Dr. Ellen McKenzie, DSLR Workgroup Co-Chair; BSC, COTPER Dr. Jack Harrald, DSLR Workgroup Co-Chair; BSC, COTPER

Appendix C
Pre-Meeting Teleconference Slide Presentations

DSLR History & Current 2005-2010 PHEP Cooperative Agreement Priorities






DSLR Organization Chart
Stacey L. Howard
Executive Assistant
Christine Kosmos
Director
Cheryl Stauss
DBS Team Lead
Christa Singleton
Associate Director for Science
Steve Boedigheimer
Deputy Director (Acting)
COTPER/ECO
Ann O'Connor
Linda Tierney
Policy Analyst (COTPER/ECO embed)
Pam Lutz
Senior Policy and Issues Manager
Todd Talbert
Associate Director for Program Planning and Development
Vacant
Public Health Analyst (unfunded)
Julie Wasil
Deputy Branch Chief
Craig Thomas
Chief, Outcome Monitoring and Evaluation Branch
Valerie Kokor
Chief, Program Services Branch
Stefan Weir
Deputy Branch Chief
John Theofilos
Training & Technical Assistance Lead
Lynn Hume
Informatics Team Lead (Acting)
Anita McLees
Data Management Team Lead (Acting)
Keesler King
Team One Lead
Karen Willis Galloway
Team Two Lead


DSLR Strategic & Tactical Roles
Strategic Roles:
Horizontal leadership across COTPER, CDC
Leadership with HHS and other agencies
Partnership development and maintenance
Program planning and evaluation
Tactical Roles:
Administers PHEP cooperative agreement
Provides funding and coordinates technical assistance
Monitors progress and evaluates performance

DSLR Structure & Function

- **2 Branches:**
  - Outcome Monitoring and Evaluation Branch
  - Program Services Branch
- **2 Major Programs:**
  - Public Health Emergency Preparedness cooperative agreement
  - Public Health Emergency Response grant

DSLR Fast Facts

- 56 approved positions – 10 are unfunded
- 25% vacancy rate
- Office of the Director
  - 6 FTEs, 1 contractor, 1 vacancy
- Outcome Monitoring and Evaluation Branch
  - 19 FTEs, 20 contractors, 4 vacancies
- Program Services Branch
  - 21 FTEs including 3 field staff, 9 vacancies

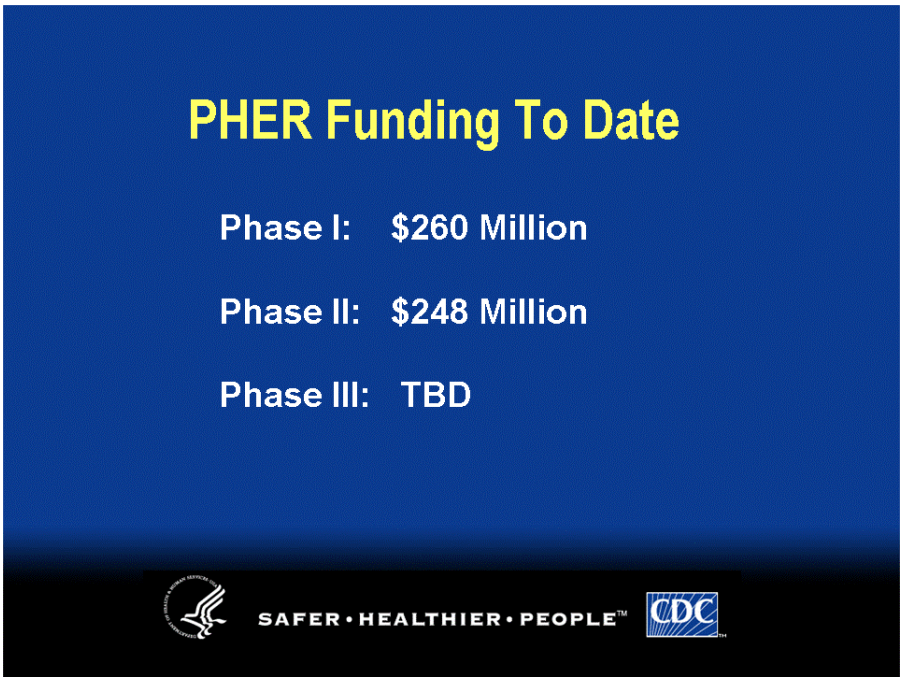
DSLR Fast Facts

- 2009 Total Budget = $689.8 million
- 99.4% of Annual Budget Awarded through Cooperative Agreements, Contracts
  - 9 contracts: $4.4 million
  - 66 cooperative agreements: $679.8 million
    - 62 state and local public health departments
    - 4 funded partner organizations
      - ✓ Association of Public Health Laboratories
      - ✓ Association of State and Territorial Health Officials
      - ✓ National Association of County and City Health Officials
      - ✓ National Emergency Management Association

Public Health and Emergency Response (PHER) Grant

- Established in 2009 by the 2009 Supplemental Appropriations Act
- Funds state and local, public health departments to prepare for H1N1 influenza pandemic planning and response in 2 focus areas:
  - Mass Vaccination, Antiviral Distribution, Community Mitigation
  - Epidemiology, Surveillance, and Laboratory

SAFER • HEALTHIER • PEOPLE™ CDC


PHER Funding To Date
Phase I: $260 Million
Phase II: $248 Million
Phase III: TBD
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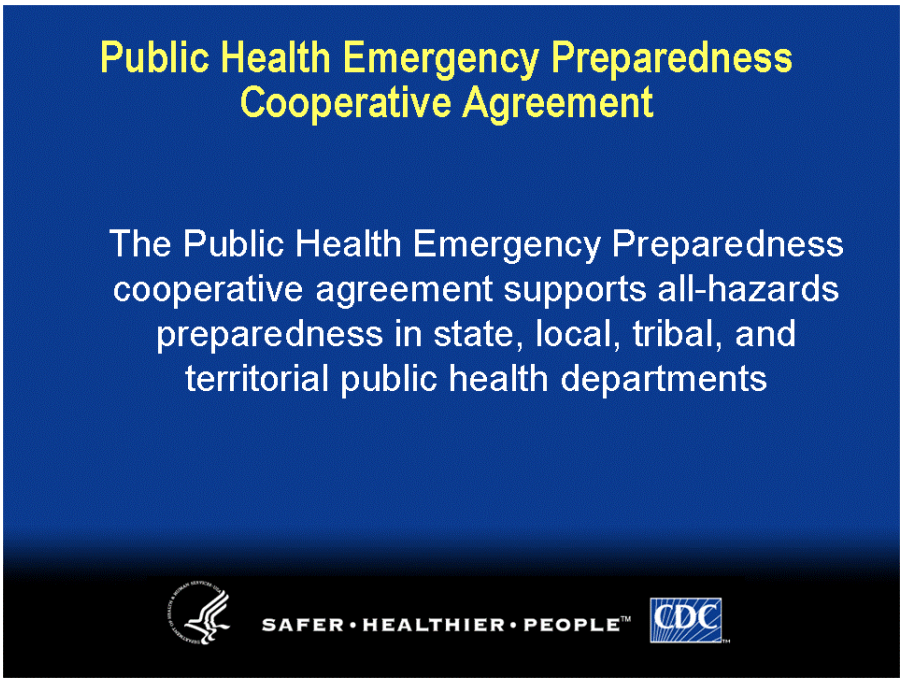
CDC


Public Health Emergency Preparedness Cooperative Agreement
The Public Health Emergency Preparedness cooperative agreement supports all-hazards preparedness in state, local, tribal, and territorial public health departments
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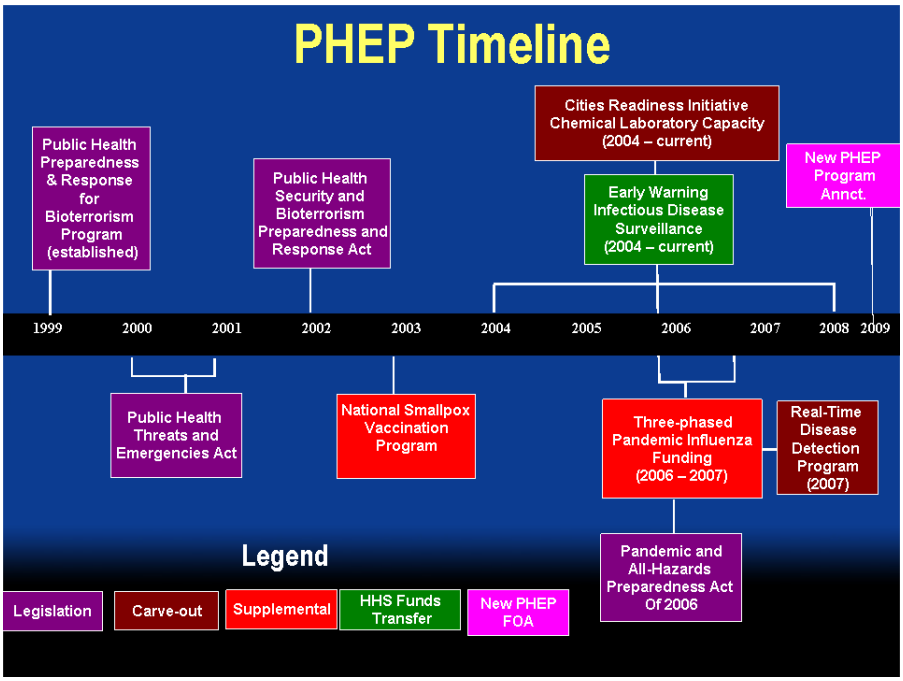
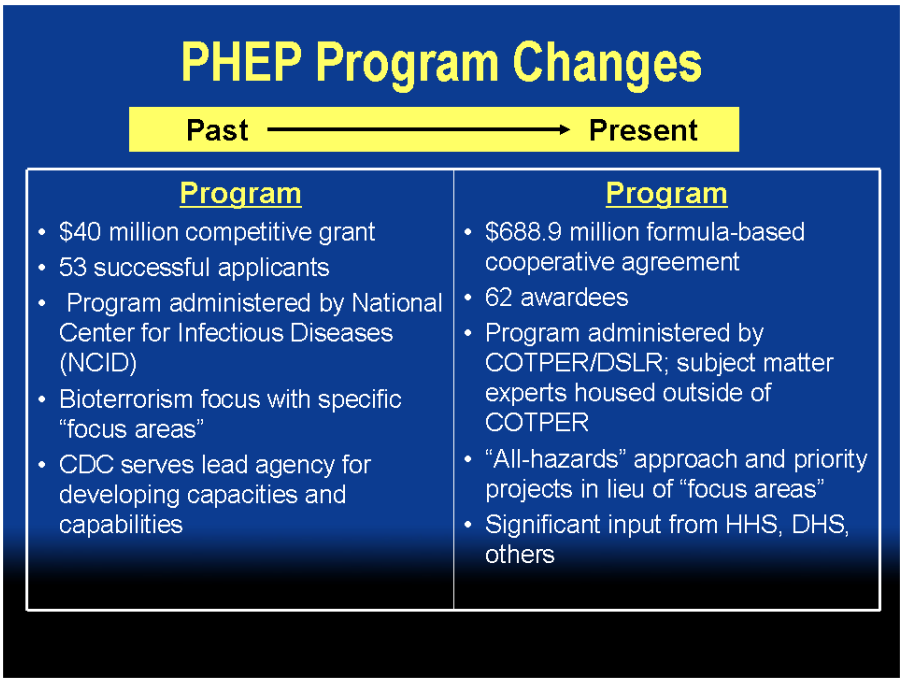
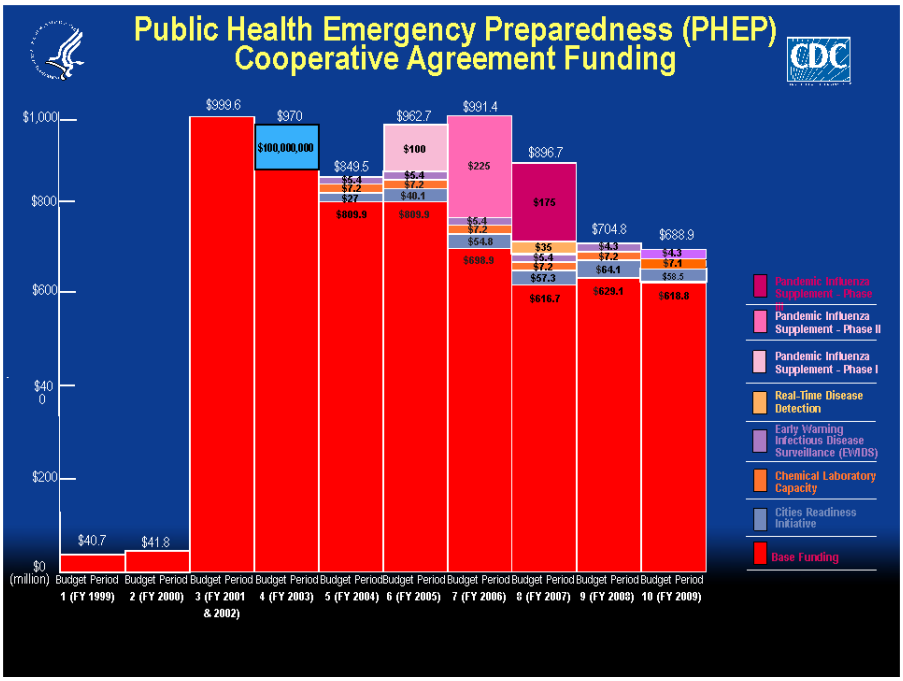
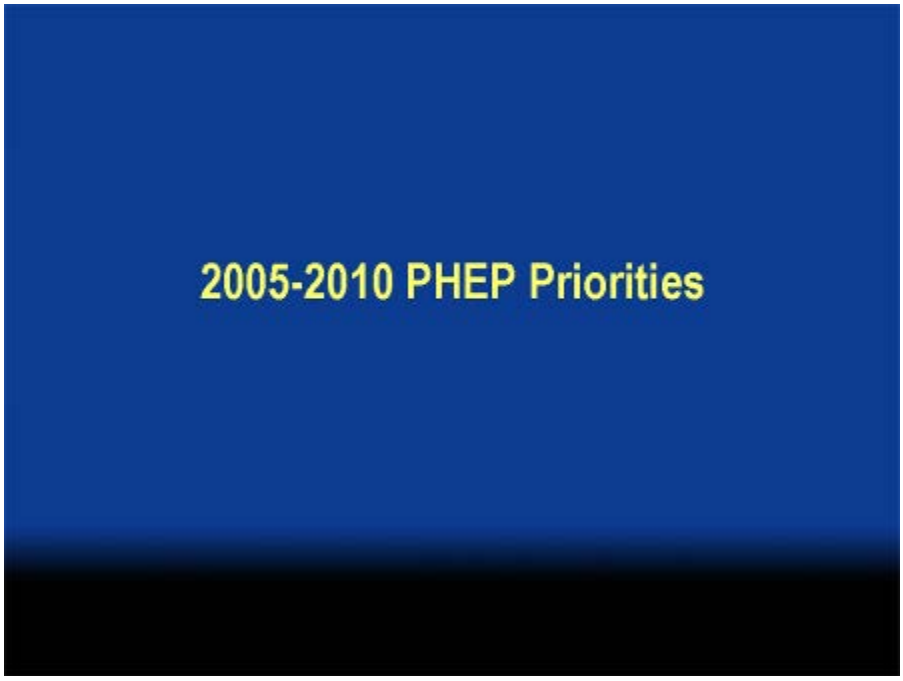
CDC


PHEP Timeline
Public Health Preparedness & Response for Bioterrorism Program (established)
Public Health Security and Bioterrorism Preparedness and Response Act
Cities Readiness Initiative Chemical Laboratory Capacity (2004 – current)
Early Warning Infectious Disease Surveillance (2004 – current)
New PHEP Program Annct.
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
Public Health Threats and Emergencies Act
National Smallpox Vaccination Program
Three-phased Pandemic Influenza Funding (2006 – 2007)
Real-Time Disease Detection Program (2007)
Pandemic and All-Hazards Preparedness Act Of 2006
Legend
Legislation
Carve-out
Supplemental
HHS Funds Transfer
New PHEP FOA


PHEP Program Changes
Past
Present
Program
$40 million competitive grant
53 successful applicants
Program administered by National Center for Infectious Diseases (NCID)
Bioterrorism focus with specific "focus areas"
CDC serves lead agency for developing capacities and capabilities
Program
$688.9 million formula-based cooperative agreement
62 awardees
Program administered by COTPER/DSLR; subject matter experts housed outside of COTPER
"All-hazards" approach and priority projects in lieu of "focus areas"
Significant input from HHS, DHS, others


Public Health Emergency Preparedness (PHEP)
Cooperative Agreement Funding
$1,000
$800
$600
$400
$200
$0
(million)
$40.7
$41.8
$999.6
$970
$100,000,000
$849.5
$5.4
$7.2
$27
$809.9
$962.7
$100
$5.4
$7.2
$40.1
$809.9
$991.4
$225
$5.4
$7.2
$54.8
$698.9
$896.7
$175
$35
$5.4
$7.2
$57.3
$616.7
$704.8
$4.3
$7.2
$64.1
$629.1
$688.9
$4.3
$7.1
$58.5
$618.8
Budget Period 1 (FY 1999)
Budget Period 2 (FY 2000)
Budget Period 3 (FY 2001 & 2002)
Budget Period 4 (FY 2003)
Budget Period 5 (FY 2004)
Budget Period 6 (FY 2005)
Budget Period 7 (FY 2006)
Budget Period 8 (FY 2007)
Budget Period 9 (FY 2008)
Budget Period 10 (FY 2009)
Pandemic Influenza Supplement - Phase
Pandemic Influenza Supplement - Phase II
Pandemic Influenza Supplement - Phase I
Real-Time Disease Detection
Early Warning Infectious Disease Surveillance (EWIDS)
Chemical Laboratory Capacity
Cities Readiness Initiative
Base Funding


2005-2010 PHEP Priorities

2005-2010

- **9 CDC Preparedness Goals**
- **Outcomes** (2005): roles and capabilities needed to respond to an event of significance
  - Selected from Department of Homeland Security (DHS) Target Capabilities List (TCL)
- **Target Capabilities** (2006-2009): Public health-related elements of the DHS TCL
- **Critical Tasks**: Significant activities similar to DHS Universal Task List (UTL) items
- **Measures**: demonstrated response capabilities

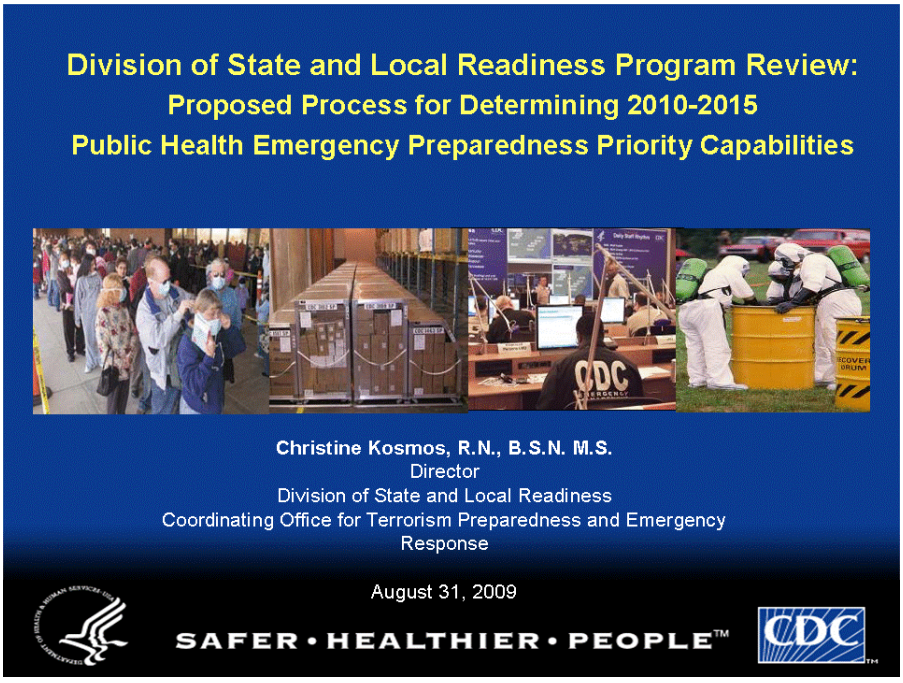
CDC Preparedness Goals + Target Capabilities

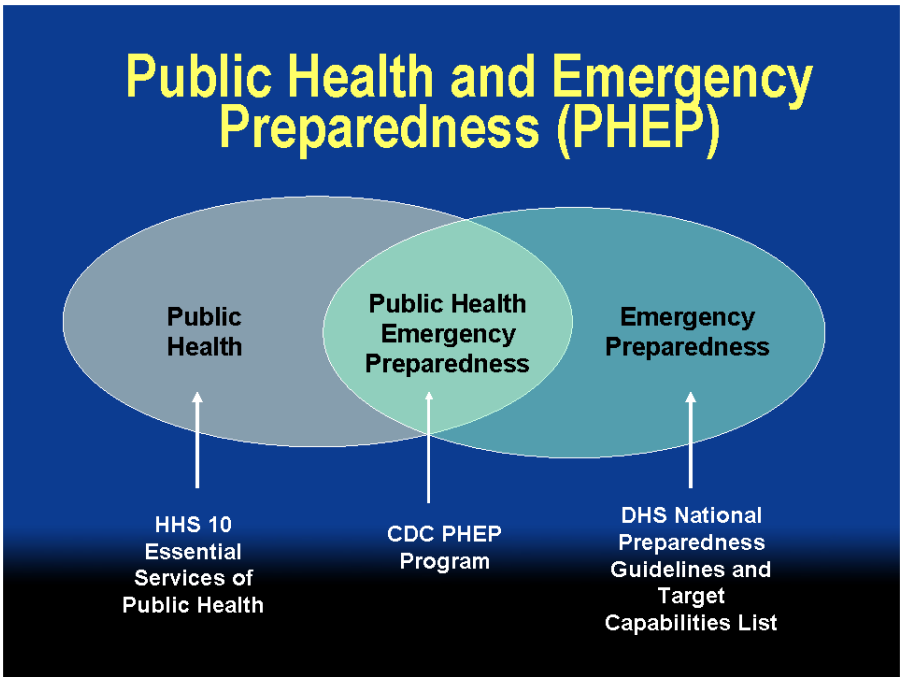
Goal		Target Capability	
1	Increase prevention interventions	1a	Planning
2	Decrease time to classify terrorism	2a	Information Gathering & Recognition of Indicators & Warning
		2b	Planning
3	Decrease time to detect agents	1a	Public Health Laboratory Testing
4	Improve communications	4a	Health Intelligence Analysis and Production
5	Decrease time to identify causes / controls	5a	Epidemiological Surveillance and Investigation
6	Decrease time to provide countermeasures	6a	Communications
		6b	Emergency Public Information and Warning
		6c	Responder Safety and Health
		6d	Isolation and Quarantine
		6e	Mass Prophylaxis
		6f	Medical Surge
		6g	Mass Care
		6h	Citizen Evacuation and Shelter-In-Place
7	Decrease time to restoration	7a	Environmental Health
8	Improve follow up	8a	Economic and Community Recovery
9	Decrease time to implement recommendations	9a	Planning

Past – 2005			Present - 2009		
Outcome Name		CTs	Target Capability Name		CTs
1a	All Hazards Planning	9	1a	Planning	11
2a	Information Collection and Threat Recognition	12	2a	Information Gathering & Recognition of Indicators & Warning	12
2b	Hazard and Vulnerability Analysis	4	2b	Planning	4
3a	Public Health Laboratory Testing	13	3a	Public Health Laboratory Testing	13
4a	Health Intelligence Integration and Analysis	7	4a	Health Intelligence Analysis and Production	7
5	Public Health Epidemiological Investigation	4	5a	Epidemiological Surveillance and Investigation	4
6a	Emergency Response Communications	10	6a	Communications	11
6b	Emergency Public Information	10	6b	Emergency Public Information and Warning	10
6c	Worker Health Safety	6	6c	Responder Safety and Health	6
6d	Isolation and Quarantine	8	6d	Isolation and Quarantine	8
6e	Mass Prophylaxis and Vaccination	7	6e	Mass Prophylaxis	7
6f	Medical and Public Health Surge	8	6f	Medical Surge	8
	NONE	0	6g	Mass Care	3
	NONE	0	6h	Citizen Evacuation and Shelter-In-Place	3
7a	Economic and Community Recovery	2	7a	Environmental Health	2
8a	No Name	3	8a	Economic and Community Recovery	3
9	No Name	4	9a	Planning	4
	TOTAL	107		TOTAL	116

