

## **Application of Public Health Laboratory Testing Performance Measures into Practice Case Study**

### **Purpose**

This case study provides PHEP Awardees with examples that will allow them to apply performance measures (PM) guidance to their jurisdictions. The case study is intended to provide examples of how the performance measures can be implemented; awardees are encouraged to review the aspects that may apply to them while ensuring that the measures apply to the particulars of their own jurisdictions.

### **PHEP 12.1 Laboratorian Reporting**

Time for initial laboratorian to report for duty at the PHEP-funded laboratory

### **PHEP 12.2 24/7 Emergency Contact Drill (Bi-Directional)**

Time to complete notification between CDC, on-call laboratorian, and on-call epidemiologist or between CDC, on-call epidemiologist and on-call laboratorian – depending on drill direction

### **PHEP 12.3 LRN Emergency Response Pop Proficiency Test (PopPT) Exercise**

Ability of PHEP-funded LRN-C Level 1 and/or Level 2 laboratories to detect and quantify biomarkers of chemical agents in clinical samples during the LRN Emergency Response Pop Proficiency Test (PopPT) Exercise

### **PHEP 12.4 Notification to Partners**

Time for PHEP-funded laboratory to notify public health partners of significant laboratory results

### **PHEP 12.5 Proficiency Testing (LRN-C Additional Methods)**

Proportion of LRN-C proficiency tests (additional methods) successfully passed by PHEP-funded laboratories

### **PHEP 12.6 Proficiency Testing (LRN-C Core Methods)**

Proportion of LRN-C proficiency tests (core methods) successfully passed by PHEP-funded laboratories

### **PHEP 12.7 Sample Collection, Packing, and Shipping (SCPAs)**

Ability of PHEP-funded LRN-C laboratories to collect, package, and ship samples properly during an LRN exercise

### **PHEP 12.8 LRN Surge Capacity Exercise**

Ability of each PHEP-funded LRN-C Level 1 laboratory to process and report results to CDC for 500 samples during the LRN Surge Capacity Exercise

### **PHEP 12.9 Communication between PHEP-funded and Sentinel Clinical Laboratories**

Time for sentinel clinical laboratories to acknowledge receipt of an urgent message from PHEP-funded LRN-B Laboratory

### **PHEP 12.10 Notification Drill associated with Proficiency Testing**

Ability of PHEP-funded LRN-B reference laboratory to contact the CDC Emergency Operations Center within 2 hours during LRN notification drill

### **PHEP 12.11 Proficiency Testing (LRN-B)**

Proportion of LRN-B proficiency tests successfully passed by PHEP-funded laboratories

### **PHEP 12.12 Sample Quality – First Responders**

Percentage of LRN nonclinical samples received by the PHEP-funded LRN-B laboratory for confirmation or rule-out testing from first responders without any adverse quality assurance events (QA)

**PHEP 12.13 Specimen Quality – Sentinel Clinical Laboratory**

Percentage of LRN clinical specimens received by PHEP-funded LRN-B laboratory for confirmation or rule-out testing from sentinel clinical laboratories without any adverse QA events

**PHEP 12.14 PFGE *E. coli***

Percentage of pulsed field gel electrophoresis (PFGE) subtyping data results for *E. coli* O157:H7 submitted to the PulseNet (PN) national database within four working days of receiving isolate at the PFGE laboratory

**PHEP 12.15 PFGE *L. monocytogenes***

Percentage of pulsed field gel electrophoresis (PFGE) subtyping data results for *Listeria monocytogenes* submitted to the PulseNet (PN) national database within four working days of receiving isolate at the PFGE laboratory

**Public Health Laboratory Testing Case Study**

Since Public Health Laboratory Testing (PHLT) is a core public health capability, Awardee X always designates a portion of PHEP (Public Health Emergency Preparedness) funding to this capability. PHEP funding contributes to the continued success of laboratories by supporting staff, equipment, and materials. Awardee X is developing plans to collect the needed Performance Measure data during budget period (BP) 1 for the 13 required PMs for this capability. These plans will be reported to the Centers for Disease Control (CDC) Division of State and Local Readiness (DSLRL) in the Performance Narrative section within the PHEP applications and followed by Awardee X to ensure the following:

- 1) PM data is collected and reported to CDC in accordance with the FOIA
- 2) Appropriate CDC supported technical assistance is available to aid awardees in achieving the measures
- 3) Funding accountability for continued success of the PHEP program.