CT = Critical Task

Proposed Process for Determining 2010-2015 PHEP Priority Capabilities





Prioritization Methodology

- Division of State and Local Readiness Priorities Workgroup developed the methodology for determining PHEP priorities
- Methodology prioritizes capabilities using the capabilities-based planning approach mandated by the National Preparedness Goal and the Pandemic and All-Hazards Preparedness Act (PAHPA)
- Key PHEP-related legislation and other CDC and partner documents are mapped to the DHS Target Capabilities List (TCL)
  - Target Capabilities are then prioritized based on number and strength of mappings

Selected Documents

- Documents were selected based on relevance to PHEP
- Documents were assigned "weights" (to be used in calculating priorities)

Legislation: Weight = 5

- **Pandemic and All-Hazards Preparedness Act (PAHPA):** Authorizing legislation for the PHEP cooperative agreement

Homeland Security Presidential Directives: Weight = 4

- **HSPD-5:** National Incident Management System (NIMS)
- **HSPD-8:** National Preparedness Goal (NPG)
- **HSPD-21:** National Strategy for Public Health & Medical Preparedness

Partner Documents: Weight = 2

- **NACCHO:** Project Public Health Ready
- **ASTHO:** Proposed DPHP survey will be included if/when complete

Prioritization Tool

- Workgroup assigned a weight to each mapping
  - Strong Match = 5, Medium Match = 3, Weak Match = 1, No match = 0
- Tool calculates "priority scores" for each Target Capability
  - Priority Score = Sum (Document Weight * Mapping Weight)

Priority Tiers

- Capabilities were placed in "tiers" based on their priority score
- Lowest scoring capabilities were excluded

Tier-One Capabilities (Count = 14)
Planning
Communications
Community Preparedness and Participation
Intelligence and Information Sharing
Epidemiologic Surveillance and Investigation
Laboratory Testing
On-site Incident Management
Responder Safety and Health
Isolation and Quarantine
Emergency Public Information and Warning
Medical Surge
Medical Supplies Management and Distribution
Mass Prophylaxis
Fatality Management

Tier-Two Capabilities (Count = 3)
Risk Management
Volunteer Management and Donations
Mass Care

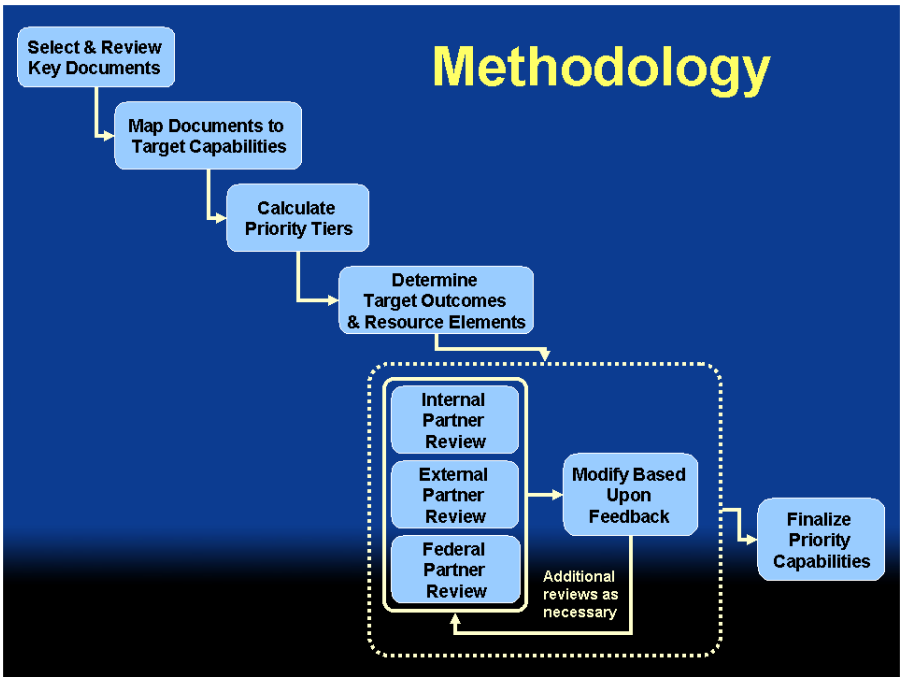
Tier-Three Capabilities (Count = 3)
CBRNE Detection
Emergency Operations Center Management
Economic and Community Recovery

Excluded Capabilities (Count = 17)

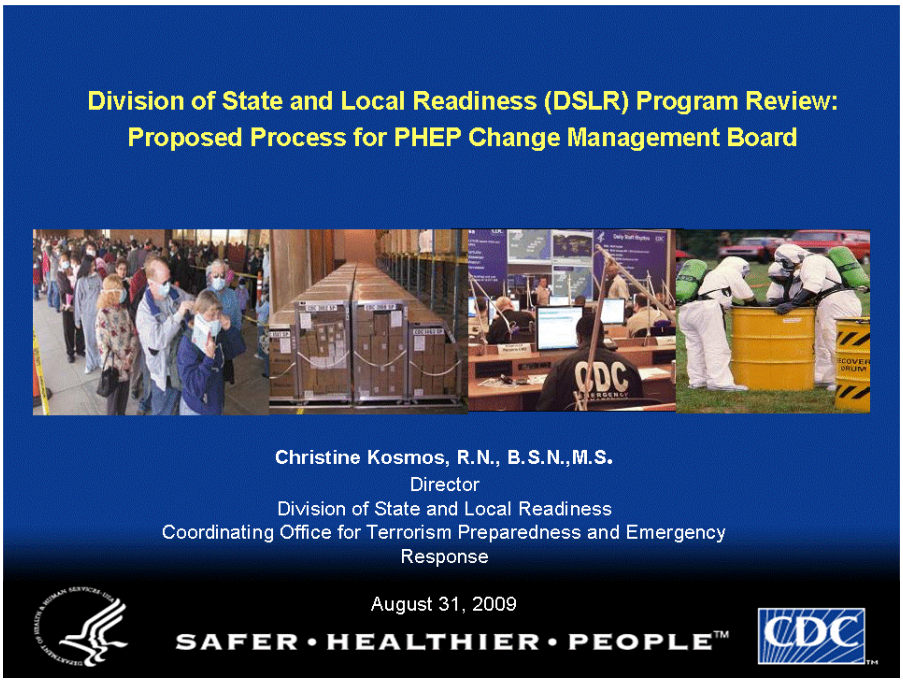
Alignment to Public Health

- Priority capabilities were mapped to 10 Essential Services of Public Health
- Some capabilities (shaded) mapped to multiple services

	Essential Service	Priority Capability
1	Monitor	Communications
		Risk Management
		CBRNE Detection
		Epidemiological Surveillance & Investigation
2	Diagnose & Investigate	Epidemiological Surveillance & Investigation
		Laboratory Testing
3	Inform & Educate	Communications
		Intelligence and Information Sharing
		Emergency Public Information and Warning
4	Mobilize & Manage	Community Preparedness and Participation
		On Site Incident Management
		Emergency Operations Center Management
		Volunteer Management and Donations
		Medical Surge (mobilization aspects)
		Medical Supplies Management and Distribution
5	Develop Policies & Plans	Planning
6	Enforce Laws	Isolation and Quarantine (legal aspects)
7	Provide Services	Medical Surge (healthcare aspects)
		Mass Prophylaxis
		Mass Care (Shelter, Food & Services)
		Fatality Management
8	Workforce	Responder Safety and Health
		Medical Surge (workforce aspects)
9	Evaluate & Improve	Economic & Community Recovery
		Cross Cutting across all Capabilities
10	Research & Best Practices	Cross Cutting across many Capabilities



Proposed PHEP Change Management Board



Presentation Intent

- Orient reviewers to examples of past and anticipated changes to the PHEP program announcement
- Present DSLR's proposed process to manage stakeholder-directed changes to the PHEP

DSLR Program History 2005-2010

- Initial Program Announcement/Guidance released in 2005
- Each subsequent year between 2005-2010 was deemed a continuation year
- In a continuation year, awardees are to continue unfinished activities from the prior year or initiate new activities all within the scope of the original cooperative agreement
- However, each year additional activities, tasks, requirements were added by internal (CDC) and external stakeholders (e.g. White House, Department of Health and Human Services)
- This is not typical cooperative agreement management practice

Examples of Program Changes

- **Countermeasure Response Administration program (CRA)**
  - Added at request of HHS/ASPR
  - No discussion between DSLR and stakeholders as to alignment with existing PHEP priorities
- **CDC SME Changes**
  - Requests by CDC SMEs for changes to the PHEP
  - SME Critical Task Changes: 107 in 2005 vs. 116 in 2009
- **"Overarching Requirements" Changes**
  - 2005: 9 Topic Areas
  - 2006: 15 Topic Areas
  - 2007: 12 Topic Areas, including single year projects in:
    - Real-Time Disease Detection
    - Poison Control Centers
    - Hospital/Clinical Laboratory/University Partners
  - 2008: 13 Topic Areas, including CRA

Examples of Funding Changes

- **2002 Smallpox, $100 million to awardees**
  - Required awardees to submit smallpox plans
  - No additional DSLR staff to review plans or monitor funds
- **2005 Cities Readiness Initiative (CRI)**
  - Initially funds "carved out" of total PHEP award
  - Second year $1 million "carved out" from each PHEP awardee
  - Additional burden on DSLR staff to train awardees but no additional staff to monitor funds
- **2006 Pandemic Influenza Supplemental**
  - March 2006 $100 million; July 2006 $225 million, Sept 2008 24 million
  - Awardees to conduct planning, pan flu preparedness
  - No additional DSLR staff to review plans or monitor funds
- **April 2007 DSLR tasked by HHS to lead review of pan flu operational plans from July 06 guidance**
  - No additional DSLR staff to review plans or monitor funds

Challenges Presented by Past Changes

- Inconsistent funding for SMEs to assist in PHEP implementation
- Only the Public Health Information Network (PHIN) and the COTPER Division of Strategic National Stockpile (DSNS) receive COTPER funding for technical assistance to the PHEP
- Other programs who provide PHEP activities are not funded to assist the PHEP's implementation

Future Changes Anticipated

- PAHPA requires PHEP to align with National Health Security Strategy
  - *Congressional requirement but document not yet available*
  - *Current Target Capabilities List (Department of Homeland Security) undergoing revision for fall 2010*

Why a Change Management Board?

- To ensure that changes to either PHEP Priority Capabilities or to components of the conceptual model are introduced in a controlled and coordinated manner
- To reduce the possibility that *ad hoc* changes will be introduced to the PHEP and add additional burden into the system, or that new changes may unilaterally undo decisions previously agreed upon by the stakeholders

Goals of the Change Management Board

- Provide a formalized structure for submitting, assessing, reviewing and approving changes to the PHEP Program
- Assess the risk and impact of the proposed change to the PHEP awardees and DSLR operations
- Establish a method to ensure all changes are documented, tracked and stored
- Ensure that key stakeholders understand the rationale for the changes and their impact

Goals of the Change Management Board

- Ensure that changes to the PHEP are made in a way that :
  - Ensures continued compliance with applicable mandates and policies
  - Minimizes disruption to current PHEP priorities, capabilities, and deliverables
  - Improves DSLR's ability to help PHEP awardees achieve the desired capabilities
  - Improves DSLR's coordination of CDC resources (DSLR and non-DSLR) involved in the implementation of the PHEP cooperative agreement

Potential Benefits

- Formalize the relationships between all internal and external groups involved in the PHEP
- Minimize last-minute changes and funding delays to awardees
- Improve the business case for changes to the PHEP
- Improve the coordination of in-scope and out-of-scope potential contributions

Potential Benefits

- Provide a mechanism to assess the costs and potential impacts of proposed additions to the 2010-2015 PHEP priorities and capabilities
- Provide a current, published project plan that spans all project stages from PHEP initiation through implementation, revisions, and evaluation
- Provide DSLR with a process for the management and resolution of issues that arise during the implementation of the PHEP

Critical Success Factors

- Executive COTPER and CDC Leadership support to ensure CDC and other stakeholders conform to the change management process
- COTPER, CDC's (OD and National Centers) and HHS/ASPR's commitment to conform to one integrated change management process
- DSLR leadership participation and support in CMB steering committee meetings
- Appropriate documentation for all change requests

Proposed Membership for the CMB

1. DSLR Director (CMB Chair)
2. DSLR Division Deputy (CMB Administrator)
3. Program Services Branch (PSB) Chief
4. Outcome and Evaluation Branch (OMEB) Chief
5. CDC Centers/Offices that align to the prioritized capabilities for the 2010-2015 PHEP (CMB Steering Committee Members)
6. HHS ASPR (CMB Steering Committee Member)
7. Procurements and Grants Office (PGO) or COTPER Division of Business Services (DBS) Representative

Proposed Operating Procedures

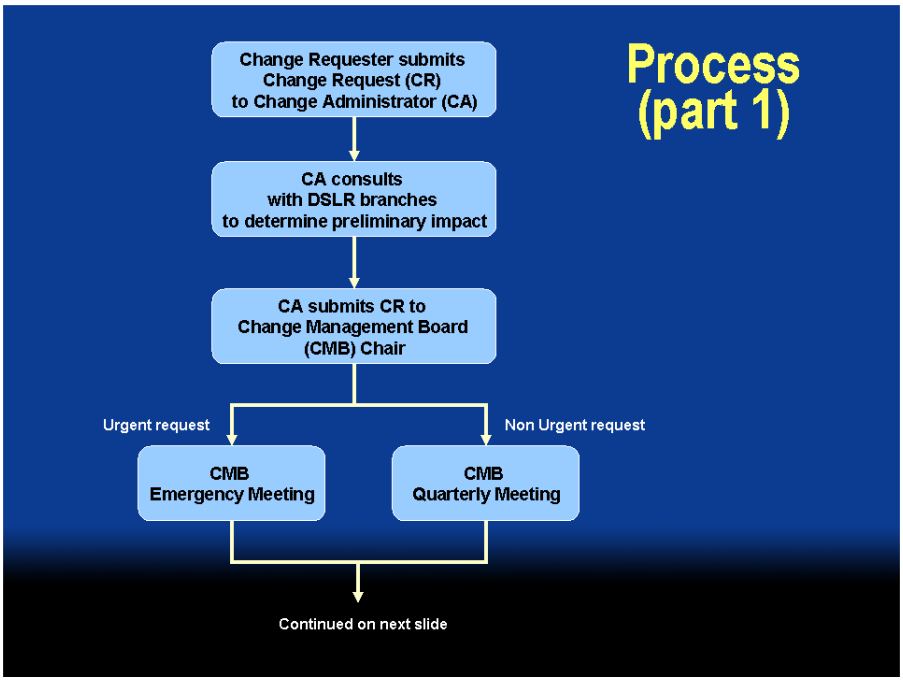
- Establishment of a formal memorandum of understanding (MOU) between COTPER/DSLR and stakeholder members regarding membership roles on the CMB
- CMB Member agreement as to the PHEP CMB process
- Quarterly meetings for non urgent change requests
- Emergency meetings for urgent change requests

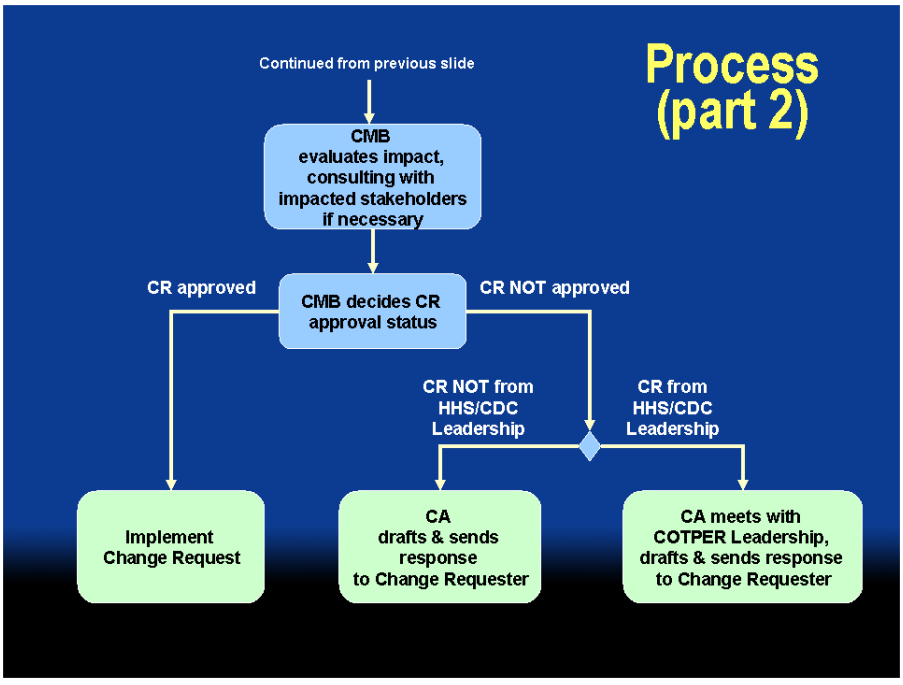
Urgent Change Requests

- A change request is deemed as "Urgent" if it meets all of the following criteria:
  - It addresses an emerging threat
  - There is supporting credible evidence that the threat exists
  - The threat is within the control of state and local public health and within the scope of the PHEP Program
  - The proposed change requires immediate implementation to effectively address the threat
- If any of the above criteria are not present, the request is deemed "Non Urgent"

Requirements for Change Requests (CR)

- CRs need to include a description of the potential impact of the proposed changes to state and local public health
- CRs must address state and local awardees capacity to perform the proposed activity or capability as well as potential additional data burdens for the awardees
- CRs must address potential impact to the 2010-2015 PHEP framework
- CRs must address and provide a solution for staffing support to implement the proposed new priority (e.g. if a center or program wants to add a topic to the PHEP, they would have to provide staffing support to DSLR)


Process (part 1)
Change Requester submits Change Request (CR) to Change Administrator (CA)
CA consults with DSLR branches to determine preliminary impact
CA submits CR to Change Management Board (CMB) Chair
Urgent request
Non Urgent request
CMB Emergency Meeting
CMB Quarterly Meeting
Continued on next slide


Process (part 2)
Continued from previous slide
CMB evaluates impact, consulting with impacted stakeholders if necessary
CR approved
CMB decides CR approval status
CR NOT approved
CR NOT from HHS/CDC Leadership
CR from HHS/CDC Leadership
Implement Change Request
CA drafts & sends response to Change Requester
CA meets with COTPER Leadership, drafts & sends response to Change Requester

Appendix D
Workgroup Meeting Agenda

Division of State and Local Readiness (DSLR) Program Review
Public Health Emergency Preparedness (PHEP) Cooperative Agreement Priorities, Awardee Capabilities, and Strategic Management Peer Review
Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER)
Centers for Disease Control and Prevention (CDC)

Emory Conference Center Hotel, Peachtree Creek Room
1615 Clifton Road, Atlanta, GA 30329
September 15 -17, 2009

Tuesday, September 15, 2009

9:00 – 9:10 a.m.	**Welcome and Individual Introductions** Dr. Jack Harrald and Dr. Ellen MacKenzie, Workgroup Co-Chairs, Board of Scientific Counselors, COTPER
9:10 – 9:20 a.m.	**Welcome Remarks** Dr. Dan Sosin, Acting Director, COTPER
9:20 – 9:25 a.m.	**Workgroup Charge and Logistics** Dr. Christa-Marie Singleton, Associate Director for Science, Division of State and Local Readiness, COTPER
9:25 – 9:50 a.m.	**Review of Proposed Process for PHEP Priority Capabilities** Ms. Christine Kosmos, Director, Division of State and Local Readiness, COTPER
9:50 – 10:15 a.m.	**Discussion and Questions**
10:15 – 10:30 a.m.	Break
10:30 – 11:15 a.m.	**Review of DSLR's Proposed Change Management Board** Ms. Christine Kosmos, Director, Division of State and Local Readiness, COTPER
11:15 – 11:45 a.m.	**Discussion and Questions**
11:45 – 12:30 p.m.	**Lunch**
12:45 – 2:30 p.m.	**DSLR PHEP Stakeholder Feedback Panel Discussion on Priority Capabilities and Change Management** ASTHO: Damon T. Arnold, MD, ASTHO Liaison, COTPER BSC NACCHO: Karen Smith, MD, NACCHO Liaison, COTPER BSC

ASPH: James Curran, MD, MPH, ASPH Liaison, COTPER BSC
CSTE: Janet Hamilton, MPH, Florida Department of Health
APHL: Mary J.R. Gilchrist, APHL Liaison, COTPER BSC

2:30 – 2:45 p.m. **Break**

2:45 – 4:00 p.m. **Discussion and Questions**

4:00 – 4:30 p.m. **Discussion of PHEP Capability Intersection with Public Health Essential Services**

- Dennis D. Lenaway, PhD, MPH, Director, CDC Office of Public Health Systems Performance, Office of Chief of Public Health Practice
- Liza Corso, MPA, CDC Office of Public Health Systems Performance, Office of Chief of Public Health Practice

4:30 - 5:00 p.m. **Identification of Additional Items Needed from DSLR**
Dr. Jack Harrald and Dr. Ellen MacKenzie, Workgroup Chairs, Board of Scientific Counselors, COTPER

5:00 p.m. **Adjourn**

6:00 p.m. Workgroup and DSLR Networking Social Hour
Location: The Club Room, Emory Conference Center Hotel, Lobby Level

Wednesday, September 16, 2009

9:00 – 9:05 a.m. **Welcome** – Meeting Convenes for Day 2
Dr. Jack Harrald and Dr. Ellen MacKenzie, Workgroup Co-Chairs, Board of Scientific Counselors, COTPER

9:05 – 10:30 am **DSLR PHEP Change Management Discussion**

- Susan True, M.Ed., CDC Foundation; former DSLR Program Services Branch Chief
- LCDR Anita Pullani, MHS, U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), Division of National Healthcare Preparedness Programs

10:30 – 10:45 a.m. **Break**

10:45 - 11:45 a.m. **Unresolved Issues from Day 1**

11:45 am– 12:30 pm **Lunch**

12:30 – 5:00 p.m. **Deliberations and Report Writing (*Closed*)**

5:00 p.m. **Adjourn**
Dr. Jack Harrald and Dr. Ellen MacKenzie, Workgroup Co-Chairs, Board of Scientific Counselors, COTPER

Thursday September 17, 2009

9:00 – 9:05 a.m. **Welcome** – Meeting Convenes for Day 3
Dr. Jack Harrald and Dr. Ellen MacKenzie, Workgroup Co-Chairs, Board of Scientific Counselors, COTPER

9:05 – 12:00 p.m. **Deliberations and Report Writing (*Closed*)**

12:00 p.m. **Adjourn**
Dr. Jack Harrald and Dr. Ellen MacKenzie, Workgroup Co-Chairs, Board of Scientific Counselors, COTPER

Appendix E
A Methodology for Prioritizing Public Health Preparedness Capabilities

COORDINATING OFFICE FOR TERRORISM PREPAREDNESS AND EMERGENCY RESPONSE

DIVISION OF STATE AND LOCAL READINESS

A METHODOLOGY FOR PRIORITIZING PUBLIC HEALTH PREPAREDNESS CAPABILITIES

Version 0.6

August 2009

DISCUSSION DRAFT – DO NOT CIRCULATE OR REPRODUCE –

FOR INTERNAL DSLR USE ONLY

VERSION HISTORY

Version #	Implemented By	Revision Date	Reviewed By	Reviewed Date	Reason
0.1	Nikolas Shumock	8/11/09	Gideon Slifkin	8/11/09	
0.2	Gideon Slifkin	8/11/09	Nikolas Shumock	8/11/09	
0.3	Gideon Slifkin	8/12/09	Christa Singleton	8/12/09	
0.4	Nikolas Shumock	8/12/09	Gideon Slifkin	8/12/09	
0.5	Gideon Slifkin	8/12/09	Nikolas Shumock	8/12/09	
0.6	Gideon Slifkin	8/13/09	Nikolas Shumock	8/13/09	

INTRODUCTION

Background

In 2002, shortly after the events of September 11, 2001, and subsequent anthrax attacks, Congress authorized funding for the Public Health Emergency Preparedness (PHEP) cooperative agreement to support nationwide preparedness in state, local, tribal, and territorial public health departments. As of 2009, this cooperative agreement has provided nearly $7 billion in funding to these public health departments.

Managed by CDC's Coordinating Office for Terrorism Preparedness and Emergency Response through the Division of State and Local Readiness (DSLR), the PHEP program's mission has evolved into an all-hazards approach, which helps ensure that public health departments have the capacity and capability to effectively respond to the public health consequences of not only terrorist threats, but also infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological threats.

One of the key elements of the PHEP program is to determine the appropriate set of PHEP priorities across the nation. PHEP funding levels have decreased in recent years, leading to concerns by PHEP awardees that they will not be able to achieve or sustain preparedness progress resulting from PHEP investments. This circumstance creates a need to establish appropriate PHEP program priorities that ensure funds are directed to the highest priority areas.

Challenges

DSLR recognizes that identifying and establishing priorities can be extremely challenging. Many factors have contributed to this challenge, including (but not limited to) the following:

- The field of PHEP is relatively new, and there is limited published evidence for determining which capabilities contribute most to improving public health emergency preparedness and response.
- The perception, reality, and political nature of the threats being addressed continually change.
- The PHEP program is mandated through legislation to address emergency preparedness priorities; however most, if not all, priorities for emergency preparedness are also priorities for traditional public health. There has been inconsistent guidance over the use of emergency preparedness funds to address overlapping priorities.
- There are many PHEP stakeholders, including federal agencies, state and local health departments, public health advocacy groups, and others. Each stakeholder may have different perceptions of preparedness priorities.
- The PHEP program comprises elements of existing CDC programs, which individually may have their own set of priorities. It has not always been clear how these priorities relate or intersect with other CDC program priorities.

- Needs vary across the awardees. Different awardees may have very different priorities based on their size, geography, demographics, and other risk factors.
- Current capabilities, both in terms of general public health capabilities and emergency preparedness capabilities, vary greatly across the awardees. A single set of priorities may not be suitable for all awardees.
- There are other federal programs which fund preparedness or PHEP-related activities, including programs funded through CDC and HHS (such as the Hospital Preparedness Program) and those funded through DHS. Ideally, all of these programs should coordinate priority setting and complement each others' funding strategies, but this level of coordination is not always feasible.
- Health departments substantially differ in terms of the scope of their responsibilities and their relationship to other emergency response departments at the state or local level. This difference in scope will impact the selection of priorities for each awardee.
- State priorities may differ from local priorities. Currently the PHEP program directly funds all 50 states, eight territories and freely associated states, and four major metropolitan areas (Chicago, Los Angeles County, New York City, and Washington D.C.). The approximately 3,000 local health departments in the United States are funded through their state health department, who directly receive the PHEP funds.
- Different stakeholders may have different perceptions and assumptions as to the scope of public health emergency preparedness. Although there may be agreement as to the general importance of a particular area of preparedness, e.g. interoperable communications systems, there may not be agreement as to whether that area should be a part of the PHEP program.

Preparedness Model

In addition to the challenges described above, there is no universally accepted PHEP model or terminology within which to define public health emergency preparedness priorities.

For example, in the emergency preparedness field, the Department of Homeland Security (DHS) has mandated a "capabilities-based approach" for defining emergency preparedness. DHS has defined a list of emergency preparedness and response target capabilities, some of which are fully relevant to public health, some of which are partially relevant to public health, and some which do not apply to public health. The target capabilities model also contains a sub-structure, which is currently under revision from version 2 to version 3 but is projected to include concepts such as "target outcomes" and "resource elements."

In the public health field, "The Ten Essential Services of Public Health" (Essential Services), has gained widespread acceptance across the United States as a standard framework.

The PHEP program exists at the intersection of public health and emergency preparedness. Decisions therefore need to be made regarding how, or if, capabilities and essential services should be prioritized or aligned.

DSLR Workgroup

To address these issues, DSLR convened an internal workgroup in March 2009. The workgroup's mandate was twofold: a) to determine an appropriate PHEP "model"; and b) to prioritize elements within that model, using as objective of an approach as possible. The workgroup combined CDC staff from DSLR's Office of the Director, Program Services Branch, Outcome Monitoring and Evaluation Branch, and contractor support. The workgroup held weekly meetings throughout the spring and summer of 2009 to determine an appropriate model for PHEP, and a prioritization methodology. The workgroup was then tasked with utilizing the model and methodology to determine priorities for the PHEP program.

This Document

This document describes the approach and methods used by the workgroup and the results obtained. It describes how DSLR selected a model for PHEP and then prioritized elements within that model to produce a set of PHEP priorities.

Since the PHEP program is authorized through legislation, this document begins in section 2 by describing the legislative drivers for the program, and how these might prescribe an approach to determining priorities. Section 2 also describes the public health aspects of the program through the Essential Services and describes the DHS Target Capabilities List, the cornerstone of emergency preparedness. This section provides the background necessary to understand the methodology for prioritization.

Section 3 describes the methodology used to prioritize target capabilities. The methodology involved selecting and reviewing documents from key stakeholders and then mapping these documents to the Target Capabilities List.

Section 4 describes the results obtained from the methodology, which include a prioritized list of target capabilities, called "priority capabilities," and an alignment between these priority capabilities and the Essential Services.

In support of the methodology, two technology-based tools were developed. These tools are a relational database system implemented in Microsoft Access and a spreadsheet implemented in Microsoft Excel.

The database system stores all the priorities, capabilities, and other information which is gathered during the course of executing the methodology, and the spreadsheet contains calculations and formulas which enable the automated calculation of suggested priorities. These will be discussed in sections 3 and 4.

Section 5 discusses limitations of the methodology, and Section 6 contains a discussion of the overall approach.

1 THE PHEP MODEL

1.1 INTRODUCTION

Before determining the priorities, a prerequisite was to determine the model for prioritization. As the PHEP program is authorized through legislation, a review of relevant legislation was conducted to determine if any legislated directives exist in this regard. A review of the Pandemic and All-Hazards Preparedness Act (PAHPA) directed us toward a "capabilities-based approach" in alignment with the target capabilities model from DHS. It was further determined that the PHEP program should also align to the HHS "10 Essential Public Health Services" model. A new model was then developed combining the target capabilities and Essential Services, and the best approach was determined to be prioritization of capabilities with subsequent alignment to services. The design of this new model and the rationale behind it are described in this section.

1.2 LEGISLATIVE DIRECTIVES REVIEW

Before developing the model, legislative and executive directives were first reviewed to determine the existence of any directives or general guidance for an approach to determining PHEP program priorities. Since PAHPA is the authorizing legislation for the program, it was deemed appropriate to focus on PAHPA for this analysis.

The review indicated that although PAHPA implicitly defines priorities through its choice of language and topics to be discussed, it rarely explicitly indicates priorities. Furthermore, PAHPA does not directly mandate any approach or methodology to be followed for determining PHEP priorities.

However, PAHPA does specify the need to maintain "consistency" with certain other national programs. Specifically, PAHPA requires that PHEP awardees submit a plan describing how they will meet the preparedness goals described in the National Health Security Strategy (NHSS)[1], and PAHPA includes a broad outline for the NHSS, with implicit priorities contained within. PAHPA also provides several other requirements for PHEP awardees, which again implicitly describe priorities; however, these requirements are not comprehensive.

PAHPA also directs that the NHSS be consistent with the National Preparedness Guidelines (the Guidelines)[2]. As PAHPA is the authorizing legislation for the PHEP program, and as PAHPA mandates that the PHEP be consistent with the NHSS, and the NHSS with the Guidelines, it is appropriate to review the Guidelines to determine the existence of an explicit or implicit priority-setting methodology.

[1] PAHPA Section 201(2)(b)(2)(A)(i)
[2] PAHPA Section 103 Subsection 2802(b)(5)

Upon reviewing the Guidelines, DSLR determined that they do provide some guidance for the selection of priorities. The Guidelines present a standard for preparedness based on establishing national priorities through a capabilities-based planning process[3].

Since PAHPA mandates "consistency" with NHSS and the National Preparedness Guidelines, the Division of State and Local Readiness (DSLR), as the steward of the PHEP program, is proposing a capabilities-based approach to setting priorities for the 2010 to 2015 PHEP cooperative agreement.

1.3 ALIGNMENT TO NATIONAL PREPAREDNESS GUIDELINES

The National Preparedness Guidelines is a framework containing many sub-components. There are two major components to the framework:

- **National Preparedness Guidelines**
  1. National Preparedness Vision
  2. National Planning Scenarios
  3. Universal Task List (UTL)
  4. Target Capabilities List (TCL)
- **National Response Framework (NRF)**
  1. Emergency Support Function (ESF)
  2. Support and Incident Annexes
  3. Partner Guides

For the purposes of this model, we will focus on the Guidelines as they are specifically mentioned within PAHPA.

There are four critical elements to the National Preparedness Guidelines:

1. **The National Preparedness Vision**, which provides a concise statement of the core preparedness goal for the nation.
2. **The National Planning Scenarios**, which collectively depict the broad range of natural and man-made threats facing our nation and guide overall homeland security planning efforts at all levels of government and with the private sector. They form the basis for national planning, training, investments, and exercises needed to prepare for emergencies of all types.
3. **The Universal Task List (UTL),** which is a menu of approximately 1,600 unique tasks that can facilitate efforts to prevent, protect against, respond to, and recover from the major events that are represented by the National Planning Scenarios. Although no single entity will perform every task, the UTL presents a common language and vocabulary that supports all efforts to coordinate national preparedness activities.

[3] NPG Page 4 Section 3.0 Paragraph 1

4. **The Target Capabilities List (TCL),** which defines 37 core capabilities that states and communities and the private sector should collectively develop to prepare for and respond effectively to disasters. The TCL also links to the National Response Framework.

Upon review of this framework, it was determined that the most relevant component for PHEP prioritization is the Target Capabilities List.

1.4 TARGET CAPABILITIES LIST (TCL)

The Target Capabilities List describes the capabilities related to the four homeland security mission areas of emergency preparedness: prevent, protect, respond, and recover. The TCL divides these mission areas (plus an additional group called "common") into 37 core capabilities.

The TCL was developed in 2005 with stakeholders from federal, local, state, territorial, and tribal governments as well the private sector and nongovernmental organization. Version 2 was released in 2007, and, currently, the list is being revised into Version 3 to create a clearer definition around roles and responsibilities and the target capabilities sub-structure.

The TCL establishes a standardized, national, capabilities-based guidance for preparing the nation for all-hazards events and provides guidance and tools in the form of a definition, expected target outcomes and resource elements necessary to accomplishing the capability, and target metrics to show progress toward achieving the capability.

Each target capability has the following elements:

- **Target Capability Name**
- **Target Capability Definition**
- **Classes and Risk Factors:** Classes are used to divide jurisdictions based on various primary and secondary risk factors. Each class will have a different set of target metrics.
- **Target Outcome:** An expected outcome of successfully executing this capability. Typically each capability will have between four and six target outcomes.
- **Target Metric:** For each outcome and for each class, a target metric is defined.
- **Relationship to Emergency Support Function (ESF):** The ESF is a structure within the NRF which details roles and responsibilities in emergency preparedness and response for federal, state and local agencies. Each target capability is linked to one or more ESFs.
- **Resource Elements:** Describe which resources (plans, personnel and teams, equipment, or training and exercises) may be required for this capability. The list of resource elements is currently descriptive and not prescriptive, and is not tied to any particular class.

Table 1: DHS Target Capabilities

Common Capabilities	
1	Planning
2	Communications
3	Risk Management
4	Community Preparedness and Participation
5	Intelligence and Information Sharing
Prevent Mission Area	
6	Information Gathering and Recognition of Indicators and Warnings
7	Intelligence Analysis and Production
8	Counter-Terror Investigation and Law Enforcement
9	CBRNE Detection
Protect Mission Area	
10	Critical Infrastructure Protection
11	Food and Agriculture Safety and Defense
12	Epidemiological Surveillance and Investigation
13	Laboratory Testing
Respond Mission Area	
14	On-site Incident Management
15	Emergency Operations Center Management
16	Critical Resource Logistics and Distribution
17	Volunteer Management and Donations
18	Responder Safety and Health
19	Emergency Public Safety and Security Response
20	Animal Disease Emergency Support
21	Environmental Health
22	Explosive Device Response Operations
23	Fire Incident Response Support
24	WMD and Hazardous Materials Response and Decontamination
25	Citizen Evacuation and Shelter-in-Place
26	Isolation and Quarantine
27	Search and Rescue (Land-Based)
28	Emergency Public Information and Warning
29	Emergency Triage and Pre-Hospital Treatment
30	Medical Surge
31	Medical Supplies Management and Distribution
32	Mass Prophylaxis
33	Mass Care
34	Fatality Management
Recover Mission Area	
35	Structural Damage Assessment
36	Restoration of Lifelines
37	Economic and Community Recovery

The TCL is the standard federal framework for emergency preparedness across all agencies, and thus these capabilities span the entire spectrum of emergency preparedness and response, including law enforcement, environmental protection, public health, and others. The TCL is aligned to the ESF framework, which gives direction as to which capabilities are within the scope and responsibility of which agencies, but it does not specifically mark capabilities as being public health capabilities.

A review of the capabilities showed that some of the capabilities are fully relevant to public health, some are partially relevant to public health, and some (as defined in the TCL) are not relevant to public health at all. Clearly, those target capabilities which are fully relevant to public health are likely to be higher priority for the PHEP program, and those capabilities which are not relevant to public health will not be priorities for the PHEP program. However, the many target capabilities which are partially relevant to public health need to be prioritized. Section 3 describes our approach to prioritizing these capabilities.

1.5 ALIGNMENT TO PUBLIC HEALTH

Although PAHPA dictates alignment to the National Preparedness Guidelines, the framework for emergency preparedness, DSLR has determined that the PHEP program should also align to public health. This decision was based on a number of reasons; primarily that the PHEP program exists at the intersection of public health and emergency preparedness and needs to align to each.

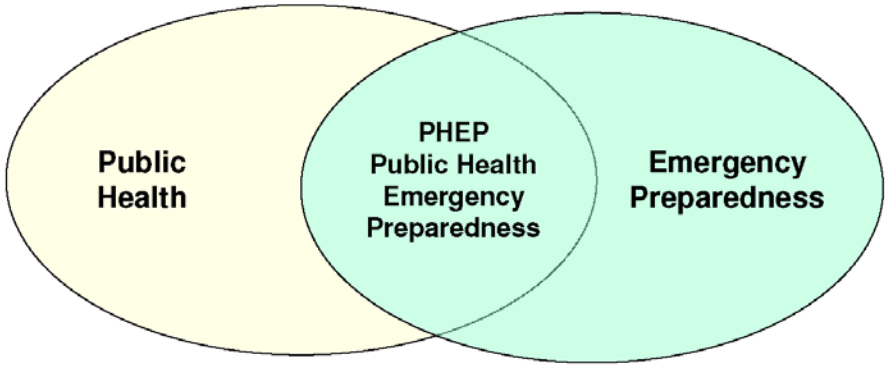


Figure 1: Intersection of Public Health and Emergency Preparedness

The most widely accepted standardized model for public health is known as the "10 Essential Services of Public Health" developed by HHS in 1994. DSLR therefore decided to align to this model.

Aligning to the Essential Services model provides additional benefits; it provides a public health viewpoint into the TCL and shows how emergency preparedness intersects with public health. Mapping the two models together also demonstrates how achievement of target capabilities will enhance the ability of the jurisdiction to provide the Essential Services.

1.6 10 ESSENTIAL SERVICES OF PUBLIC HEALTH

The U.S. Public Health Service (PHS) convened the Public Health Functions Steering Committee (PHFSC) in 1993 to develop a descriptive model for public health. The PHFSC was chaired by the Surgeon General and included representatives from most PHS agencies and from a number of national public health organizations. In the fall of 1994, the committee produced *Public Health in America*, a document that described a vision, a mission statement, a list of public health goals, and a list of 10 public health services needed to carry out basic public health responsibilities. The committee's specific intent was that these essential services represent the full range of responsibility in public health across federal, state, and local levels. The essential services were subsequently called the "10 Essential Public Health Services", and by 2000 were widely recognized as the standard framework for organizing the work of public health. CDC's National Public Health Performance Standards Program, a voluntary program developed under the guidance of the Centers for Disease Control and Prevention and a number of national partners, has used the Essential Services as a model for performance measurement tools.

Figure 2: The 10 Essential Public Health Services

The table below shows the Essential Services definitions.

Table 2: 10 Essential Public Health Services

	Short Label	Definition
1	**Monitor Health Status**	Monitor health status to identify and solve community health problems.
2	**Diagnose and Investigate**	Diagnose and investigate health problems and health hazards in the community.
3	**Inform and Educate**	Inform, educate, and empower people about health issues.
4	**Mobilize Community**	Mobilize community partnerships and action to identify and solve health problems.
5	**Develop Policies and Plans**	Develop policies and plans that support individual and community health efforts.
6	**Enforce Laws**	Enforce laws and regulations that protect health and ensure safety.
7	**Link People to Health Services**	Link people to needed personal health services and assure the provision of health care when otherwise unavailable.
8	**Assure Competent Workforce**	Assure competent public and personal health care workforce.
9	**Evaluate Services**	Evaluate effectiveness, accessibility, and quality of personal and population-based health services.
10	**Research**	Research for new insights and innovative solutions to health problems.

1.7 ALIGNMENT OF ESSENTIAL SERVICES TO TARGET CAPABILITIES

A number of approaches to alignment were considered. A basic challenge was that the Essential Services descriptions were written pre-9/11 and do not contain language specific to PHEP. In addition, services and capabilities are different constructs and do not always directly map to each other. After an analysis, it was determined that we could align capabilities to services using a "best fit approach," expanding some of the existing services definitions to include relevant PHEP concepts and language, while keeping within the original spirit of the services definitions. The resultant model combines the Essential Services with the target capabilities. As the Essential Services are relatively broad, while the capabilities are more focused, it was decided to denote the services as the top level

structure, with the capabilities cascading underneath them. For a simple model, each capability would map to one service, however this was not always the case.

It is important to note that only the prioritized capabilities were aligned to the Essential Services. This is for two reasons: a) to reduce unnecessary effort and b) non-public health relevant capabilities do not align to the Essential Services. The alignment of target capabilities to services was thus only performed after the selection of the priority capabilities, as described in the next section.

2 PRIORITIZATION METHODOLOGY

2.1 INTRODUCTION

This section of the document describes the methodology used for prioritizing target capabilities. One of the most significant challenges in setting priorities is that there were many stakeholders involved, both internal and external to CDC, each with a potentially different perspective as to what the priorities should be or on how to set the priorities.

DSLR proposed that a review of all these different stakeholder perspectives was appropriate to determine where there was agreement, and where there were differences. By reviewing the various perspectives, each of these critical stakeholder groups was given a voice in the process and DSLR maximized the quality of the output through consensus.

Not all perspectives are of equal importance, so the methodology allowed greater weight to be placed on the perspectives and priorities of certain stakeholders. For example, the PHEP program is authorized through legislation and must follow the directives of that legislation. Therefore, greater weight was placed on the priorities implied through legislation.

There are many ways to review the perspectives of each of these stakeholders: however DSLR elected to review official reports. Using official reports as the source enables comprehensive tracking and tracing from source documents to final decisions.

By reviewing reports produced by each stakeholder, DSLR was able to gather input from diverse sources, and determine areas of commonality. Although each stakeholder may internally utilize different methods and approaches for determining their priorities, this did not affect the DSLR methodology, since we were interested in the outcomes of each organization's approach, and not the internal methodology they used to determine those outcomes.

2.2 SELECTED STAKEHOLDERS AND DOCUMENTS

The first step in the methodology was to determine which stakeholders and associated documents would be reviewed. The types of stakeholders and literature that were considered for review included:

1. Legislation and Executive Directives
2. Relevant Federal Agencies
3. PHEP Program Historical Data
4. PHEP Program Partners
5. Third-Party Organizations

The actual selected stakeholders and documents will typically vary on each application of the methodology. For our purposes, as there was limited time to interview stakeholders directly, the stakeholder selection process was directed by the available literature. If there was no available relevant literature, the stakeholder was excluded from the application of the methodology.

The following documents were included in the review:

Legislation and Executive Directives

1. **Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA)**
   PAHPA is the authorizing legislation for the PHEP program. This document was chosen as part of the literature review as it indicates specific programmatic processes, requirements, and priorities that must be followed per congressional mandate.

2. **Homeland Security Presidential Directive 5 (HSPD-5)**
   HSPD–5 establishes a National Incident Management System (NIMS). This document was chosen as part of the literature review as it states Presidential mandates for development of NIMS, a key preparedness element of the National Health Security Strategy.

3. **Homeland Security Presidential Directive 8 (HSPD-8)**
   HSPD 8 mandates the development of a National Preparedness Goal (NPG). This document outlines the priorities necessary to include in the National Preparedness Goal and as such was chosen as part of the literature review.

4. **Homeland Security Presidential Directive 21 (HSPD-21)**
   HSPD–21 establishes a National Strategy for Public Health and Medical Preparedness and indicates the necessary components of this strategy. This document was chosen as part of the literature review as it states Presidential mandates to be included in the National Health Security Strategy for preparedness.

Program Partners

5. **NACCHO: Project Public Health Ready**
   Project Public Health Ready is the only nationally accepted and peer reviewed standard for public health preparedness for local health departments. This document was chosen as part of the literature review to provide the best representation of the NACCHO partner perspective.

2.3 DOCUMENT REVIEW AND MAPPING

Selected stakeholder documents were reviewed line by line to extract any mandates, priorities, or other suggestions that are relevant to the PHEP program or preparedness as a whole. The reviewer(s) may have used a computer-aided search to assist in looking for key words within the document as a supplement to the process, but fundamentally the review process required the reviewer to read and understand the entire document in context to the document's stated intent. The extracts from the document were then matched to the appropriate target capabilities from the DHS TCL.

To reduce subjectivity as much as possible, a number of reviewers were first tasked to independently review each document, develop the mappings, and provide justifications for each mapping. The results were then combined, and where differences between the

reviewers were found, consensus was reached through discussion and analysis of the various justifications.

The reviewers were instructed to identify three types of matches:

1. **Strong match**

   Strong match means there is an exact match of the target capability to a capability or concept described in the reviewed document. This was typically found when the source document itself was based on the TCL or when the source document used a capabilities-based approach. Another method of determining a strong match is that there was a match on a concept or content within the standardized capability and the reviewed document, even though the terminology used might be different, as long as both described substantially the same concept.

2. **Medium match**

   A medium match means that there was a match on a concept or content within the standardized capability and the reviewed document, even though the terminology used might be different. The difference between a medium match and a strong match is that a medium match is typically only a partial match to one part of the target capability, whereas a strong match would be a full match to all of the target capability.

3. **Weak match**

   A weak match is where there is not a match on content, but the reviewer perceived that the intention of the two documents could be inferred to be similar and as such should be matched.

Each document has its own unique structure and approach, and the matching process for each varied as described here:

- **PAHPA**

  Although PAHPA directs that the PHEP program and the NHSS must align with the Guidelines, PAHPA itself does not directly align with the Guidelines or the TCL. PAHPA makes no explicit references to target capabilities, and does not use any aspect of the TCL. Hence, when reviewing the PAHPA literature, the reviewer had to determine the intent of the various sections and the language contained therein and then match that language to the relevant target capabilities. In some cases there was a direct match between the PAHPA language and a particular target capability. In other cases, the match was based on partial content or inference. The review of PAHPA was limited to two key sections; one section that describes the NHSS and another that describes requirements for PHEP awardees.

- **HSPD-5, HSPD-8, HSPD-21**

  Like PAHPA, HSPD-5, 8 and 21 do not explicitly utilize a capabilities-based approach, and so these documents had to be mostly matched to capabilities by content or inference, with some strong matches found where applicable. The entire text of these documents was included in the review.

- **NACCHO PPHR**
  NACCHO Project Public Health Ready (PPHR) measures local health departments on a capabilities-based approach. However, the capabilities were not all exact matches for the TCL elements and so were matched using key words with some content matches. Although PPHR is directed at local health departments, the priorities contained within could be applied to state health departments.

For each match between a source document extract and a specific target capability, a detailed justification was provided, identifying the source document citation and explaining why this was matched to a particular capability. These justifications were entered into a relational database system designed to support the process.

The detailed justifications for each match as reported from the database can be found in the attached document, titled *Legislative and Partner Match Justification Results*.

2.4 PRIORITIZATION

The output from the document review stage was compiled into the spreadsheet tool, displaying the matches from each document to the target capabilities. To arrive at a prioritization of capabilities based on the number of matches that capability has, various calculations were employed and weights were assigned. This section describes the calculations and weights, and demonstrates how the final prioritized list was calculated. This process is designed to be flexible; different weights and calculations from the ones described here may be used in the future, if desired.

Match Type Weight

To place more value on stronger matches, matches were weighted as follows:

Match Type	Weight
Strong Match	**5**
Medium Match	**3**
Weak Match	**1**

Document Weight

In addition to the match type weights, each stakeholder document was assigned an individual weight. The purpose of this weight was to provide increased value to those documents or stakeholders which were deemed to be more important. For example, legislative documents or stakeholders received higher weights. The following stakeholder/document weights were used. Please note that these weights were chosen by the workgroup solely for the purposes of the methodology, and do not necessarily reflect

the agency or DSLR position on the relative importance or merits of the individual stakeholders or associated documents.

	Stakeholder / Document	Weight	Rationale
1	**PAHPA**	5	Authorizing legislation for the PHEP
2	**IISPD-5**	4	Presidential Directive
3	**HSPD-8**	4	Presidential Directive
4	**HSPD-21**	4	Presidential Directive
5	**NACCHO - PPHR**	2	Partners participate in program and so their opinions should carry weight higher than third parties but less than legislation

Priority Score

Once the match type and document weights were established, the match-type weight was multiplied by the stakeholder/document weight to produce a numerical value for each match. For example, if Document A was assigned a document weight of 3, and strong match was assigned a weight of 5, then if there was a strong match from Document A to Target Capability 1, that resulted in a score of 15 (3*5) for the match between Document A and Target Capability 1. This process was repeated for each document, and the scores were summed up by capability to produce a total priority score. The priority score was a numerical reflection of how many of the documents included that particular capability and the strength of the inclusion.

The priority score for each capability was the sum of the individual scores of the matches from each of the reviewed documents. Each individual score was a combination of three factors:

1. The decision of which match type (if any) is appropriate
2. The weight assigned to that match type
3. The weight assigned to that document.

Priority Tiers

Capabilities were grouped into tiers based on their priority scores. This system of tiers was established to parallel the system currently used by the Hospital Preparedness Program.

To determine which capabilities should fit into which tiers, the workgroup analyzed the range of priority scores obtained. There was no clear distinction between groups of scores, with scores spanning a wide range from high to low. Various calculated options

for dividing the capabilities into tiers were considered and rejected. In the final analysis it was decided to allow the top 14 scoring capabilities into Tier 1, six of the next highest scoring capabilities divided equally into Tier 2 and Tier 3, and the 17 lowest scoring capabilities were excluded entirely. These decisions were made based on the public health and emergency preparedness experience of the workgroup.

3 RESULTS

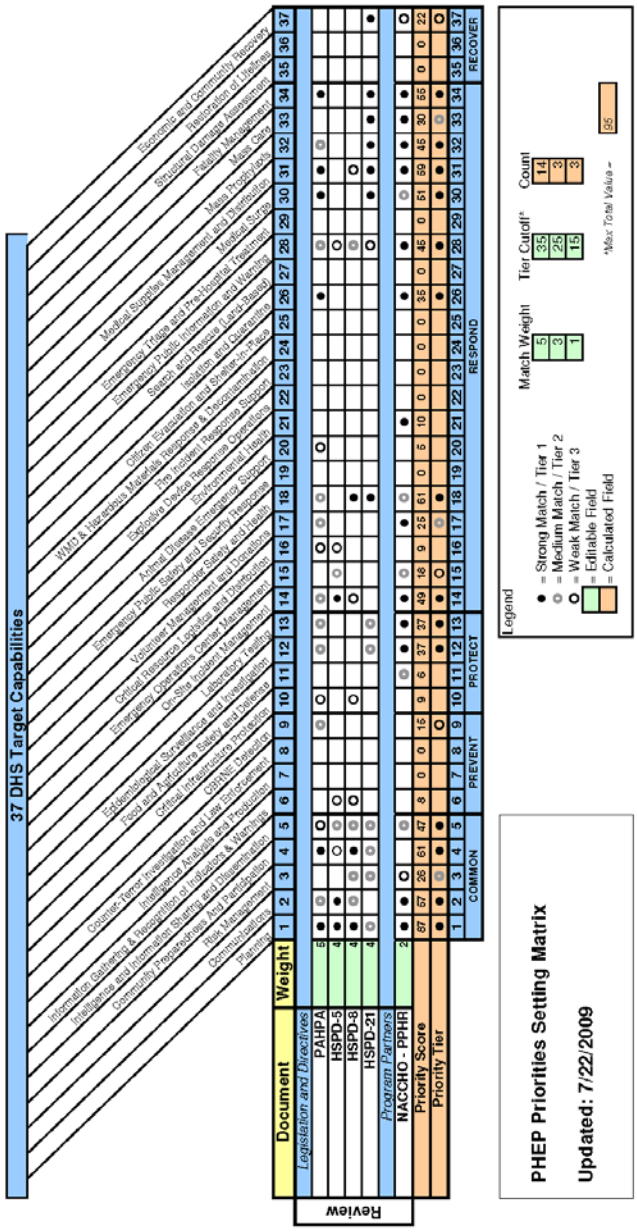
3.1 PRIORITY CAPABILITIES

After applying the methodology, the following results were obtained[4]:

Tier One Capabilities / High Priority	
1	Planning
2	Communications
4	Community Preparedness and Participation
5	Intelligence and Information Sharing
12	Epidemiological Surveillance and Detection
13	(Public Health) Laboratory Testing
14	Os-site Incident Management
18	Responder Safety and Health
26	Isolation and Quarantine
28	Emergency Public Information and Warning
30	Medical Surge
31	Medical Supplies Management and Distribution
32	Mass Prophylaxis
34	Fatality Management
Tier Two Capabilities / Medium Priority	
3	Risk Management
17	Volunteer Management and Donations
33	Mass Care
Tier Three Capabilities / Low Priority	
9	CBRNE Detection[5]
15	Emergency Operations Center Management
37	Economic and Community Recovery
Tier Four Capabilities / Excluded	
6	Information Gathering and Recognition of Indicators and Warnings
7	Intelligence Analysis and Production
8	Counter-Terror Investigation and Law Enforcement
10	Critical Infrastructure Protection
11	Food and Agriculture Safety and Defense
16	Critical Resource Logistics and Distribution
19	Emergency Public Safety and Security Response
20	Animal Disease Emergency Support
21	Environmental Health
22	Explosive Device Response Operations
23	Fire Incident Response Support
24	WMD and Hazardous Materials Response and Decontamination
25	Citizen Evacuation and Shelter-in-Place
27	Search and Rescue (Land-Based)
29	Emergency Triage and Pre-Hospital Treatment
35	Structural Damage Assessment
36	Restoration of Lifelines

[4] The numbers in the table reference the DHS Target Capability number.
[5] Chemical, Biological, Radiological, Nuclear, Explosive
Please note: The list above is the result of the application of the methodology, and is not the definitive list of priority capabilities for the PHEP program.

The following matrix illustrates the matches between each document and the associated target capability and shows the final priority score for each capability.



3.2 ESSENTIAL SERVICES ALIGNMENT

After the selection of the priority capabilities, the selected capabilities were then aligned to the Essential Services. In some cases the alignment was clear; in other cases a decision was made as to how to best fit the capability into one service. Service definitions were expanded in some cases to enable a better fit. The following table shows the proposed alignment with the new definitions. Capabilities that are shaded are those which aligned to multiple services.

Service			Capability		
	Name	Proposed Definition		Name	Tier
1	Monitor	Monitor the population and environment to identify and manage risks to public health	2	Communications (Platform)	1
			3	Risk Management	2
			9	CBRNE Detection	3
			12	Epidemiological Surveillance & Investigation	1
2	Diagnose & Investigate	Determine the nature and cause of any health threats to the population	12	Epidemiological Surveillance & Investigation	1
			13	Laboratory Testing	1
3	Inform & Educate	Share information across jurisdictions and with the general public	2	Communications (Platform)	1
			6	Intelligence and Information Sharing	1
			28	Emergency Public Information and Warning	1
4	Mobilize & Manage	Mobilize, manage and coordinate public health, community and other organizations and resources to address public health needs and threats	4	Community Preparedness and Participation	1
			14	On Site Incident Management	1
			15	Emergency Operations Center Management	3
			17	Volunteer Management and Donations	2
			30	Medical Surge (mobilization aspects)	1
			31	Medical Supplies Management and Distribution	1
5	Develop Plans	Develop plans for Public Health activities and for emergency preparedness and response	1	Planning	1
6	Enforce Laws	Enforce laws and regulations, including during times of public health emergency	26	Isolation and Quarantine (legal aspects)	1
7	Provide Services	Ensure availability of and/or provide public health interventions and services including and especially during times of public health emergency	30	Medical Surge (healthcare aspects)	1
			32	Mass Prophylaxis	1
			33	Mass Care (Shelter, Food & Related Services)	2
			34	Fatality Management	1
8	Workforce	Educate, train, and equip public health workforce	18	Responder Safety and Health	1
			30	Medical Surge (workforce aspects)	1
9	Evaluate & Improve	Evaluate and improve programs, response efforts and community health	37	Economic & Community Recovery	3
				Cross Cutting across all Capabilities	
10	Research & Best Practices	Determine best and promising practices		Cross Cutting across multiple Capabilities	

4 LIMITATIONS

4.1 PRIORITIZATION WITHIN THE CAPABILITIES

Many of the target capabilities are fairly broadly defined and contain many sub-topics with associated target outcomes and resource elements. The methodology focused on prioritizing the target capabilities themselves but does not proceed to prioritize elements within the target capabilities; for example, prioritizing certain target outcomes over others. It is possible that target outcomes and resource elements might need to be prioritized as well, especially within very broad capabilities. For example, the target capability "Laboratory Testing" includes chemical, biological, and radiological laboratories.

A complicating factor to be considered is that the TCL currently is under revision, and many of the target outcomes and resource elements have not yet been defined for the revised version of the TCL. Under direction from DHS and HHS, CDC is currently revising three of the target capabilities (Mass Prophylaxis, Isolation and Quarantine, and Epidemiological Surveillance and Investigation), but these are not yet complete.

DSLR plans to pursue an approach to aligning PHEP priorities with the new definitions upon completion but must proceed currently without those definitions having yet been completed. DSLR plans to engage a wide variety of internal and external program partners to review and provide input for the list of priority target capabilities and the target outcomes and resource elements within these capabilities. The expectation is that a minimum set of outcomes and resources will be defined for each target capability, with no additional prioritization beyond that.

4.2 SELECTION OF STAKEHOLDERS AND DOCUMENTS

The outcome of the prioritization approach is clearly dependant on the stakeholders and documents selected for review. The workgroup did not define precise criteria for stakeholder or document selection but attempted to select as broad a range of relevant stakeholders and documents as possible. Ultimately, many of the initially selected stakeholders and documents were excluded from the scoring process for reasons described in the following list:

1. **PHEP Program Priorities 2002-2010**
   It was initially thought that the past priorities of the PHEP program should influence the results and be scored as part of the methodology. However, the PHEP program has evolved over the years with differing priorities having been set each year in response to multiple drivers, including DSLR, COTPER, CDC and HHS leadership, perceived threat scenarios such as bioterrorism threats, and other factors. Given the wide variety of past priorities, these were ultimately all excluded from the final formal scoring process.

2. **Budget Period 9 (BP9) Performance Measures Guidance (CDC/DSLR)**
   This document describes the development of CDC's PHEP program performance measures through an extensive process of stakeholder engagement and program prioritization activities, thus reflecting a broad range of stakeholder opinions. Five broad capability "groups" were identified by the PHEP Evaluation Workgroup as being high priority, but these were not used to influence the scoring process as the process for defining these capability "groups" is incomplete.

3. **ASTHO: Directors of Public Health Preparedness Goals – Draft, April 2008**
   The Health Preparedness Capability Prioritization Project, developed by the Association for State and Territorial Health Officials (ASTHO) Directors of Public Health Emergency Preparedness emphasizes the importance of integrating routine response capabilities with public health emergency preparedness. This document was determined to not be an official representation of ASTHO priorities, and ASTHO is currently planning another effort to determine their priorities. Depending on timelines and other constraints, it is possible that the ASTHO priorities could be included into the scoring in future and may affect the final list of priorities.

4. **National Preparedness Guidelines Emergency Support Function 8 (ESF) 8**
   ESF – 8: Public Health and Medical Services, outlines functions that are the primary responsibility of the Department of Health and Human Services and its 11 operating divisions. This document was originally chosen as part of the literature review to provide the DHS perspective as to what is within the purview of HHS as DHS has the role as lead agency in emergency preparedness. However, due to the lack of a distinction between what is the responsibility of public health and what is the responsibility of the medical community, this item was not included in the final scoring.

5. **RAND: Conceptualizing & Defining Public Health Emergency Preparedness**
   In May 2008, HHS's Office of the Assistant Secretary of Preparedness and Response (HHS/ASPR) asked RAND to convene an expert panel to develop a clear and widely applicable definition of public health emergency preparedness that can provide common terms for discussion and establish a basis on which to develop a small core of critical standards and measures. The panel produced a document outlining 13 priorities for public health emergency preparedness. However, this document was ultimately not included in the scoring as the priorities were fairly high level and cross-cutting, and were not specific to individual target capabilities.

6. **TFAH: Ready or Not 2008**
   This report was developed by the Trust for America's Health (TFAH) to assess health emergency preparedness capabilities across the nation. It contains state-by-state health preparedness scores based on 10 key indicators. This document was initially considered to be part of the literature review as TFAH is a frequently cited advocacy organization who has created multiple reports regarding the public health system in general and preparedness in particular. However, this document was not included in the scoring due to the 10 indicators not aligning strongly to the target capabilities at a detailed level.

7. **Hospital Preparedness Program 2008 Guidance (HHS – ASPR)**

The Hospital Preparedness Program is the counterpart to CDC's PHEP program. This program receives funds for hospital preparedness as outlined in PAHPA Section 201 Sub Section 319(C)-2. This document was initially considered as part of the literature review to assist in excluding capabilities from the PHEP program to reduce any redundancies in effort between the two programs. However, many questions were raised as to how exactly the HPP guidance would or should affect the PHEP priorities, and it was excluded from the final scoring.

8. **National Preparedness Guidelines Core Document**
   The Guidelines Core Document was excluded from the priority-setting process as the TCL, which is a companion to the core document, provides much more detailed and direct information indicating priorities for all-hazards emergency preparedness.

9. **National Response Framework (NRF) Core Document**
   The NRF Core Document was excluded from the priority-setting process as there was minimal reference to determining the priorities of a preparedness program, and there are several other government sources cited in this literature review that do indicate priorities.

10. **CDC Goal Action Plan for Preparedness**
    The CDC Goal Action Plan for emergency preparedness identifies five all-hazards preparedness objectives and nine time-phase strategic preparedness goals. Although this plan reflects the agency priorities, it is extremely broad and does not directly prioritize capabilities within emergency preparedness and thus was excluded from the scoring.

11. **TFAH: Blueprint for a Healthier America**
    This document was excluded from the review as it indicates high-level solutions, whereas the TFAH "Ready or Not" report provides much more specific recommendations for priorities.

12. **NACCHO: Leveraging Community Outcomes**
    This document was created to display an analysis of preparedness functions across the NACCHO constituency and to describe what was happening or could happen to these functions should the funding for the PHEP program continue to decline. As this document was providing projected or actual declines in capabilities rather than explicit priorities, it did not meet the needs of this review.

4.3 MAPPING OF DOCUMENTS TO CAPABILITIES

Target capabilities are often broad in scope. Each includes many related target outcomes and resource elements. Thus it is often the case that a match may be made to one portion of the capability but not the whole capability. For each match, a justification is then written explaining the type of match and the point of linkage between the reviewed literature and the DHS target capability.

Each document may be matched to one or more capabilities, and each capability may be matched to one or more documents. It is also possible that a capability may not match any documents or that a document may not match any capabilities.

In theory, the matching from any one document to any one capability could be based on multiple match points from the source document. However, to simplify the methodology, the methodology captured the strongest match point between each document and any specific capability. If a document contains a number of medium matches which in sum cover an entire capability, then certainly this can be rated as a strong match overall.

Note that for the methodology to function correctly there must be a consistent definition for the capabilities to which documents are mapped. The DHS TCL provides a very comprehensive description for each capability, and the use of this document was crucial in many of these discussions to precisely define the capability.

4.4 WEIGHTS

The methodology used a relatively simple system of strong, medium, and weak matches. It would certainly be possible to develop a more precise system of matches, for example to further distinguish partial from full matches. However the workgroup decided that this simple system would be sufficient.

Each of the three types of matches proposed in the methodology was assigned a numerical weight which was intended to be proportional to the strength of match type. The workgroup chose 1, 3, and 5 as the weights for weak, medium, and strong matches respectively, but different weights could be chosen, which could possibly affect the results. The workgroup determined that it was not feasible to develop objective criteria for the match type weights; thus the workgruop consequently selected a fairly simple weighting system.

The workgroup also found that there was no reliable and objective way to determine appropriate weights for stakeholders or documents. In general more important stakeholders and documents should have stronger (i.e. higher value) weights. Adjusting the document weights will result in different outcomes, especially with stakeholders who have very different perspectives.

Although the selection of numerical values for match type weights and the stakeholder/document weights is somewhat subjective, the final result is dependent on the relative differences between the priority scores, rather than the absolute values. As long as the match types and documents are weighted appropriately relative to each other, a correct result will be obtained.

Upon completion of the methodology, the workgroup felt that the weights were appropriate and that the results obtained were justified.

4.5 CAPABILITY TIERS

This aspect of the methodology used the experience gained by DSLR in managing the PHEP program over the past nine years to manually set the tier cut-offs to produce the desired tiers though a process of manually adjusting the tier score ranges until the desired results were obtained.

Other more automated approaches were considered, for example designating the top 16% of priority scores to tier 1, but none of these automated approaches had any benefit over the manual adjustment process, as none of these automated approaches could be objectively justified.

Ultimately, the workgroup reached the conclusion that determining the tiers would have to be done manually, using the experience and judgment of the workgroup participants. This did not detract from the objective value obtained through the process of document review, matching to target capabilities and justifications.

5 DISCUSSION

Based on the experience of the workgroup, the following strengths and weaknesses were noted to this methodology.

One strength of this approach is that the mandates of legislation, the priorities of HHS, CDC and program partners, and of other groups who have public health knowledge and expertise are taken into account. In a sense, this is a meta-methodology providing balance among, and giving weight to, those who are knowledgeable on the subjects of public health and preparedness, without requiring that expertise in the users of the methodology. Another advantage is that each stakeholder can each use his or her own approach to determine priorities, and this methodology will benefit from the results obtained.

An associated (but unavoidable) weakness is that the results obtained from this methodology are sensitive to the relative weights given to each document and to the initial decision as to which stakeholders and documents to include. By varying the document weights, different results can be obtained. This aspect is unavoidably the most subjective limitation of the approach.

The workgroup members themselves felt that the approach was valuable. The rigorous review of multiple documents, combined with the requirement to specify and justify match types, forced the reviewers to develop as objective a mapping as possible.

Mapping the target capability list to the Essential Services was another valuable step. Traditionally, the worlds of emergency preparedness and public health have maintained separate models and frameworks. By aligning the target capabilities with the essential services, the workgroup created the first formal combined model for public health emergency preparedness, showing how the two disciplines overlap and complement each other.

APPENDIX A: DOCUMENT APPROVAL

The undersigned acknowledge they have reviewed this document and agree with the approach it presents. Changes to this document will be coordinated with and approved by the undersigned or their designated representatives.

Signature: _____ Date: _____

Print Name: _____

Title: _____

Role: _____

Signature: _____ Date: _____

Print Name: _____

Title: _____

Role: _____

Signature: _____ Date: _____

Print Name: _____

Title: _____

Role: _____

APPENDIX B: ACRONYMS

The following table provides definitions for terms relevant to this document.

Acronym	Definition
CDC	Centers for Disease Control and Prevention
COTPER	Coordinating Office for Terrorism Preparedness and Emergency Response
DHS	Department of Homeland Security
DSLR	Division of State and Local Readiness
ESF	Emergency Support Function
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
NACCHO	National Association of County and City Health Officials
NHSS	National Health Security Strategy
NPG	National Preparedness Goal / Guidelines
PAHPA	Pandemic and All-Hazards Preparedness Act
PHEP	Public Health Emergency Preparedness
TCL	Target Capabilities List
UTL	Universal Task List

Appendix F

DSLR Development and Implementation of the 2005-2010 PHEP Cooperative Agreement

DISCUSSION DRAFT 8/11/2009

DSLR Development and Implementation of the 2005-2010 PHEP Cooperative Agreement

Background

As of 2009, Congress has appropriated nearly $7 billion in funding for the Public Health Emergency Preparedness (PHEP) cooperative agreement. The Centers for Disease Control and Prevention (CDC), specifically its Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER), administers the federal PHEP program for its eligible awardees. COTPER's Division of State and Local Readiness (DSLR) administers the PHEP cooperative agreement, which funds state and local efforts to build and strengthen their preparedness and infrastructure to respond to all types of hazards, including infectious diseases, natural disasters, and biological, chemical, and radiological threats. Funding has been awarded to 62 awardees, which include 50 states, eight territories and freely associated Pacific jurisdictions, and four metropolitan areas (Chicago, Los Angeles County, New York City, and Washington, D.C.). The resources provided through the PHEP cooperative agreement support the development of critical public health preparedness capacities, including preparedness planning and readiness assessment; surveillance and epidemiology; biological, chemical, and radiological laboratory capacity; communications systems and information technology; health information dissemination and risk communication; and education and training.

Development of the Guidance for the PHEP Cooperative Agreement

PGO and DSLR Role

CDC´s Procurement and Grants Office (PGO) is the only entity within CDC which can obligate federal funds. PGO awards grants and cooperative agreements on behalf of the federal government to eligible organizations annually. PGO provides nonprogrammatic management for all CDC financial assistance activities (grants and cooperative agreements) and manages and awards all CDC contracts.

PGO and DSLR develop guidance for the PHEP cooperative agreement where funds and activities required to implement the program are identified. PGO provides assistance in determining the appropriate award instrument to be utilized prior to the development of the announcement and provides the request for application/program announcement (RFA/PA) templates necessary to begin the funding opportunity process. DSLR develops strategies and activities to assist the awardees in the development and maintenance of their public health emergency preparedness programs. The activities are based on legislative requirements and on COTPER's preparedness objectives within five core public health functions:

- Health Monitoring and Surveillance
- Epidemiology and Other Assessment Sciences
- Public Health Laboratory Science and Service
- Response and Recovery Operations
- Public Health System Support.[1]

PGO and DSLR also ensure that the final version complies with HHS Grant Policy Statement 107, Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) [Appendix B], and Pandemic and All-Hazards Preparedness Act (P.L. 109-417) [Appendix C].

> Under the HHS project period system, a project may be approved for a multiyear period but generally is funded in annual increments known as "budget periods." This system provides the awardees with an indication of CDC's intent to noncompetitively fund the project during the approved project period as long as required information is submitted, funds are available, and certain criteria are met. The PHEP cooperative agreement is approved for a five-year project period with approval of funding annually in each budget period, dependent on Congressional appropriation. Awardees submit applications to CDC annually.

ECO Role

COTPER's Enterprise Communication Office (ECO) is responsible for reviewing and clearing documents with policy or programmatic implications. After DSLR and PGO have agreed on the content of the guidance, ECO reviews the annual PHEP continuation guidance, coordinates clearance of the guidance within COTPER and across CDC, and forwards the guidance to CDC's Division of Issues Management and Executive Secretariat for review and clearance by the CDC director.

Subject Matter Expert Role

A CDC subject matter expert (SME) is a specialist who has gained expertise in one or more of the core sciences of public health (e.g., epidemiology, laboratory science and service, or health monitoring and other assessments), or has expertise in areas that support public health functions (e.g., grants management, communication, informatics). The need for coordination of various SMEs across CDC is unique to the PHEP cooperative agreement. The SMEs of the Division of Strategic National Stockpile (DSNS) are the only ones who are administratively housed within COTPER. All other SMEs are housed within other CDC centers and offices, and these SMEs are not directly funded to support to the PHEP cooperative agreement. The various SMEs involved in the implementation of the cooperative agreement are consulted on the content of the guidance to assure that all important activities are included. Language specific to COTPER's preparedness objectives within the core public health functions of Health Monitoring and Surveillance, Epidemiology and Other Assessment Sciences, Public Health Laboratory Science and Service, Response and Recovery Operations and Public Health System Support is written by the appropriate SMEs.

Federal Partner Roles

HHS' Office of the Assistant Secretary for Preparedness and Response (ASPR) serves as the Secretary's principal advisory staff on matters related to bioterrorism and other public health emergencies. ASPR also coordinates interagency activities between HHS, other federal departments, agencies, and offices, and state and local officials responsible for emergency preparedness and the protection of the civilian population from acts of bioterrorism and other public health emergencies. DSLR works with ASPR staff, including, the Hospital Preparedness Program staff, to discuss the PHEP guidance and areas of potential coordination with the public health and hospital preparedness cooperative agreement programs. ASPR-recommended revisions to the PHEP guidance content are reviewed, with many of the suggested changes made. In the past, this ASPR review process has ranged from several weeks to as long as six months. This was due to an HHS requirement that final clearance of the PHEP cooperative agreement occur at the HHS level. In January 2009, HHS's Assistant Secretary for Resources and Technology (ASRT), Office of Grants, delegated

authority for final clearance to CDC's chief grants management official in PGO, which greatly simplified and expedited the process, resultling in final clearance in April 2009.

Prior to that decision in January 2009, DSLR solicited comments from other HHS offices, including:

Assistant Secretary for Administration and Management (ASAM)
Assistant Secretary for Resources and Technology (ASRT)
Assistant Secretary for Health (ASH)
Assistant Secretary for Legislation (ASL)
Assistant Secretary for Planning and Evaluation (ASPE)
Assistant Secretary for Public Affairs(ASPA)
Homeland Security Council (HSC), Executive Office of the President of the United States

Office of the General Counsel (OGC)
Office of Policy and Strategic Planning (OPSP)

Implementation of the PHEP Cooperative Agreement

Technical Review of the applications

The 62 awardees eligible for PHEP funding submit applications once a year to DSLR through the Preparedness Emergency Response System for Oversight, Reporting, and Management Services (PERFORMS) electronic management information system. Awardees submit their PHEP funding applications through this system, and all fiscal and programmatic reports are monitored here. Applications undergo a technical review by DSLR, PGO, and selected SMEs that results in a Technical Assistance Review Summary (TARS) and a Budget Exception Review Summary (BERS) which is attached to the Notice of Award (NoA). Technical reviewers assess the applications to determine:

- the applicant's current capability to perform the outcomes and critical tasks;
- that the operational plan clearly and adequately addresses the goals, outcomes, tasks, and measures;
- the extent to which the applicant clearly defines an evaluation plan that leads to continuous quality improvement of public health emergency response; and
- the extent to which the applicant presents a detailed budget with a line item justification and any other information to demonstrate that the request for financial assistance is consistent with the purpose and objectives of the cooperative agreement.

A recommendation for funding goes to PGO at the end of the review period, generally in late July or early August.

Notice of Award

The Notice of Award (NoA) is the legal document issued to the awardees that indicates an award has been made and that funds may be requested from the designated HHS payment system or office. An NoA showing the amount of federal funds authorized for obligation and any future-year commitments is issued for each budget period in the approved project period. The NoA is issued by PGO after the technical review of the applications is completed and recommendations for funding and programmatic activities have been made by DSLR, PGO, and the SMEs.

Monitoring

Awardees are responsible for managing the day-to-day operations of PHEP cooperative agreement-supported activities using their established controls and policies, as long as they are consistent with the CDC program and budget requirements of the cooperative agreement. However, to fulfill its role in regard to the stewardship of federal funds, CDC monitors the PHEP cooperative agreement to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the awardees, audit reports, site visits, and other information available to CDC. DSLR project officers (POs) are the technical programmatic monitors and PGO grant management specialists (GMSs) are the fiscal monitors, reviewing expenditures for conformance with CDC cost policies.

The 62 awardees eligible for PHEP funding are required to submit mid-year progress reports and end-of-year progress reports which are reviewed by the project officers and SMEs. This review includes an assessment of the response to each requirement, using a standard set of questions to ensure that essential elements of the expected response are present. These questions are individually scored as inadequate, adequate, or superior based on PO/SME judgment. Awardees should achieve improvements in their assessment scores on guidance-required items between their mid-year and end-of-year progress reports. Those who do not achieve an assessment of adequate on a required item by the end-of -year report receive additional technical assistance to enable them to document adequate performance or better by the following mid-year progress report.

Technical Assistance

CDC technical assistance to PHEP awardees is designed to aid the cooperative agreement recipient in meeting program objectives and goals. Technical assistance to the 62 awardees funded by the PHEP cooperative agreement is provided by the DSLR Program Services Branch (PSB) project officers, by DSLR Outcome Monitoring and Evaluation Branch (OMEB) staff, by Division of Strategic National Stockpile (DSNS) technical consultants and by selected SMEs in other CDC centers and offices. Examples of SME interactions can be found in Appendix A.

DSLR

The PSB PO is the CDC official responsible for coordinating the programmatic, scientific, and/or technical aspects of the PHEP cooperative agreement. The PO's responsibilities include assistance in the development of awardee programs to meet the mission; coordination of programmatic technical assistance; post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the GMS. The PO and the GMS work as a team on many of these activities.

Consultation Plans

The DSLR consultation plan for each awardee is developed by the PO and the director of the awardee PHEP program. It identifies the areas in which the awardee needs improvement, as well as specific actions that CDC and/or the awardee will take to ensure the improvement can be realized. By prioritizing these actions, the consultation plan results in a working agreement that shapes interactions between awardees and CDC resources for the upcoming year. The consultation plan serves as a map to guide conversations, site visits, and technical assistance for the individual awardee. It provides a vehicle for frequent updates on the awardees' progress and the efforts of the PO and appropriate SMEs.

Site Visits and Site Visit Reports

The DSLR project officer schedules an initial site visit within 60 days of the NoA to verify that the approved work plan and budget is realistic and likely to produce the stated objectives; to assist the awardee in developing its responses to the TARS weaknesses and recommendations; and to begin building a collaborative partnership between the awardee and the PO. A technical assistance site visit should occur at least once a year.

Within the month following the site visit, the PO prepares a site visit report that includes recommendations and follow-up activities. The site visit report is one of the most important documents that the PO will create, and it is shared with the awardee, SMEs, DSLR management, and PGO. It provides a framework for disciplined collaboration with mutual accountability for results.

Performance Measurement

In response to Congress' requirement for accountability of funds in the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, the Outcome Monitoring and Evaluation Branch (OMEB) was charged with developing performance measures to evaluate and report PHEP awardees' ability to perform key preparedness and response capabilities.

Recognizing the vast knowledge and experience gained over the past eight years at the state and local levels in PHEP, OMEB initiated an extensive stakeholder engagement process addressing the challenges set forth by PAHPA. A central component of the process has been to convene the PHEP Evaluation Workgroup. Comprised of representatives from local and state health departments (LHDs/SHDs), national partner organizations, federal agencies, and nongovernmental organizations, the PHEP Evaluation Workgroup provides guidance and input to OMEB on the identification, development, and implementation of a standardized performance measurement system for the PHEP program.

As a relatively new program, PHEP still lacks a clear definition as well as a robust evidence base. Consequently, the first task of the PHEP Evaluation Workgroup was to prioritize program activities for evaluation and identify those program elements that are worth measuring. Using the Department of Homeland Security's Target Capabilities List as well as priorities set forth by PAHPA and Homeland Security Presidential Directive 21 as a starting point, the PHEP Evaluation Workgroup used the following criteria to develop standardized performance measures that are:

- critical to public health's role at state and local levels,
- largely under public health's control,
- measurable at state and local levels,
- useful for accountability at the local, state, and federal levels, and
- responsive to policy and legislative mandates.

The PHEP Evaluation Workgroup then identified the following five PHEP capabilities as priorities for the development of measures:

- incident management
- crisis and emergency risk communication (CERC) with the public,
- biosurveillance (including, but not limited to, laboratory, epidemiology, and surveillance),
- countermeasure delivery (including distribution and dispensing), and

- community mitigation strategies (including, but not limited to, isolation and quarantine).

Incident management and *CERC with the public* were identified as the first capabilities for which performance measures would be developed. Topic-specific subgroups comprised of local and state public health department content and/or measurement experts were convened in April 2008 to develop performance measures for these two capabilities. The subgroups used process mapping to identify elements of each capability that meet the following criteria at the state and local levels:

- critical to achievement of that capability,
- measurable,
- feasible to collect and report,
- relevant in multiple contexts, and
- able to be collected through real incidents, not just exercises.

Topic-specific measurement subgroups will be convened throughout 2009 and into 2010 for the remaining priority capabilities.

The above process has resulted in the introduction of four incident management and one CERC with the public capability-based performance measures required for reporting in CDC's PHEP cooperative agreement for Budget Period 9 (BP9) fromAugust 10, 2008, through August 9, 2009. These new measures are currently being applied only to CDC's directly funded grantees (50 states, four directly funded cities, and eight territories) with the intent of collecting data on the measures by local health departments in future years.

Summary

The development and implementation of the PHEP cooperative agreement has been a complex process. The objectives and activities of the cooperative agreement have undergone many changes based on legislative authority, changing national priorities, varying interests of federal partners, and perceived public health threats. As a result, the cooperative agreement activities have shifted during the five-year project period. This has made it difficult to assess the improvement of state and local public health emergency preparedness programs and to evaluate the progress made in individual jurisdictions. It is CDC's intention to develop the guidance for the new project period (2010-2015) in a strategic fashion that identifies the priorities and capabilities most relevant to public health preparedness.

With the current economic challenges facing state and local health departments and potential decreases in public health preparedness funding in the next five years, CDC and state and local health departments must find new ways, including enhanced collaborations, to conduct program activities. CDC may also have to make difficult decisions about what the highest priority activities are and what must be postponed. Public health departments at state and local levels may have to make similar choices.[2]

[1] Key Findings from *Public Health Preparedness: Strengthening CDC's Emergency Response*, January 2009 p. 2

[2] Ibid., p. 7.

Appendix A
Examples of CDC SME Interaction with the PHEP Cooperative Agreement

CENTER	Examples of PHEP Cooperative Agreement Interaction
Division of Strategic National Stockpile (DSNS)	Conduct State and Local Technical Assistance Reviews (TAR) that are an independent assessment of a community's plans to receive, distribute, and dispense Stockpile assests during a catastrophic health event. The Strategic National Stockpile Extranet is a password-protected website that serves as a listserve-based forum for thousands of state and local level response planners as well as a trusted source of information and helpful tools. Mass Antibiotic Dispensing Satellite Broadcasts series are used to highlight key elements of preparedness. Archived video broadcasts can be viewed on the internet and are also available on CD ROM and VHS upon request. Computer modeling and simulation software is designed to aid in planning and to complement live exercises and drills. Computer modeling assists state and local service providers in simulating a real event. With these tools, planners can help assess the capabilities of distribution and dispensing plans. Workshops and conferences are hosted in a collaborative partnership with the National Association of County and City Health Officials and the Association of State and Territorial Health Officials. These workshops provide a forum to share strategies, best practices, and lessons learned. SNS guidance documents help clarify to public health planners what the necessary requirements are to receive stage and store Stockpile assets. The SNS Exercise Program not only validates DSNS' ability to effectively deliver critical medical assets to the site of a national emergency in a series of response scenarios but also provides support to state and local Stockpile exercises designed to test and validate their emergency operations plans.
Laboratory CDC's Environmental Health Laboratory assists public health laboratories in states, territories, cities, and counties with expanding their chemical laboratory capacity to prepare and respond to chemical terrorism incidents or other emergencies involving chemicals.	Bimonthly conference calls with staff of LRN-Chemical laboratories Biannual face-to-face meetings with staff of the 10 Level 1 surge laboratories Participation in the annual LRN meetings Education meetings and education courses for PHEP awardees Availability of an active web board for all analysis methods and general topics

	Review of chemical lab plans in the PHEP funding applications, encouraging adequate funds be allotted for staff, supplies, equipment, and instrumentation. Participation in site visits when requested by DSLR/PSB project officers to address specific issues/concerns with chemical preparedness activities. Participation in "joint" exercises with the Environmental Protection Agency (EPA) in regions where the public health laboratories (PHL) want to participate Support laboratory exercises by providing samples, sometimes incorporating CDC Rapid Toxic Screen and Surge Capacity Exercises with public health laboratories
Epidemiology/Surveillance CDC's National Center for Preparedness, Detection, and Control of Infectious Diseases/Division of Bioterrorism Preparedness and Response (DBPR) has technical advisors who provide assistance to the PHEP awardees through their coordination with DLSR and through their status as technical advisors for the Laboratory Response Network (LRN)	Conference calls (when requested) with the awardees and DSLR project officers to address any issues of concern relayed to biological lab issues. Provide recommendations on biological equipment/supplies to the project officers during the review of the PHEP funding applications, and during the year if funds need to be redirected. Provide training classes to awardees at off-site locations (regional and CDC) and, when deemed necessary, provide on-site training in LRN techniques. Participate in site visits with DSLR project officers (when requested) . During site visits, monitor and provide guidance on issues such as biological laboratory equipment, biosafety/biosecurity training, LRN protocols and reagents, and proficiency testing as provided by the LRN. Serve as point of contact for interactions between the awardee labs and the LRN on biological laboratory technical issues (e.g. provide equipment list of what is supported by the LRN and allowable to purchase with PHEP funds).
Public Health Information Network (PHIN) CDC"s National Center for Public Health Informatics (NCPHI)/Division of Alliance Management and Consultation (DAMC) coordinates the Public Health Information Network (PHIN) and provides technical assistance to state and local partners to implement interoperable public health information systems allowing for the exchange of data across organizational and jurisdictional boundaries.	Participate in technical review of PHEP funding applications and progress reports for PHIN activities. Participate in DSLR PO site visits to address awardee questions and concerns around PHIN-related activities. Provide advice to awardees on PHIN implementation plans, system upgrades and modifications. Serve as an information broker to awardees, assisting partners with exchanging implementation strategies to meet PHIN requirements. Identifying gaps and helping awardees develop mitigation strategies. Provide awardees' perspective to CDC development teams. Construct opportunities for awardees to collaborate on programmatic and technical areas. Promote information sharing between CDC and awardees.
Career Epidemiology Field Officer (CEFO) Program Placement of skilled epidemiologists (federal assignees) at the request of the jurisdiction, to selected state and local health departments	Examples of CEFO work include: Participating in preparedness efforts for pandemic influenza, including the development of isolation and quarantine guidelines and protocols, planning and execution of local, regional, and statewide exercises; Providing epidemiology and scientific expertise to state

	preparedness and emergency response planning and policy; Providing leadership, training, planning, and technical support for building local epidemiologic capacity; Developing and writing agency and state response plans; Unlike other CDC SMEs, CEFOs are COTPER employees who live in the assigned state or local jurisdiction for a minimum of two years.
Public Health Advisor (PHA) Expertise Awardees may request a CDC public health advisor be assigned to their jurisdictions to provide assistance in the management of the PHEP cooperative agreement	Dependent on the jurisdictional needs, duties may include program planning and development, project management, budgetary consultation, or program evaluation. PHAs promote and enhance capacity-building through consultation, demonstration, and technical expertise. PHAs are COTPER employees who live in the assigned state or local jurisdiction for as long as the jurisdiction and CDC agree there is a need. Awardees must allocate funds for PHAs through the PHEP cooperative agreement.

Appendix B
Public Health Security and Bioterrorism Preparedness and Response Act of 2002
(P.L. 107-188)
Selected Text related to Public Health Emergency Preparedness in State and Local Health Departments

The Act addresses national, state, and local preparedness and response planning and security issues. It reauthorizes or amends several important grant programs established under the Public Health Threats and Emergencies Act and the Public Health Service Act, and also provides significant new grant opportunities for states and local governments. The Act also addresses other related public health security issues. Some of these provisions include:

- New controls on biological agents and toxins,
- Additional safety and security measures affecting the nation's food and drug supply,
- Additional safety and security measures affecting the nation's drinking water, and
- Measures affecting the Strategic National Stockpile and development of priority countermeasures to bioterrorism.

On June 12, 2002, the President signed the "Public Health Security and Bioterrorism Preparedness Response Act of 2002 (P.L. 107-188)" into law. It is designed to improve the ability of the United States to prevent, prepare for and respond to bioterrorism and other public health emergencies. It requires people possessing, using or transferring agents or toxins deemed a threat to public health to notify the Secretary of the U.S. Department of Health and Human Services (HHS). It also requires people possessing, using, or transferring agents or toxins deemed a threat to animal or plant health and to animal or plant products to notify the Secretary of the U.S. Department of Agriculture (USDA). [For USDA, the section of the new Act that pertains to agents and toxins that pose a severe threat to animal and plant health and to animal and plant products is called the "Agricultural Bioterrorism Protection Act of 2002".]

Title I: National Preparedness for Bioterrorism and Other Public Health Emergencies

Directs the Secretary of HHS (the Secretary) to further develop and implement a coordinated preparedness plan. This includes establishing new positions, creating working groups, and providing for education and training. The provisions also establish grants for States to improve emergency preparedness infrastructure and programs.

Subtitle: A: National Preparedness and Response Planning, Coordinating, and Reporting

The Secretary shall collaborate with the States toward the goal of ensuring that the activities of the Secretary regarding bioterrorism and other public health emergencies are coordinated with activities of the States and local governments. The National Preparedness Plan shall include:

- Evaluation of progress - providing for specific benchmarks and outcome measures for evaluating the progress of the Secretary and the States and local governments.
- Provide effective assistance to State and local governments in the event of bioterrorism or other public health emergencies. Ensuring that State and local governments have appropriate capacity to detect and respond effectively to such emergencies, including capacities for:
    - Effective public health surveillance and reporting mechanisms at the State and local levels.
    - Appropriate laboratory readiness.
    - Properly trained and equipped emergency response, public health, and medical personnel.
    - Health and safety protection of workers responding to such an emergency.
    - Public health agencies that are prepared to coordinate health services (including mental health services) during and after such emergencies.

- Participation in communications networks that can effectively disseminate relevant information in a timely and secure manner to appropriate public and private entities and to the public.

- Developing and maintaining medical countermeasures (such as drugs, vaccines and other biological products, medical devices, and other supplies) against biological agents and toxins that may be involved in such emergencies.
- Ensuring coordination and minimizing duplication of Federal, State and local planning, preparedness, and response activities, including during the investigation of a suspicious disease outbreak or other potential public health emergency.
- Enhancing the readiness of hospitals and other health care facilities to respond effectively to such emergencies.
- Coordinate the operations of the National Disaster Medical System and any other emergency response activities within the HHS that are related to bioterrorism and other public health emergencies.
- The Secretary shall submit Reports to Congress concerning progress with the Plan, from several advisory committees (e.g. Emergency Public Information and Communications, National Advisory Committee on Children and Terrorism) that provide expert recommendations to assist workgroups in carrying out their responsibilities.
- Interagency coordination between HHS and other federal agencies, state and local entities with responsibility for emergency preparedness.

Subtitle B: Strategic National Stockpile; Development of Priority Countermeasures
The Secretary in coordination with the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergencies.

Subtitle C: Improving State, Local and Hospital Preparedness for and Response to Bioterrorism and Other Public Health Emergencies:
The Secretary shall make awards of grants or cooperative agreements to eligible entities to enable such entities to:

- Develop statewide and community-wide plans for responding to bioterrorism and other public health emergencies that are coordinated with the capacities of applicable national, state and local health agencies and health care providers (including poison control centers);
- Purchase and/or upgrade equipment, supplies, pharmaceuticals or other priority countermeasures to enhance preparedness for response to bioterrorism;
- Conduct exercises to test the capability and timeliness of public health emergency response activities;
- Develop and implement the trauma care and burn center care components of the State plans for the provision of emergency medical services;
- Improve training or workforce development to enhance public health laboratories;
- Train public health and health care personnel to enhance the ability to detect, provide accurate identification of symptoms and epidemiological characteristics of exposure to a biological agent that may cause a public health emergency; and to provide treatment to individuals who are exposed to such an agent.

Title II: Enhancing Controls on Dangerous Biological Agents and Toxins:
The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety. The Secretary shall consider:

- The effect on human health of exposure to the agent or toxin;
- Degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;
- The availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

- Any other criteria, including the needs of children and other vulnerable populations that the Secretary considers appropriate.

The Secretary shall consult with appropriate Federal departments and agencies and scientific experts.

Title III: Protecting Safety and Security of Food and Drug Supply

The President's Council on Food Safety shall, in consultation with the Secretaries of Transportation and Treasury, other relevant Federal agencies, the food industry, consumer and producer groups, scientific organizations and states, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. Such strategy shall address threat assessments; technologies and procedures for securing food processing and manufacturing facilities and modes of transportation; response and notification procedures; and risk communications to the public.

Title IV: Drinking Water Security and Safety

Each community water system serving a population of greater than 3,300 persons shall conduct an assessment of the vulnerability of its system to a terrorist attack or other intentional acts intended to substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water. The vulnerability assessment shall include, but not be limited to, a review of pipes and constructed conveyances, physical barriers, water collection, pretreatment, treatment, storage and distribution facilities, electronic, computer or other automated systems which are utilized by the public water system, the use, storage, or handling of various chemicals, and the operations and maintenance of such system. Each community water system shall prepare or revise an Emergency Response Plan that incorporates the results of vulnerability assessments that have been completed.

The Emergency Response Plan shall include, but not be limited to, plans, procedures, and identification of equipment that can be implemented or utilized in the event of a terrorist or other intentional attack on the public water system. It shall include actions, procedures, and identification of equipment which can obviate or significantly lessen the impact of terrorist attacks or other intentional actions on the public health and the safety and supply of drinking water provided to communities and individuals. Community water systems shall, to the extent possible, coordinate with existing local emergency planning committees established under the Emergency Planning and Community Right-to-Know Act (42 U.S.C. 11001 et seq.) when preparing or revising an emergency response plan.

The Administrator, in consultation with the Centers for Disease Control and Prevention and with appropriate Federal agencies, State and local governments, shall review (or enter into contacts or cooperative agreements) current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and source water for community water systems, including each of the following:

- Methods, means and equipment, including real-time monitoring systems, designed to monitor and detect various levels of chemical, biological, and radiological contaminants.
- Methods and means to provide sufficient notice to operators of public water systems, and individuals served by such systems, of the introduction of chemical biological or radiological contaminants and the possible effect of such introduction on public health and the safety and supply of drinking water.
- Develop educational and awareness programs for community water systems.
- Procedures and equipment necessary to prevent the flow of contaminated drinking water to individuals served by public water systems.
- Methods, means, and equipment which could negate or mitigate deleterious effects on public health and the safety and supply caused by the introduction of contaminants into water intended to be used for drinking water technologies in removing, inactivating, or neutralizing biological, chemical, and radiological contaminants.
- Biomedical research into the short-term and long-term impact on public health of various chemical, biological and radiological contaminants that may be introduced into public water systems through terrorist or other intentional acts.

Appendix C
Pandemic and All-Hazards Preparedness Act
(P.L. 109-417)
Selected Text related to Public Health Emergency Preparedness in State and Local Health Departments

On December 19, 2006, President George W. Bush signed the Pandemic and All-Hazards Preparedness Act (PAHPA), which is intended to improve the organization, direction, and utility of preparedness efforts. PAHPA centralizes federal responsibilities, requires state-based accountability, proposes new national surveillance methods, addresses surge capacity, and facilitates the development of vaccines and other scarce resources. The Act established with the Department of Health and Human Services (HHS) a new Assistant Secretary for Preparedness and Response (ASPR); provided new authorities for a number of programs, including the advanced development and acquisition of medical countermeasures; and called for the establishment of a quadrennial National Health Security Strategy.

Title I: National Preparedness and Response, Leadership, Organization and Planning

The Secretary of HHS (the Secretary) shall lead all Federal public health and medical response to public health emergencies and incidents covered by the National Response Plan. The Secretary in collaboration with the Secretaries of Veterans Affairs, Transportation, Defense, Department of Homeland Security (DHS) and the head of any other relevant Federal agency, shall establish an interagency agreement, consistent with the National Response Plan or any successor plan; under which agreement the Secretary of HHS shall assume operational control of emergency public health and medical response assets as necessary, in the vent of a public health emergency. Except that members of the armed forces, they shall remain under the command and control of the Secretary of Defense.

Public Health and Medical Preparedness and Response Functions of the Secretary of Health and Human Services -- Assistant Secretary for Preparedness and Response

Established within HHS is the position of the Assistant Secretary for Preparedness and Response (ASPR). The ASPR shall carry out the following functions:

- Serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies.
- Register, credential, organize, train, equip and have the authority to deploy Federal public health and medical personnel under the authority of the Secretary, including the National Disaster Medical System (NDMS) and coordinate such personnel with the Medical Reserve Corps and the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR VHP).
- Oversee advanced research, development and procurement of qualified countermeasures, pandemic or epidemic products.
- Coordinate with relevant Federal officials to ensure integration of Federal preparedness and response activities for public health emergencies.
- Coordinate with State, local and tribal public health officials, the Emergency Management Assistance Compact, health care systems and emergency medical service systems to ensure effective integration of Federal public health and medical assets during a public health emergency.
- Promote improved emergency medical services medical direction, system integration, research and uniformity of data collection, treatment protocols and policies with regard to public health emergencies.
- In coordination with the Secretaries of Veterans Affairs, Homeland Security, General Services Administration and other public and private entities, provide logistical support for medical and public health aspects of Federal responses to public health emergencies.
- Provide leadership in international programs, initiatives and policies that deal with public health and medical emergency preparedness and response.

- In coordination with the Director of the Centers for Disease Control and Prevention (CDC), shall have authority over and responsibility for: the NDMS, Hospital Preparedness Cooperative Agreement Program, Medical Reserve Corps (MRC), ESAR VHP, Strategic National Stockpile (SNS) and Cities Readiness Initiative (CRI).
- Oversee the implementation of the National Preparedness goal of taking into account the public health and medical needs of at-risk individuals in the event of a public health emergency.
    - Ensure the contents of the Strategic National Stockpile take into account at-risk populations;
    - Oversee the progress of the Advisory Committee on At-Risk Individuals and Public Health Emergencies;
    - Oversee curriculum development for the public health and medical response training program on medical management of casualties, as it concerns at-risk individuals;
    - Disseminate novel and best practices of outreach to and care of at-risk individuals before, during and following public health emergencies; and
    - Submit a Report to Congress describing the progress made on implementing the duties described in this section.

National Health Security Strategy: The Secretary shall submit to Congress a coordinated strategy (to be known as the National Health Security Strategy) for public health emergency preparedness and response. The National Health Security Strategy shall identify the process for achieving the preparedness goals and shall be consistent with the National Preparedness Goal, the National Incident Management System and the National Response Plan. The National Health Security Strategy shall include an evaluation of the progress made by Federal, State, local and tribal entities based on the evidence-based benchmarks and objective standards that measure levels of preparedness. It shall include a national strategy for establishing an effective and prepared public health workforce (e.g. defining the functions, capabilities, gaps, strategies to recruit, retain and protect workforce from workplace exposures).

Preparedness Goals of the National Health Security Strategy are:

- Integration of public health and public and private medical capabilities with other first responder systems;
- Developing and sustaining Federal, State, local and tribal essential public health security capabilities (e.g. disease situational awareness, disease containment (isolation and quarantine), risk communication and rapid distribution of medical countermeasures);
- Increasing the preparedness, response capabilities, and surge capacity of hospitals, health care facilities (including mental health facilities) and trauma care health emergencies;
- Taking into account the public health and medical needs of at-risk individuals in the event of a public health emergency;
- Ensuring coordination between Federal, State, local and tribal planning, preparedness and response activities; and
- Ensuring continuity of operations. Maintaining vital public health and medical services to allow for optimal Federal, State, local and tribal operations in the event of a public health emergency.

Title II: Public Health Security Preparedness

Improving State and Local Public Health Security: The Secretary shall award cooperative agreements (i.e., grants) to eligible entities to improve public health security. All eligible entities must submit to the Secretary an application containing 'such information as the Secretary may require' (e.g. All-Hazards Public Health Emergency Preparedness and Response Plan, annual reporting on evidence-based benchmarks and object standards, and annual exercise or drills to test the preparedness and response capabilities). In making awards, the Secretary shall consult with the Secretary of DHS to ensure maximum coordination of the public health and medical preparedness and response activities with the Metropolitan Medical Response System, minimize duplicative funding of programs and activities, develop recommendations and guidance on best practices and disseminate information via a single Internet site regarding best practices and lessons learned from drills, exercises, disasters, and other emergencies.

Entities that do not meet benchmark requirements will have the opportunity to correct non-compliance. Beginning FY 2009, the Secretary shall withhold funds from entities that have failed to meet benchmarks or have failed to submit a Pandemic Influenza Plan.

Using Information Technology to Improve Situational Awareness in Public Health Emergencies: The Secretary in collaboration with State, local, tribal public health officials, clinical laboratories, pharmacies, poison control centers and animal health organizations, shall establish a real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies that originate domestically or aboard.

The Secretary in consultation with the Federal Communications Commission (FCC) and other relevant Federal agencies shall:

- Conduct an inventory of telehealth initiatives in existence, including the specific location of network components -- medical, technological, and communications capabilities, functionality, capacity and ability of such components to handle increased volume during the response to a public health emergency.
- Identify methods to expand and interconnect the regional health information networks funded by the Secretary, State and regional broadband networks funded through the rural health care support mechanism pilot program funded by the FCC and other telehealth networks.
- Evaluate ways to prepare for, monitor, respond rapidly to, or manage the events of, a public health emergency through the enhanced use of telehealth technologies, including mechanisms for payment or reimbursement for use of such technologies and personnel during public health emergencies.
- Identify methods for reducing legal barriers that deter health care professionals from providing telemedicine services. Utilizing State emergency health care professional credentialing verification systems, encouraging States to establish and implement mechanisms to improve interstate medical licensure cooperation, facilitating the exchange of information among States regarding investigations and adverse actions and encouraging State to waive the application of licensing requirements during a public health emergency.
- Evaluate ways to integrate the practice of telemedicine interagency telemedicine and health information technology initiatives.
- Promote greater coordination among existing Federal interagency telemedicine and health information technology initiatives.

Public Health Workforce Enhancements: Authorizes the Secretary to provide grants to States for tuition loan repayment to individuals who agree to serve for at least 2-years in State, local or tribal health departments. The loan repayment program will support degree programs appropriate for serving in State, local and tribal health departments.

Vaccine Tracking and Distribution: Authorizes the Secretary to cooperate with manufacturers, wholesalers, and distributors during a pandemic on tracking initial distribution of federally purchased influenza vaccine. In addition, the law requires that the Secretary promote communication among State, local and tribal public health officials and manufactures, wholesalers and distributors regarding the effective distribution of seasonal influenza vaccine to high priority populations during vaccine shortages and supply disruptions.

National Science Advisory Board for Biosecurity (NSABB): When requested by the Secretary, the NSABB shall provide to relevant Federal agencies -- advice, guidance or recommendations concerning:

- A core curriculum and training requirements for workers in maximum containment biological laboratories; and
- Periodic evaluations of maximum containment biological laboratory capacity nationwide and assessments of the future need for increased laboratory capacity.

Revitalization of Commissioned Corps: The Secretary shall organize members of the Corps into units for rapid deployment to respond to urgent or emergency public health care needs that cannot otherwise be met at the Federal, State and local levels.

Title III: All-Hazards Medical Surge Capacity

National Disaster Medical System (NDMS): Transfer of NDMS functions, personnel, assets and liabilities from the DHS to the HHS.

Enhancing Medical Surge Capacity: The Secretary shall evaluate the benefits and feasibility of improving the capacity of HHS to provide additional medical surge capacity to local communities in the event of a public health emergency. To improve surge capacity through:

- Acquisition and operation of mobile medical assets by the Secretary to be deployed, on a contingency basis, to a community in the event of a public health emergency;
- Integrating the practice of telemedicine within the NDMS; and
- Other strategies to improve such capacity as determined appropriate by the Secretary.

Encouraging Health Professional Volunteers: Strengthens federal support and structure for the Medical Reserve Corps (MRC) program, beginning with the appointment of a Director by the Secretary. The Director will be responsible for overseeing activities of state, local and tribal corps chapters. This legislation aims to establish, through the ESAR VHP an interoperable network of connected state systems to verify the credentials and licenses of healthcare professionals who volunteer during public health emergencies. The system will be accessible to all state and local health departments.

Core Education and Training: The Secretary in collaboration with the Secretary of Defense and relevant public and private entities, shall develop core health and medical response curricula and trainings related to: medical management of casualties; public health and mental health aspects of public health emergencies; national incident management, including coordination among Federal, State, local, tribal, international agencies and other entities; and protecting health care workers and first responders from workplace exposures during a public health emergency.

The Secretary shall establish 20 Epidemic Intelligence Service (EIS) Officer positions in the EIS Program. This program is managed by CDC, a 2-year postgraduate program of service and on-the-job training for health professionals interested in epidemiology. Individuals work for at least 2 years at a state, local or tribal health department that serves an area in which there is a shortage of health professionals, a medically underserved population, or a high-risk of public health emergency.

Partnerships for State and regional hospital preparedness to improve surge capacity: The Secretary shall award competitive grants or cooperative agreements to eligible hospital and healthcare facilities to improve surge capacity and enhance community and hospital preparedness for public health emergencies.

Title IV: Pandemic and Biodefense Vaccine and Drug Development

The Secretary shall develop a strategic plan (within 6 months of enactment), to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, and the procurement of qualified countermeasures and pandemic or epidemic products.

Biomedical Advanced Research and Development Authority: The Secretary shall coordinate the acceleration of countermeasure and product advanced research and development by establishing the Biomedical Advanced Research and Development Authority (BARDA). Operating within HHS, BARDA will facilitate the development of new medicines and vaccines (i.e., medical countermeasures) to counter biological, chemical, radiological, nuclear, and other security threats. A Director will be appointed by the Secretary.

Establishment of the Biodefense Medical Countermeasure Development Fund which allows BARDA to fund the development of products across the so-called "Valley of Death" between NIH-funded basic research and end-stage

procurement by the BioShield program. The law authorizes $1.07 billion for FY 2006-2008 for the fund. This Fund is separate from the preexisting BioShield purchase fund. It may also be used to support innovation in biomedical research tools and other strategic initiatives intended to improve overall medical countermeasure development.

National Biodefense Science Board: The Secretary shall establish the National Biodefense Science Board to provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to HHS regarding current and future chemical, biological, nuclear and radiological agents, whether naturally occurring, accidental or deliberate.

The Board will consist of U.S. government officials, 4 representatives of the biopharma and medical device industry, 4 academic representatives and 5 other including at least one practicing healthcare professional and one representative of healthcare consumers.

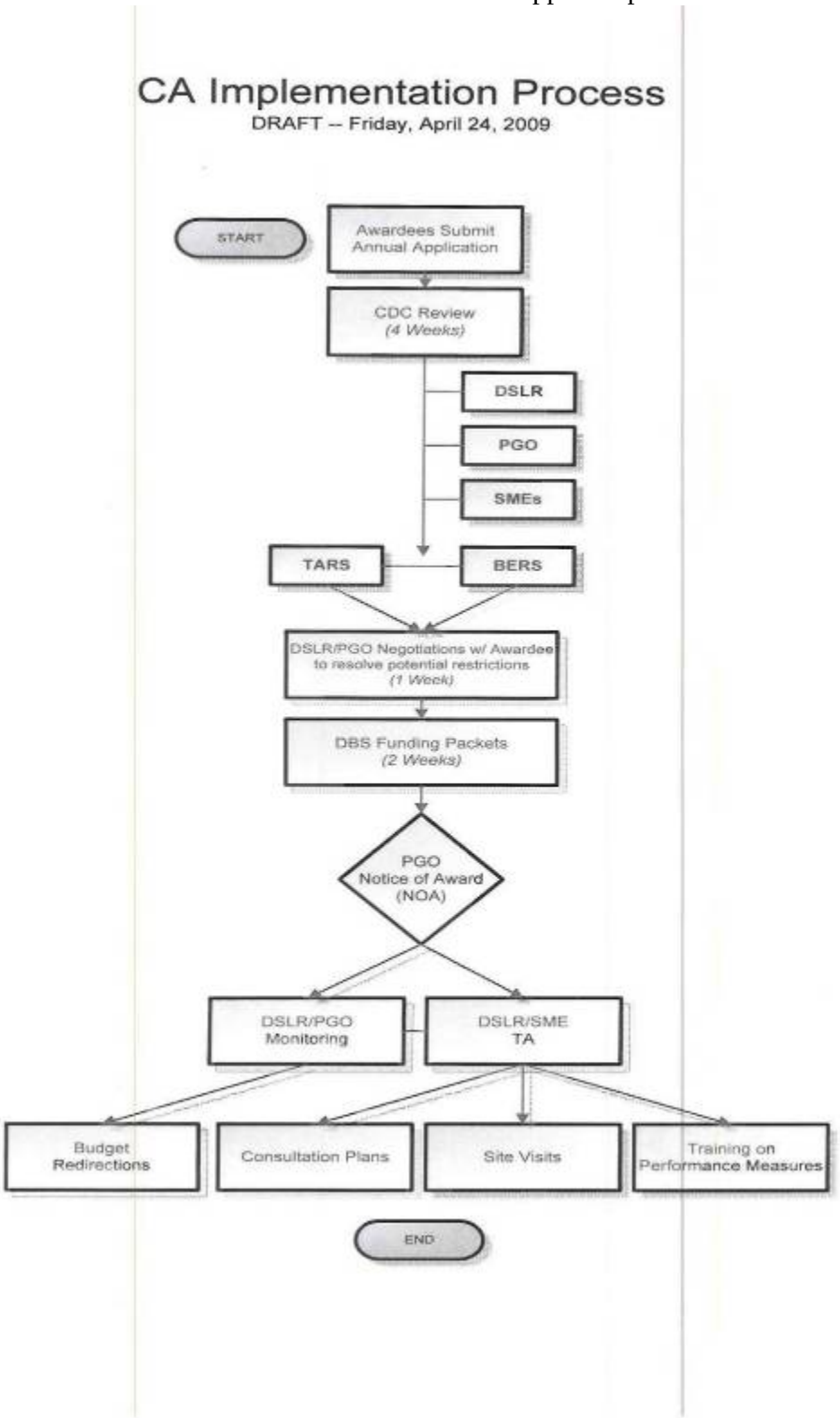
Technical Assistance: The Secretary shall establish within FDA a team of experts on manufacturing and regulatory processes to provide technical assistance to the developers of medical countermeasures.

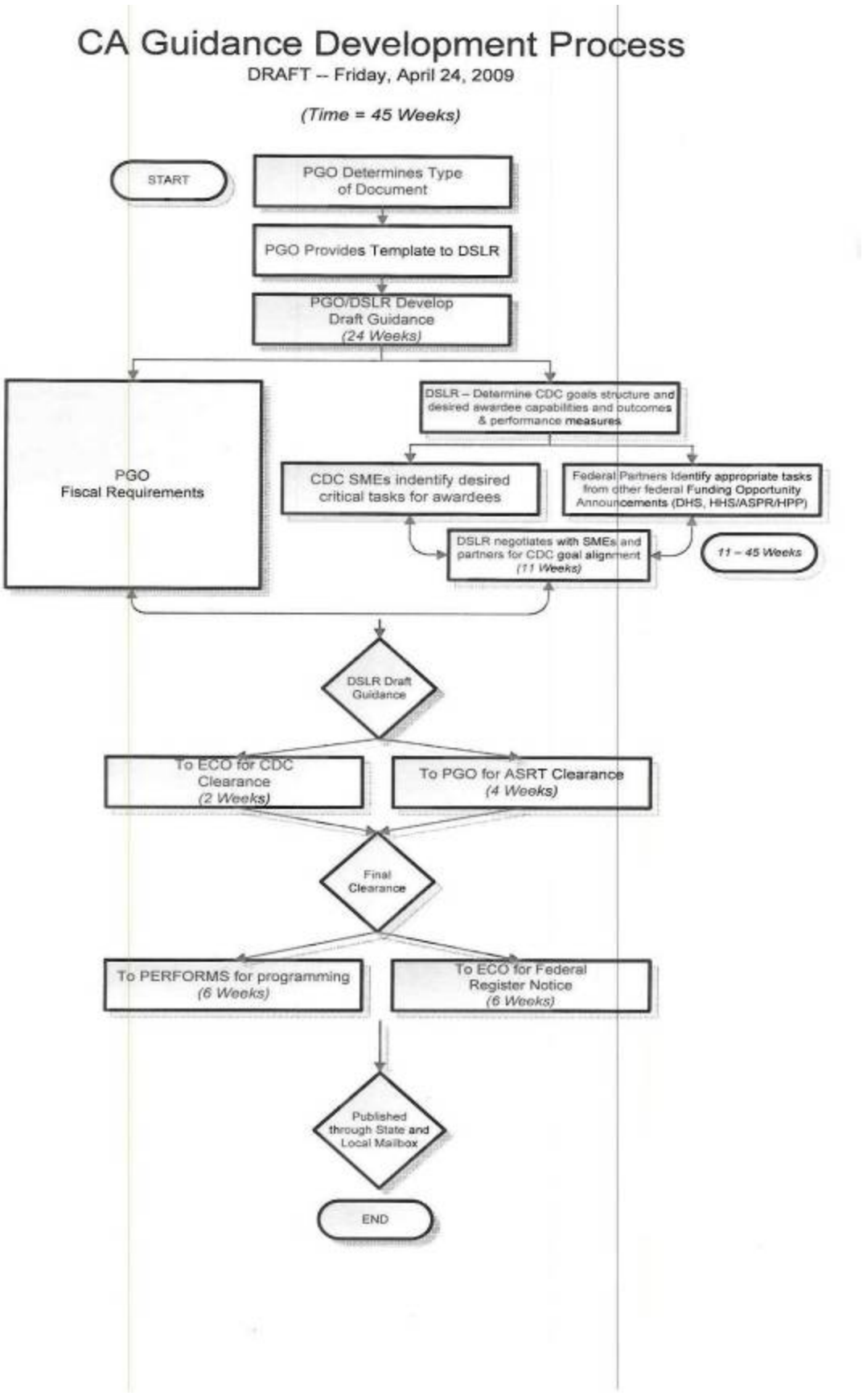
Collaboration, coordination and procurement: The Secretary shall:

- Establish limited anti-trust exemptions to allow biopharma companies to better collaborate with each other and with government in the development of medical countermeasures. This provision will sunset after six years;
- Make reforms to the BioSheild procurement program;
- Allow HHS to enter into an exclusive contract with a vendor; and
- Give HHS the authority to contract for domestic "warm base surge capacity" for a developer to establish a warm base manufacturing capacity for a countermeasure that may be brought on-line quickly (e.g. during a crisis).

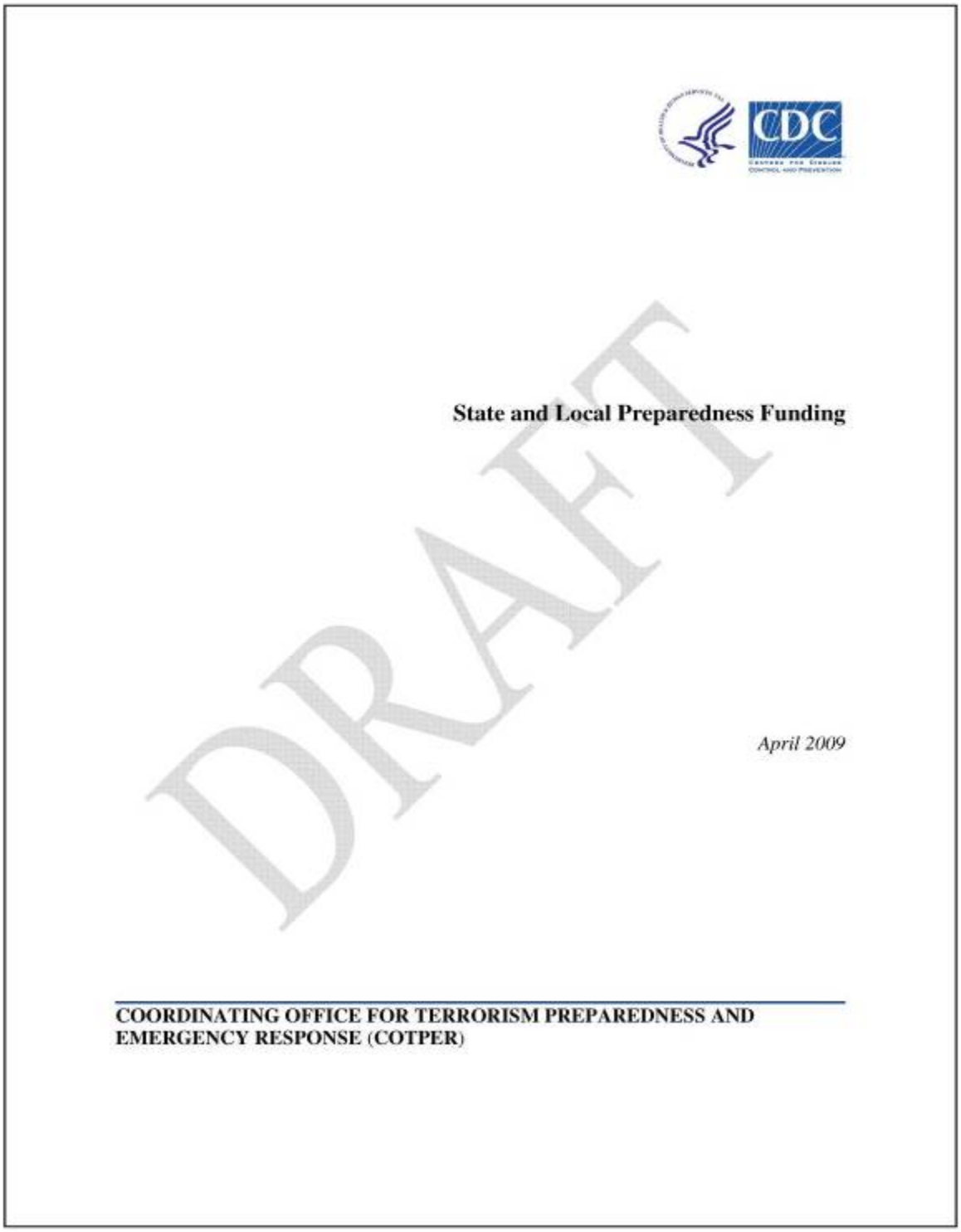
Appendix G

Flow chart of the 2005-2010 PHEP approval process




CA Guidance Development Process
DRAFT -- Friday, April 24, 2009
(Time = 45 Weeks)
START
PGO Determines Type of Document
PGO Provides Template to DSLR
PGO/DSLR Develop Draft Guidance (24 Weeks)
PGO Fiscal Requirements
DSLR – Determine CDC goals structure and desired awardee capabilities and outcomes & performance measures
CDC SMEs indentify desired critical tasks for awardees
Federal Partners Identify appropriate tasks from other federal Funding Opportunity Announcements (DHS, HHS/ASPR/HPP)
DSLR negotiates with SMEs and partners for CDC goal alignment (11 Weeks)
11 – 45 Weeks
DSLR Draft Guidance
To ECO for CDC Clearance (2 Weeks)
To PGO for ASRT Clearance (4 Weeks)
Final Clearance
To PERFORMS for programming (6 Weeks)
To ECO for Federal Register Notice (6 Weeks)
Published through State and Local Mailbox
END

Appendix H
State and Local Preparedness Funding, April 2009



Public Health Emergency Preparedness Background

The Centers for Disease Control and Prevention's (CDC) Public Health Emergency Preparedness (PHEP) cooperative agreement is a critical source of funding for state and local health departments. The cooperative agreement began in 1999 to help state and local health departments (also referred to as awardees or jurisdictions) to improve bioterrorism preparedness and response capabilities. After the terrorist attacks of September 11, 2001, and the anthrax attacks in October 2001, Congress appropriated supplemental funding to CDC to distribute to 62 state, local, and territorial public health departments to implement a comprehensive terrorism preparedness and emergency response program. In fiscal year 2005, a new program announcement for the bioterrorism program was issued and the activity was renamed the Public Health Emergency Preparedness program. As of fiscal year 2008, CDC has provided more than $6.3 billion in funding to state, local, and territorial public health agencies.

CDC administers the PHEP cooperative agreement and provides technical assistance to each jurisdiction to develop critical public health preparedness capacities, including preparedness planning and readiness assessment, surveillance and epidemiology, biological and chemical laboratory capability and capacity, communications systems and information technology, health information dissemination and risk communication, as well as education and training. The technical assistance includes sharing CDC's public health expertise, identifying promising practices, providing guidance for exercises, and developing performance goals.

The PHEP cooperative agreement supports ongoing enhancement of state and local public health programs through a continuous cycle of planning, training, exercising, and improvement plans. With funding support from the PHEP cooperative agreement, public health departments have developed response plans, implemented a formalized incident command structure, and conducted exercises. In addition, public health departments can better detect and investigate diseases because of improvements in the public health workforce and in data collection and reporting systems. Also, public health laboratories now have increased capability to test for biological and chemical threats and to quickly communicate information to clinical laboratories

Funding History and Overview

The PHEP cooperative agreement has been the predominant federal source of state and local public health preparedness and emergency response funding for the past nine years. Managed by CDC's Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER) through the Division of State and Local Readiness (DSLR), the program's mission has evolved into an all-hazards approach, which helps ensure that public health departments have the capacity and capability to effectively respond to the public health consequences of not only terrorist threats, but also infectious disease outbreaks, natural disasters, and biological, chemical, nuclear, and radiological emergencies. These emergency preparedness and response efforts are designed to support the National Response Framework (NRF) and the National Incident Management System (NIMS) and are targeted specifically for the development of emergency-ready public health departments.

Public Health Preparedness and Response for Bioterrorism Program

CDC's Public Health Preparedness and Response for Bioterrorism Program, the precursor to the PHEP cooperative agreement, focused on preparedness and response capabilities related to bioterrorism with limited resources available. In fiscal year 1999, approximately $40 million was awarded through a competitive grant process. The bioterrorism program initially targeted critical capacities in several focus areas. They included planning and readiness assessment; surveillance

and epidemiology capacity; biological and chemical laboratory capacity; and the Health Alert Network, which enables the rapid exchange of critical public health information.

In November 2000, the restoration of a neglected public health infrastructure was authorized under the *Public Health Threats and Emergencies Act (P.L. 106-505)* to:

- ✓ Train public health personnel;
- ✓ Develop electronic disease detection network;
- ✓ Develop plan for responding to public health emergencies; and
- ✓ Enhance laboratory capacity and facilities.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

After the terrorist attacks of September 11, 2001, followed by the anthrax attacks in October 2001, public health preparedness funds increased dramatically. Recognizing the potential weaknesses in the nation's public health system highlighted by the terrorist attacks, Congress passed the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188),* which reauthorized several important grant programs established under the *Public Health Threats and Emergencies Act* and the *Public Health Service Act*. The new legislation was designed to improve the ability of the United States to prevent, prepare for, and respond to, bioterrorism as well as other public health emergencies.

Following passage of this legislation, Congress appropriated nearly $1 billion in fiscal years 2001-2002 to support preparedness and emergency response activities nationwide (see Table 1). This supplemental funding was distributed to 62 state, local, and territorial public health departments to implement comprehensive terrorism preparedness and emergency response programs. With the substantial infusion of funds from Congress, the program's focus expanded over the next two years to include additional focus areas. The new focus areas were communication and information technology; communicating health risks and disseminating health information; and education and training. In fiscal year 2003, Congress authorized supplemental funding to support a renewed smallpox initiative.

Public Health Emergency Preparedness Program

In fiscal year 2005, a new program announcement for the bioterrorism program was issued, and the activity was renamed the Public Health Emergency Preparedness program. At that time, the focus changed to required critical tasks based on the synchronization of the Department of Homeland Security Target Capabilities List[1] with the CDC Preparedness Goals to create a preparedness framework that identifies the key needs of the public health community.

Fiscal years 2002 to 2008 saw significant reductions in overall PHEP funds totaling approximately $300 million. Declining appropriations in fiscal year 2004, along with a Congressional redirect of $54.9 million in PHEP funding to establish the Cities Readiness Initiative (CRI) and to support other programs, began a trend of the federal government prescribing how state and local health departments were to spend their funds, limiting their flexibility to address their own specific preparedness priorities. This trend of competing priorities continued with the passage of the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006 and the Homeland Security Presidential Directive-21 (HSPD-21) of 2007,

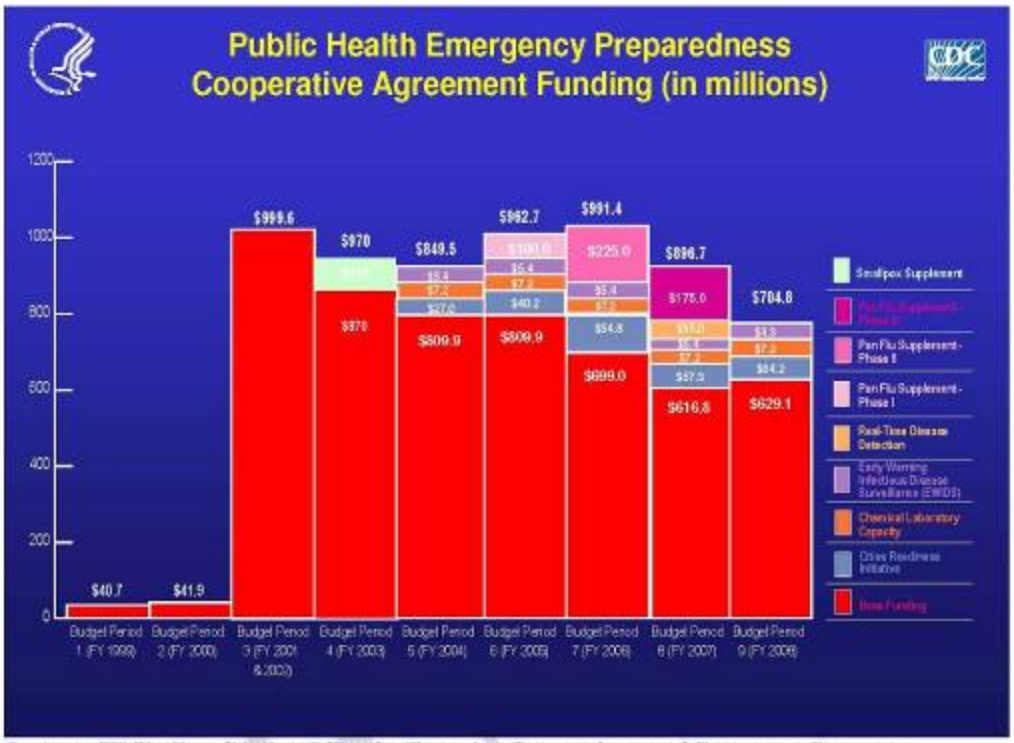
[1] The Target Capabilities List (TCL), created by the Department of Homeland Security, outlines standards that hold health departments accountable for demonstrating levels of preparedness. The TCL describes the capabilities related to the four homeland security mission areas: Prevent, Protect, Respond, and Recover. It defines and provides the basis for assessing preparedness. It also establishes national guidance for preparing the nation for major all-hazards events, such as those defined by the National Planning Scenarios

both of which led to more unfunded requirements and further limitations on how individual state and local health departments could spend their preparedness dollars.

For the next three years (2005-2007) PHEP grantees received supplemental funding for pandemic influenza planning totaling $524 million. These supplemental funds were discontinued in fiscal year 2008; however, the pandemic influenza requirements remain in place and PHEP grantees are expected to continue established activities in this area through partnerships, PHEP base funding, and other nonfederal funding sources.

These reductions in PHEP funds have a huge negative impact on the nation's public health infrastructure in terms of maintaining a trained workforce, developing response plans and exercising those plans, sustaining critical infrastructure, and limiting state and local health departments' ability to meet the Target Capabilities List in support of the National Preparedness Guidelines. The guidelines provide a national framework for a capabilities-based preparedness system and direct individual federal, state, local, tribal, and territorial governments and agencies to establish in advance of a public health incident a preparedness cycle that includes planning, organizing and staffing, equipping, training, exercising, and evaluating and improving.

Table 1: Overall PHEP Funding (1999-2008)



Source: CDC's Coordinating Office for Terrorism Preparedness and Emergency Response.

Legislative and Executive Mandates and Carve-outs

The PAHPA provisions included several unfunded mandates. ***In addition, carve-outs have reduced PHEP awardees' ability to address critical priority areas in individual jurisdictions.*** Carve-outs became significant in fiscal year 2004 when PHEP funds were redirected from base funding to cover programs such as the CRI and chemical laboratory capacity. This began a trend of redirecting base funds to specific uses and limiting the flexibility of state and local health departments to use funding for other priorities as well as all-hazards emergency planning and preparedness activities.

Pandemic Influenza Supplemental Funds

Pandemic influenza funds were awarded as part of Congressional supplemental funding.

- $600 million was appropriated through the Pandemic Influenza Supplement for state and local preparedness and was awarded in three phases: Phase I - $100 million, Phase II - $250 million and Phase III - $250 million (Congress appropriated $350 million in December 2005 and $250 million in June 2006).
- $100 million (Phase I) was awarded in March 2006 for the awardees to conduct statewide pandemic influenza preparedness summits, assess preparedness gaps, and develop approaches for filling the identified gaps.

- ✓ Preparedness summits
- ✓ Pandemic influenza preparedness summits were conducted to facilitate
- ✓ communitywide planning
- ✓ Self-assessment tool for preparedness gap analysis
- ✓ Awardees used this CDC-provided assessment tool to conduct a preparedness gap analysis and to develop approaches for filling these gaps
- ✓ Budget allocations for addressing preparedness gaps
- ✓ Awardees submitted budgets based on their funding to address the gaps in their pandemic influenza preparedness; the expense categories include:

  55% - Contractual Expenses (this category reflects state distribution of funds to local/county health departments for pandemic influenza planning, training, and exercising)
  31% - Educational/Training Materials, Summit Meetings, Personnel, Travel, Fringe, Indirect and Other Expenses
  8% - Supply Expenses (i.e., masks, lab supplies and test kits)
  6% - Equipment Expenses (i.e., computers, software and instruments)

- $225 million was awarded in September 2006 (Phase II) to conduct exercises at the state and local levels (mass vaccination using seasonal flu clinics, community-based school closures, and medical surge), develop antiviral distribution plans, and review/update state pandemic influenza operations plans.

  - ✓ Pandemic influenza mass vaccination and school-closure exercise results were submitted to CDC in March 2007 (Medical surge exercise results were submitted to the Department of Health and Human Services [HHS])
  - ✓ State and local antiviral drug distribution plans were submitted to CDC for review in April 2007.
  - ✓ Abstracts of State Pandemic Influenza Operations Plans were submitted to CDC in April 2007. Reviews occurred at CDC, HHS, and the respective federal agencies.

- $1 million in Phase II funding was awarded to the National Governors Association to conduct 10 regional workshops to address operational plans for a pandemic influenza response.

- The $24 million remaining from the Phase II funds was awarded to select awardees in September 2008 through a competitive application process in which awardees proposed to implement promising practices or novel approaches to seven pandemic influenza preparedness challenges.

- The third phase of funding (Congressional appropriation of $250 million) was released in August 2007. This funding was designated to assist awardees' in their efforts to fill gaps identified in Phases I and II by using the Department of Homeland Security's Exercise and Evaluation Program (HSEEP) cycle of planning, training, and exercises. A portion of the funding ($75 million) was allocated for upgrading state and local pandemic influenza preparedness capacities through the Hospital Preparedness Program administered by HHS' Office of the Assistant Secretary for Preparedness and Response (ASPR).

Appendix I

DSLR Program Announcement Change Management Board Proposal

DISCUSSION DRAFT 8/24/2009

Public Health Emergency Preparedness (PHEP) Program Announcement Change Management Board (CMB) Proposal

Background

The Public Health Emergency Preparedness (PHEP) program was initially established in 1999 as a competitive grant program to provide funds to enhance the ability of state, local, territorial, and tribal public health departments to develop their capacity to respond effectively to terrorism-related public health emergencies. In 2002, shortly after the events of September 11, 2001, and subsequent anthrax attacks, Congress authorized funding for the Public Health Emergency Preparedness (PHEP) cooperative agreement to support preparedness nationwide in state, local, tribal, and territorial public health departments. In 2002, the PHEP program changed from a competitive grant to a noncompetitive cooperative agreement, with guidance provided to awardees in seven critical "focus areas": planning and assessments; surveillance and epidemiology capacity; biologic laboratory capacity; chemical laboratory capacity; health alerting, communications, and information technology; risk communication and information dissemination; and education and training. In 2005, there was a reorganization of the cooperative agreement to reflect an "all-hazards approach", emphasizing the achievement of various emergency preparedness, detection, response, and recovery capabilities via a "critical task" format similar to the Department of Homeland Security's Targeted Capabilities List. Since then, for each subsequent year of the cooperative agreement, CDC provided continuation guidance under which awardees continue unfinished activities from the prior year or initiate new activities within the scope of the original cooperative agreement.

Rationale for a Change Management Board (CMB)

Each year of the 2005-2010 PHEP cooperative agreement there were additional activities added to the initial list of critical tasks by either CDC centers associated with one of the CDC preparedness goals or during the concurrence process with the Department of Health and Human Services/Assistant Secretary for Preparedness and Response office (HHS/ASPR). Some of these activities also included input related to priorities identified by the White House Homeland Security Council. The level of these additions has varied in complexity and the time to manage them has ranged from an estimated 11 weeks to 45 weeks each year. Program activities included few defined goals or objective performance measures, were subjectively assessed, did not address the entire list of awardees activities, and awardees were often confused as to what their priorities should be because the list of PHEP subject matter expert (SME) program activities was not defined as requirements and often varied in specificity depending on the SME contributor.

As a result, the PHEP program has suffered from a lack of clarity in program priorities by stakeholders, shifting program strategy; and a lack of defined performance measures for preparedness. An example of these changes is illustrated as follows: in late 2007, HHS/ASPR, through the CDC Coordinating Center for Infectious Disease, National Center for Infectious and Respiratory Diseases (NCIRD), requested DSLR add a requirement for awardees to collect and report vaccine doses administered to NCIRD's Countermeasure Response Administration program (CRA) from a minimum of eight seasonal influenza clinics over any four consecutive weeks between October 1 and December 31, 2008. The CRA was designed to support CDC's

1

cross-jurisdictional reporting needs by providing flexible methods for accepting data from other systems or by extracting summarized data. This additional activity was added to the 2008 PHEP budget period as a reporting requirement, but there was neither a discussion between DSLR, NCIRD, and other federal stakeholders as to how this reporting requirement aligned with existing PHEP priorities or activities or if this project replaced existing PHEP activities. Although the NCIRD staff who supported the CRA project provided periodic conference call training sessions with PHEP awardees who elected to utilize electronic CRA options, there was not widespread coordination between NCIRD staff and PHEP project officers regarding technical assistance needed for achieving this deliverable.

An additional challenge to the management of PHEP activities is the level of funding for SMEs to assist in the cooperative agreement's implementation. DSLR has determined that SME programs that are not funded to assist DSLR in helping awardees achieve the SME-derived PHEP activities experience time and resource challenges in managing SME activities with DSLR. Currently, only the Public Health Information Network and the COTPER Division of Strategic National Stockpile (DSNS) receive COTPER funding to provide technical assistance to PHEP awardees; those programs who provided PHEP activities but are not funded to assist in implementation are often limited to only providing comments to awardees' activity progress reports twice yearly.

DSLR does not currently have a process to manage requests for additional tasks, awardees activities, priority initiatives, SME requests, or SME involvement in the PHEP once the initial program announcement guidance has been cleared and released. Since PHEP stakeholder interests vary in complexity and content, COTPER and DSLR senior leadership recognize the need to establish a more transparent, objective process to manage change requests made once the program announcement guidance is officially approved and implemented. The 2010-2015 PHEP Program Announcement will involve a methodology for identifying priority capabilities for emergency preparedness at the state and local levels and a PHEP conceptual model; to efficiently manage changes, DSLR proposes the creation of a PHEP program announcement change management board (CMB) to ensure that changes to either PHEP capabilities or components of the conceptual model are introduced in a controlled and coordinated manner. This CMB would reduce the possibility that *ad hoc* changes will be introduced to the PHEP, adding additional burdens to the system, or that changes may unilaterally undo earlier changes agreed upon by stakeholders.

The purpose of this document is to propose a change management process that will govern how changes will be managed by DSLR in subsequent funding years after the 2010-2015 Program Announcement has been approved and released. This document only includes a high-level change management process; the accompanying sub-processes, activities, roles, and metrics will be provided in detail once the initial concept has been vetted and approved.

This CMB process is informed by the COTPER Information Resource Change Management Process Guide, Version 1.2

Purpose of Change Management Board (CMB)

The purpose of the DSLR CMB is to establish a process for managing and implementing change requests to CDC's 2010-2015 PHEP program announcement in all subsequent years of the continuation guidance. The PHEP priorities will be managed by soliciting any proposed changes from stakeholders, evaluating impact to all components of the PHEP, executing changes in a controlled manner, verifying changes when complete, evaluating impact after changes are made, and updating affected PHEP documents in a timely manner. Appendix B provides definitions for the terms related to change management used in this document.

Goals of the DSLR PHEP CMB

The goals of the DSLR PHEP CMB will be to:

- Provide a formalized structure for submitting, assessing, reviewing, and approving changes to the 2010-2015 PHEP Program Announcement.
- Assess the risk and impact of the proposed change to PHEP awardees and DSLR operations.
- Establish a method to ensure all changes are documented, tracked, and archived
- Ensure that key stakeholders understand the rationale for the changes and their impact
- Reduce the burden on DSLR staff in managing the change by creating a transparent change management process.
- Ensure that changes to the PHEP program are made in a way that :
    - Ensures continued compliance with applicable mandates and policies.
    - Minimizes disruption to current PHEP priorities, capabilities, and deliverables,
    - Improves DSLR's ability to help PHEP awardees achieve the desired capabilities
    - Improves DSLR's coordination of CDC resources (DSLR and non-DSLR) involved in the implementation of the PHEP cooperative agreement.

Proposed Benefits of the CMB for DSLR's Management of the PHEP Cooperative Agreement

The CMB will improve DSLR's overall PHEP governance by:

- Formalizing the relationships between all internal and external groups involved in the PHEP.
- Ensuring a consistent review of proposed changes within a priority capability or within the conceptual model.
- Ensuring that required approvals and direction for the PHEP capabilities are obtained throughout the development and implementation of the PHEP program to minimize last-minute changes and funding delays to awardees.
- Improving the business case for changes to the PHEP and improving the coordination of in-scope and out-of-scope potential contributions.
- Providing a mechanism to assess the costs and potential impacts of the proposed additions to the 2010-2015 PHEP priorities and capabilities.
- Providing a defined method of communication to and between each stakeholder.

- Providing a current, published project plan that spans all project stages from PHEP initiation through implementation, revisions, and evaluation.
- Providing DSLR with a process for the management and resolution of issues that arise during the implementation of the PHEP program.

Critical Success Factors

The following factors are critical for the successful implementation of an integrated DSLR change management process for the PHEP program:

- COTPER leadership and CDC Leadership support to ensure CDC and other stakeholders accept the process and to minimize impact to the PHEP cooperative agreement implementation.
- Commitment by COTPER, CDC, (OD and National Centers), and HHS/ASPR to conform to one integrated change management process.
- Ongoing communication with DSLR PHEP framework teams on process changes and process improvements needed.
- DSLR leadership participation and support in CMB steering committee meetings.
- Proper documentation of all changes submitted.

Guiding Principles

Guiding principles set the tone and govern the execution of the overall DSLR change management process. The following principles must guide the DSLR change management process:

- All changes, except for routine modifications, will require a formal change request to the DSLR CMB.
- No changes to PHEP priorities, capabilities, activities, or measures can be performed without an approved change request.
- All proposed changes will be supported by documentation that meets the requirements for proposed PHEP cooperative agreement changes (Appendix A).
- An impact assessment on state and local capacity to implement the proposed change must be conducted for all changes prior to approval.
- Changes will be categorized to facilitate adequate review depending on the nature of the change request.
- All changes will be reviewed by the DSLR CMB.
- A standard documented procedure will be in place to handle routine modification.
- Changes will be evaluated for impact based on the triple constraints in project management including time, cost, quality, and scope

Proposed CMB Membership

- DSLR Director (CMB Chair)

- DSLR Division Deputy (CMB Administrator)
- Program Services Branch (PSB) Chief
- Outcome Monitoring and Evaluation Branch (OMEB) Chief
- CDC Centers/Offices that align to the prioritized capabilities for the 2010-2015 PHEP (CMB Steering Committee Members)
- HHS ASPR (CMB Steering Committee Member)
- CDC Procurement and Grants Office (PGO) or COTPER Division of Business Services (DBS) Representative (CMB Steering Committee Member)

Proposed Roles and Responsibilities

Role	Office	Responsibility
Change Requestor	Anyone in COTPER, HHS/ASPR, CDC SME Centers/Offices	• Completes change request form and submits to Change Administrator. • Participates in the CMB Steering Committee meeting.
Change Administrator	DSLR Division Deputy	• Reviews the change request form for completeness • Assigns a change request number • Reviews and evaluates the change request against program requirements and standards. • Submits the change request form to CMB chair. • Convenes the CMB Steering Committee • Obtains approval/denial signature from CMB and/or Steering Committee member. • If the requestor is a CDC center notifies them about the disposition of the request. • Forwards the completed change request form to all stakeholders affected by the change. • Complete the closeout statement of the change request form.
CMB Chair	DSLR Director	• Overall strategic leader • Reviews the change request and approves routine changes.

		• Requests the Change Administrator to convene the CMB Steering Committee for significant change requests. • Meets with COTPER Director to drafts response to requests from CDC or HHS/ASPR leadership that outlines any concerns the CMB may have with the proposed change.
CMB Steering Committee	CDC Centers/Offices that align to the proposed priorities/capabilities for the 2010-2015 PHEP, HHS/ASPR, DSLR OD, CDC SMEs, PGO or DBS Representative, PSB Branch Chief, OMEB Branch Chief	• Discusses change request against program requirements and 2010-2015 PHEP conceptual model • Approve or deny the request.
Implementer	DSLR Staff, SMEs, Awardees	• Individuals or teams who have to implement the approved changes.

Standard Operating Procedures for the Change Management Board

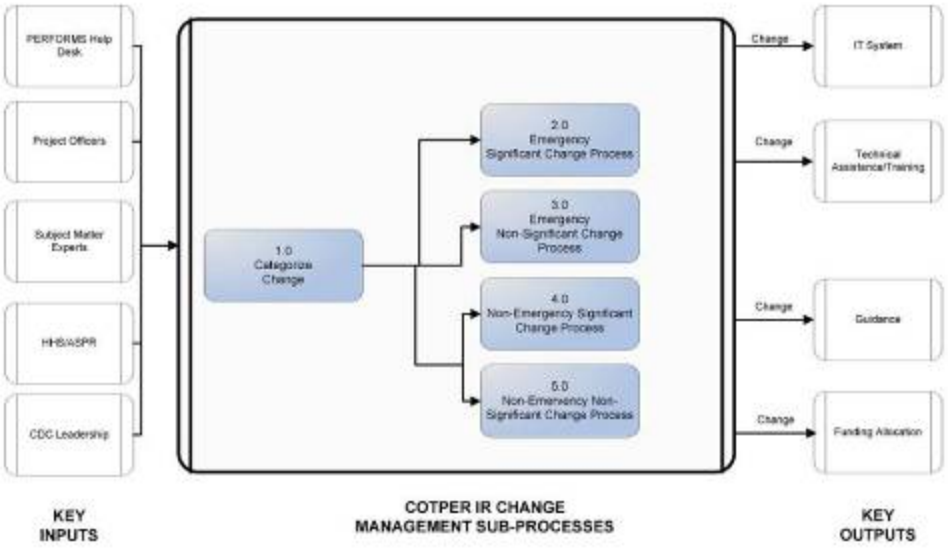
The following outlines the standard operating procedures for the CMB:

- DSLR proposes there be a formal memorandum of understanding (MOU) between COTPER/DSLR and its stakeholder members that outlines their membership roles on the CMB as members of the CMB Steering Committee.
- PHEP CMB stakeholder members must agree to the PHEP CMB process for managing any proposed additions to the PHEP (during a project year or for a particular continuation year, regardless if the proposed change was coming from an internal CDC requestor, an external CDC requestor, e.g. HHS, DHS, or the CDC OD)
- The CMB will meet on a quarterly basis, or as determined by the CMB Chair and CMB Steering Committee.
- The CMB meeting will be scheduled by the DSLR Change Administrator and notification of the date, time, and location will be distributed to all steering committee members.
- The Change Administrator will take, maintain, and distribute meeting minutes for each CMB meeting.
- The CMB meetings will operate as follows:

- Attendance
- Progress report on implementation of PHEP changes to date
- Status reports on SME involvement with implementation of proposed new priorities (see Appendix E Criteria)
- New proposed PHEP change requests
- Presentation and vote

High-Level Process Overview

The following provides a high level view of the complete PHEP change management Process



The process flow consists of three parts:

- Key inputs represent the processes that may trigger an event that initiates the change management process
- Sub-processes represent the main components of the change management process
- Key outputs represent the processes and products that may be impacted by the results or completion of the change management process

INPUTS: Sources of the Change Request

Inputs	Description
CDC SMEs	Feedback is solicited from COTPER and CDC SMEs that align to the proposed priorities/capabilities for the 2010-2015 PHEP
PERFORMS Help Desk	The Preparedness Emergency Response System for Oversight Reporting and Management Services (PERFORMS) is a web-based grants management system that helps automate the entire PHEP life cycle. Awardees call the help desk for assistance with technical aspects of working with the system. Issues may be generated during these help desk calls that may have implications for programmatic changes. The PERFORMS help desk therefore serves as a valuable source for potential changes to the guidance
DSLR Project Officer	Project officers, during the course of their interactions with awardees, may have suggestions for changes to the system
HHS/ASPR	The Department of Health and Human Services and the Assistant Secretary for Preparedness Response may recommend changes to the PHEP as this agency has oversight over CDC activities.
CDC Procurement and Grants Office (PGO)	This office has the authority to clear the guidance and to direct how the grants management processes are implemented.
DSLR OD	Changes may be recommended by staff in the DSLR Office of the Director.
CDC Leadership	Requests for changes may come from CDC leadership outside of DSLR OD.

OUTPUTS: Processes that can be impacted by Changes

Outputs	Descriptions
Guidance Documents	Change request can result in modifications to the guidance documents
TA/Technical	Change request can result in modifications to the technical assistance (TA)

Assistance	that is delivered to grantees
PHEP Conceptual Model	Change request can result in modifications to one or more components of the PHEP conceptual model
PHEP Business Process	Change request can result in modifications to the awardee management process
Funding Allocation	Change request can result in modifications to the funding distribution
IT Systems	Change requests can result in modifications to the grants management system, PERFORMS, that automates the entire life cycle of the PHEP.

Sub-Processes

This section outlines, at a high level, the activities, inter-relationships, and responsibilities involved in each of the four sub-processes within the change management process. The four sub-processes are:

1. Emergency Significant Change Process
2. Emergency Non-Significant Change Process
3. Non Emergency Significant Change Process
4. Non-Emergency Non-Significant Change Process

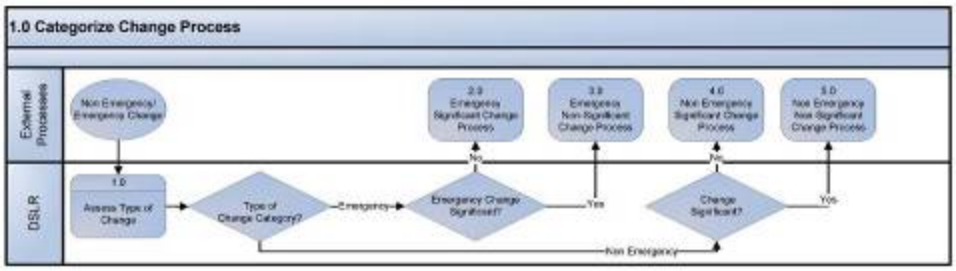
DSLR will also be identifying routine modifications that do not require a formalized change request. Routine modifications are not part of the change categorization process, because they do not require a change request.

Sub-process 1: Categorize Change Process

During this sub-process, the CMB Chair classifies the category of the change. Listed below are five change categories for this process:

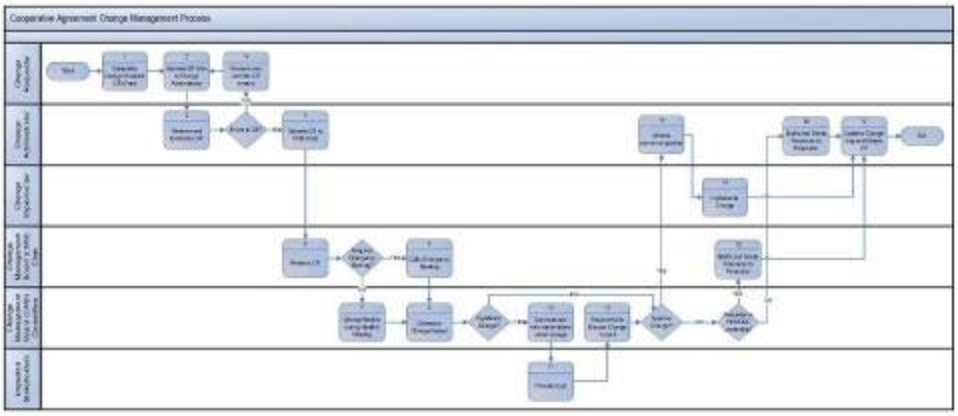
Change Category	Description
Emergency Significant Change Process	A change request is an emergency and meets the criteria of an emerging threat, namely that there is supporting credible evidence that the threat exists, evidence that the threat is within the control of state and local public health, and evidence that this proposed change requires immediate implementation. A significant change results in modifying the PHEP conceptual model or any agreed-upon reporting requirements.
Emergency Non-Significant Change Process	A change request is an emergency and meets the criteria of an emerging threat, namely that there is supporting credible evidence that the threat exists, evidence that the threat is within the control of state and local public health, and evidence that this proposed change requires immediate implementation. A non-significant change does not change the PHEP conceptual model or any agreed-upon reporting requirements.
Non-Emergency- Significant Change Process	A change request is not an emergency if it does not meet the criteria of an emerging threat and there is no supporting credible evidence that the threat is within the control of state and local public health and that the proposed change requires immediate implementation. A significant change results in modifying the PHEP conceptual model or any agreed-upon reporting requirements.
Non-Emergency- Non-Significant Change Process	A change request is not an emergency if it does not meet the criteria of an emerging threat and there is no supporting credible evidence that the threat is within the control of state and local public health and that the proposed change requires immediate implementation.
No Change Needed	The request is determined to not require any changes to the PHEP program.

Sub-Process 1.0 Categorize Change Process



Sub-Process 2-5

1. Emergency Significant Change Process
2. Emergency Non-Significant Change Process
3. Non Emergency Significant Change Process
4. Non-Emergency Non-Significant Change Process



Sub-Process 2: Emergency, Significant

- The change requester completes the change request (CR) form (# 1)
- The Change Requester submits the CR form to the Change Administrator (# 2)
- The Change Administrator reviews and evaluates the CR form (# 3), convening any applicable DSLR branches to preliminarily assess the impact of the proposed change.
- If there are errors:
    - The Change Requester reviews and corrects the errors (# 4)
    - The Change Requester resubmits the CR form (# 2)
- If there are no errors, the Change Administrator submits the CR to the Change Management Board (CMB) Chair (# 5)
- The CMB Chair reviews the CR (# 6)
- The CMB Chair calls an emergency meeting with the CMB Steering Committee (# 8)
- The CMB Steering Committee determines the change impact (# 9)
- The CMB Steering Committee communicates with the affected stakeholders about the change (# 10)
- The affected stakeholders provide their input (# 11)
- The CMB Steering Committee reconvenes to discuss the change impact (# 12)
- If the CMB Steering Committee approves the change:
    - The Change Administrator informs the concerned parties (# 13)
    - The Change Implementer implements the change (# 14)
- If the CMB Steering Committee denies the change:
    - If the requester is from HHS/CDC leadership, the CMB Chair meets with the COTPER Director to advise as to the CMB Steering Committee's recommendation; based upon the results of that meeting, drafts and sends a response to the requester on behalf of COTPER (# 15)
    - If the requester is not from HHS/CDC leadership, the Change Administrator drafts and sends a response to the requester (#16)
- The Change Administrator updates the change log and closes the CR (#17)

Sub-Process 3: Emergency, Non-Significant

- The Change Requester completes the change request (CR) form (# 1)
- The Change Requester submits the CR to the Change Administrator (# 2)
- The Change Administrator reviews and evaluates the CR (# 3), convening any applicable DSLR branches to preliminarily assess the impact of the proposed change.
- If there are errors:
    - The Change Requester reviews and corrects the errors (# 4)
    - The Change Requester resubmits the CR (# 2)
- If there are no errors, the Change Administrator submits the CR to the Change Management Board (CMB) Chair (# 5)
- The CMB Chair reviews the CR (# 6)
- The CMB Chair call an emergency meeting with the CMB Steering Committee (# 8)

- The CMB Steering Committee determines the change impact (# 9)
- If the CMB Steering Committee approves the change:
  - The Change Administrator informs the concerned parties (# 13)
  - The Change Implementer implements the change (# 14)
- If the CMB Steering Committee denies the change:
  - If the requester is from HHS/CDC leadership, the CMB Chair meets with the COTPER Director to advise as to the CMB Steering Committee's recommendation; based upon the results of that meeting, drafts and sends a response to the requester on behalf of COTPER (# 15)
  - If the requester is not from HHS/CDC leadership, the Change Administrator drafts and sends a response to the requester (#16)
- The Change Administrator updates the change log and closes the CR (#17)

Sub-Process 4: Non-Emergency, Significant

- The Change Requester completes the change request (CR) form (# 1)
- The Change Requester submits the CR to the Change Administrator (# 2)
- The Change Administrator reviews and evaluates the CR (# 3), convening any applicable DSLR branches to preliminarily assess the impact of the proposed change.
- If there are errors:
  - The Change Requester reviews and corrects the errors (# 4)
  - The Change Requester resubmits the CR (# 2)
- If there are no errors, the Change Administrator submits the CR to the Change Management Board (CMB) Chair (# 5)
- The CMB Chair reviews the CR (# 6)
- The CMB Steering Committee reviews the change during their quarterly meeting (# 7)
- The CMB Steering Committee determines the change impact (# 9)
- The CMB Steering Committee communicates with the affected stakeholders about the change (# 10)
- The affected stakeholders provide their input (# 11)
- The CMB Steering Committee reconvenes to discuss the change impact (# 12)
- If the CMB Steering Committee approves the change:
  - The Change Administrator informs the concerned parties (# 13)
  - The Change Implementer implements the change (# 14)
- If the CMB Committee denies the change:
  - If the requester is from HHS/CDC leadership, the CMB Chair meets with the COTPER Director to advise as to the CMB Steering Committee's recommendation; based upon the results of that meeting, drafts and sends a response to the requester on behalf of COTPER (# 15)
  - If the requester is not from HHS/CDC leadership, the Change Administrator drafts and sends a response to the requester (#16)
- The Change Administrator updates the change log and closes the CR (#17)

Sub-Process 5: Non-Emergency, Non-Significant

- The Change Requester completes the change request (CR) form (# 1)
- The Change Requester submits the CR to the Change Administrator (# 2)
- The Change Administrator reviews and evaluates the CR (# 3), convening any applicable DSLR branches to preliminarily assess the impact of the proposed change.
- If there are errors:
  - The Change Requester reviews and corrects the errors (# 4)
  - The Change Requester resubmits the CR (# 2)
- If there are no errors, the Change Administrator submits the CR to the Change Management Board (CMB) Chair (# 5)
- The CMB Chair reviews the CR (# 6)
- The CMB Steering Committee reviews the change during their quarterly meeting (# 7)
- The CMB Steering Committee determines the change impact (# 9)
- If the CMB Steering Committee approves the change:
  - The Change Administrator informs the concerned parties (# 13)
  - The Change Implementer implements the change (# 14)
- If the CMB Steering Committee denies the change:
  - If the requester is from HHS/CDC leadership, the CMB Chair meets with the COTPER Director to advise as to the Committee's recommendation; based upon the results of that meeting, drafts and sends a response to the requester on behalf of COTPER (# 15)
  - If the requester is not from HHS/CDC leadership, the Change Administrator drafts and sends a response to the requester (#16)
- The Change Administrator updates the change log and closes the CR (#17)

Appendix A

Requirements for Proposed PHEP Cooperative Agreement Changes

- Emerging threats need to be supported by credible evidence and evidence that the threat is within the control of state and local public health
- Proposed changes need to include a description of the potential impact of the proposed changes to state and local public health
- Proposed changes must address state and local awardees capacity to perform the proposed activity or capability as well as potential data burdens for the awardees
- Proposed changes must address potential impact to the 2010-2015 PHEP framework,
- Proposed changes must address and provide a solution for staffing support to implement the proposed new priority (e.g. if a center or program wants to add a topic to the PHEP, they would have to provide staffing support to DSLR)

Appendix B

Terminology

Term	Definition
Change	A change consists of any variation from the PHEP conceptual framework, established business processes driving the work of awardees and project officers, and requirements for the PHEP cooperative agreement.
Change Request (CR)	This is a formal request for changes to be made. A change request includes details of the proposed change and may be recorded on paper or electronically
Change Management Board (CMB)	A change management board (CMB) is a formally constituted group of stakeholders responsible for reviewing, evaluating, approving, or rejecting the implementation of changes within a project.
Routine Modifications	Low-risk, frequently occurring changes with low programmatic impact on DSLR or the awardees. Once a type of change is approved as a routine modification, it can be implemented without formal approval but still needs documentation.
Triple Constraints	Triple constraints involve tradeoffs between scope, time, cost, and quality for a project. While changes are inevitable, when there is a change to one of the triple constraints, such as cost, it is vital to make appropriate adjustment to other areas like scope and schedule.

Appendix J
List of Briefing Materials Provided in Advance to the Workgroup

Table of contents of the briefing book provided to the workgroup

Tab 1: External Reviewer Roles and Responsibilities

Tab 2: Scope of Review

Tab 3: Review Objectives and Process

Tab 4: Individual Reviewer Comment Form for Review Questions

Tab 5: Meeting Agenda

Tab 6: Meeting Presentations (*available at meeting*)

Tab 7: Pre-Meeting Webinar – August 31, 2009

A. Agenda

B. Presentations (*to be provided via e-mail week of August 24, 2009)*

Tab 8: Biographies

A. External Reviewer Biographies

B. DSLR Staff Biographies

C. Invited Speaker Biographies (*available at meeting*)

Tab 9: Acronyms List

Tab 10: Background Materials for Reviewers

*** All materials considered required background reading except those noted as optional below.*

A. A Methodology for Prioritizing Public Health Preparedness Capabilities

B. DSLR Development and Implementation of the 2005-2010 PHEP Cooperative Agreement

C. PHEP cooperative agreement requirements and authorizations
   - Appendices B and C of the DSLR Development and Implementation of the 2005-2010 PHEP Cooperative Agreement

D. Flow chart of the 2005-2010 PHEP approval process and role of significant stakeholder inputs to that process

E. "State and Local Preparedness: Reality of Preparedness"
   - Draft white paper from COTPER's Enterprise Communication Office describing PHEP funding history and funding issues

F. DSLR Program Announcement Change Management Board Proposal

G. Miscellaneous (*optional*)

   a. DSLR Fact Sheet

b. PHEP Fact Sheet

c. 2005-2010 PHEP cooperative agreement (initial Program Announcement AA154 and subsequent annual budget period continuation guidance 2006 – 2010) – *files provided via CD-ROM*

d. Department of Homeland Security Target Capability List User Guide

e. Funding Opportunity Primer Summary Sheet

f. Organizational Charts (COTPER, DSLR)

Appendix K
Acronyms and Definitions

AAR	After Action Report
APHL	Association of Public Health Laboratories
ASPR	(Office of the) Assistant Secretary for Preparedness and Response (HHS)
ASTHO	Association of State and Territorial Health Officials
ATSDR	Agency for Toxic Substances and Disease Registry (CDC)
BARDA	Biomedical Advanced Research and Development Authority (HHS)
BP (BP9)	Budget Period. This is used to refer to a required budget period (i.e. BP9) for PHEP reporting. Previously referred to as the Interim Progress Report
BSC	Board of Scientific Counselors
CA	Cooperative Agreement. This an award of financial assistance that is used to enter into the same kind of relationship as a grant but is distinguished from a grant in that it provides for substantial involvement between the federal agency and the recipient in carrying out the activity contemplated by the award
CBRNE	Chemical, Biological, Radiological, Nuclear, and Explosive agents
CCEHIP	Coordinating Center for Environmental Health and Injury Prevention (CDC)
CCID	Coordinating Center for Infectious Diseases (CDC)
CDC	Centers for Disease Control and Prevention
CEFO	Career Epidemiology Field Officer (CDC)
CERC	Crisis and Emergency Risk Communications
CoCHIS (CCHIS)	Coordinating Center for Health Information and Service (CDC)
CoCHP (CCHP)	Coordinating Center for Health Promotion (CDC)
COGH	Coordinating Office for Global Health (CDC)
COOP	Continuity of Operations Plan or Continuation of Operation Plan
COTPER	Coordinating Office for Terrorism Preparedness and Emergency Response. COTPER has primary oversight and responsibility for all programs that comprise CDC's terrorism preparedness and emergency response portfolio. COTPER has 5 divisions.
CPHP	Centers for Public Health Preparedness
CRI (CRI-MSA)	Cities Readiness Initiative or Cities Readiness Initiative Metropolitan Statistical Area
CSTE	Council of State and Territorial Epidemiologists
DBS	Division of Business Services. DBS is the COTPER Division that supports resource management, planning, organizing, and

	day to day operations of other COTPER Divisions.
DEO	Division of Emergency Operations. DEO is the COTPER Division responsible for overall coordination of CDC's preparedness, assessment, response, recovery, and evaluation prior to and during public health emergencies. The DEO has overall responsibility for the CDC Emergency Operations Center (CDC-EOC) which maintains situational awareness 24/7/365, and when activated, the EOC is the centralized location for event management.
DFO	Designated Federal Official
DHHS/HHS	U.S. Department of Health and Human Services
DHS	U.S. Department of Homeland Security
DOD/DoD	U.S. Department of Defense
DSAT	Division of Select Agents and Toxins. DSAT is the COTPER Division that regulates the possession, use, and transfer of biological agents and toxins (select agents) that could pose a severe threat to public health and safety. This regulatory activity is carried out by DSAT's Select Agent Program. The Program ensures compliance with safety and security standards for possession, use, and transfer of select agents by providing guidance for implementing standards and evaluating and inspecting entities.
DSLR	Division of State and Local Readiness. DSLR provides support technical guidance, and fiscal oversight to state, local, tribal, and territorial public health department grantees for the development, monitoring and evaluation of public health plans, infrastructure and systems to prepare for and respond to terrorism, outbreaks of disease, natural disasters and other public health emergencies.
DSNS	Division of the Strategic National Stockpile. DSNS is the COTPER Division that maintains a deployable national repository of medical materiel for use during "public health emergencies." The DSNS also provides technical assistance to ensure federal, state, and local capacity is developed to receive, stage, store and distribute SNS assets.
EIS	Epidemic Intelligence Service (CDC)
Epi-X	Epidemic Information Exchange
ESAR-VHP	Emergency System for Advance Registration of Volunteer Health Professionals
EWIDS	Early Warning Infectious Disease Surveillance
FACA	Federal Advisory Committee Act
FOA	Funding Opportunity Announcement
FSR	Financial Status Reports
FTE	"Full Time Equivalent" employee. Refers to the Federal Civilian workforce as opposed to individuals employed by contracting agencies.

GAO	Government Accounting Office
HHS/DHHS	U.S. Department of Health and Human Services
HSEEP	Homeland Security Exercise and Evaluation Program
HSPD-21	Homeland Security Presidential Directive-21
IAP	Incident Action Plan
ICS	Incident Command System
IPR	Interim Progress Report. Currently referred to as a BP (budget period) update
LRN	Laboratory Response Network (CDC)
MOF	Maintenance of Funding
MSF	Maintaining State Funding. MSF represents an applicant's historical level of contributions related to federal programmatic activities which have been made prior to the receipt of federal funds expenditures (money spent)
NCCDPHP	National Center for Chronic Disease Prevention & Health Promotion (CDC)
NCEH	National Center for Environmental Health (CDC)
NCHM	National Center for Health Marketing (CDC)
NCHS	National Center for Health Statistics (CDC)
NCHSTP	National Center for HIV, STD, and TB Prevention (CDC)
NCID	National Center for Infectious Diseases (CDC)
NCIPC	National Center for Injury Prevention and Control (CDC)
NCIRD	National Center for Immunization and Respiratory Diseases
NCPHI	National Center for Public Health Informatics (CDC)
NCTC	National Counterterrorism Center
NCZVED	National Center for Zoonotic, Vector-Borne, and Enteric Diseases (CDC)
NEXS	National Exercise Schedule
NHSS	National Health Security Strategy is a quadrennial report required (by PAHPA) to be developed by the Secretary of HHS and submitted to Congress. The first NHSS is due to Congress in 2009 and is not anticipated to be completed until December 2009.
NIMS	National Incident Management System
NJTTF	National Joint Terrorism Task Force
NNDSS	National Notifiable Diseases Surveillance Systems (CDC)
NOPHG	National Office of Public Health Genomics (CDC)
NRF	National Response Framework
NRP	National Response Plan
OD	Office of the Director (CDC)
OMB-PRA	Office and Management and Budget Paperwork Reduction Act. OMB PRA clearance is required to conduct federally sponsored data collections.
OMEB	Outcome Monitoring and Evaluation Branch (one of two DSLR Branches). OMEB is generally responsible for

	maintaining a sophisticated grantee reporting platform, developing grantee performance measure targets, and evaluating grantee data submissions.
OPR	Office of Preparedness and Response (HHS)
OCSO	Office of the Chief Science Officer. The Chief Science Officer and staff provide CDC/ATSDR with scientific vision and leadership in science innovation, research, ethics, and science administration.
OSPHP	Office of Science and Public Health Practice (COTPER, CDC)
OWCD	Office of Workforce and Career Development (CDC)
PAHPA	Pandemic All Hazards Preparedness Act. (Public Law 109-417 signed in December, 2006). PAHPA centralizes federal responsibilities, requires state-based accountability, proposes new national surveillance methods, addresses surge capacity, and facilitates the development of vaccines and other scarce resources.
PGO	Procurement and Grants Office. PGO provides non-programmatic management for all CDC financial assistance activities (grants and cooperative agreements) and manages and awards all CDC contracts.
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHEP (or PHEP CA)	Public Health Emergency Preparedness Cooperative Agreement. The name for the Cooperative Agreement managed by DSLR.
PHIN	Public Health Information Network
PERFORMS	Preparedness Emergency Response System For Oversight, Reporting, and Management Services. PERFORMS is an electronic management information system. Awardees submit their funding applications through this system, and all fiscal and programmatic reports are monitored here.
POD	Point of Dispensing
PSB	The Program Services Branch (one of two DSLR Branches). PSB Project Officers generally provide grantee oversight (budget, timelines, other administrative requirements, etc.) and coordinate PHEP grantee activities with applicable SME's and other internal/external stakeholders.
SME	Subject Matter Expert. SME(s) generally provide targeted technical assistance within very specific programmatic areas (e.g. DSAT speaking with state laboratory Directors about chemical agent testing). DSLR Project Officers sometimes rely on SME(s) to help grantees achieve specific emergency preparedness activities.
SNS	Strategic National Stockpile. Term refers to the actual medical materiel maintained by the DSNS
TA	Technical Assistance. As it applies to the PHEP, the general activity of providing clarification, successful practices and

	other information with partners and grantees.
TARs	Technical Assessment Reviews (conducted by SNS program technical advisory staff)
TCL	Target Capabilities List (HHS)