Successful execution of the PHLT performance measures require coordination and communication between Awardee X's Public Health Emergency Preparedness program (PHEP) and their PHEP funded laboratory; therefore, Awardee X's PHEP Director schedules a meeting with the Laboratory (Lab) Director to discuss coordinating reporting and validation activities associated with the PHLT performance measures. Awardee X's biological (bio) and chemical (chem) laboratory function as a single entity, for that reason the PHEP Director only needs to collaborate with one Lab Director on reporting efforts. If Awardee X had a separate biological and chemical laboratory then the PHEP director would need to meet with both lab directors. The PHEP Director has also incorporated the deliverables pertaining to performance measure data collection into a written contract with the laboratory since the PHEP program is providing funding.

During the meeting, Awardee X's PHEP and Lab Directors first discuss the July 1, 2012- June 30, 2013 Performance Measure Specification and Implementation Guidance for the PHLT performance measures (pg 91-120) with the goal of identifying when, what, and how they will need to communicate performance as well as other lab related results collected by PHEP and the Laboratory Response Network (LRN). They decide not to report on the 2 optional measures (PHEP PM 12.1 & PHEP PM 12.9) during this budget period so that they can concentrate on meeting the required measures first.

The directors discuss the 7 CDC LRN-B and LRN-C collected PHEP performance measures next. Since Awardee X has a level 1 chemical lab, the Lab Director shares that they are responsible for reporting on the LRN Emergency PopPT (PopPT) Exercise (PHEP PM 12.3), 2 LRN-C proficiency tests (core and additional) (PHEP PM 12.5 & 12.6), LRN-B proficiency test (PHEP PM 12.11), Sample Collection, Packing and Shipping (SCPaS) (PHEP PM 12.7), the Surge Capacity Exercise (PHEP PM 12.8), and Notification Drill associated with proficiency testing (PHEP PM 12.10). After reading through the measure's guidance requirements, the directors realize that they simply need to communicate with each other to meet the reporting requirements for the PHEP lab measures currently collected by CDC LRN offices. PHEP lab measures collected by the CDC LRN offices require the PHEP Director to confirm, in PERFORMS, that the reported results for these drills and exercises are accurate. Therefore, the Lab Director agrees to email the results of their LRN drills and exercises to the PHEP Director after the lab has validated and, if necessary, remediate those results with the relevant CDC LRN office. The Lab Director agrees to provide the PHEP Director with the validated results within a week of confirming their accuracy with the CDC LRN-B or LRN-C offices so that the PHEP Director will have the results available to confirm the results in PERFORMS. They discuss the importance of continuing their conversation about the LRN-B and LRN-C performance measures throughout the year. The PHEP Directors realize that the continued success of their lab and the PHEP depends not only on performance outcomes but on consistent communication about both successes and challenges concerning the lab. However, both Directors take note that if they do not pass or participate in the Biological or Chemical Proficiency Tests, the PHEP Director will have to communicate the reasons and the corrective actions to be implemented to DSLR. Upon not passing a proficiency test, even after remediation, or not participating in a proficiency test, they agree to have another meeting so the Lab Director can communicate to PHEP Director the root causes preventing them from passing or participating and the corrective actions being initiated to prevent future occurrences of the critical error/event. The Directors then move on to discussing the 4 required PHEP specific performance measures that are not collected by the CDC LRN programs directly (PHEP PM 12.2, 12.4, 12.12, 12.13).

They begin the PHEP specific performance measure discussion with the 24/7 Emergency Contact Drill for both the chemical and biological laboratories (PHEP PM 12.2). The PHEP Director provides the Lab Director with a copy of the Drill Overview that was provided by CDC. Since two drills were already conducted, the Lab Director is familiar with the process. However, both directors review the pre-drill, drill, and post drill activities sections together. They discuss the importance of providing and updating both the CDC LRN website and the DSLR project officers with the correct contact information for the on-call laboratorians and epidemiologists, respectively, as well as ensuring that the on-call

laboratorians and epidemiologists have each other's contact information. The importance of communicating the drill procedures and results with all key personnel involved is also discussed. Since the 24/7 Emergency Contact Drill requires the direct involvement of the laboratorian and the epidemiologist, the PHEP director may not be able to validate the accuracy of the reported drill time without consulting with the Lab Director. Therefore, the PHEP Director assures the Lab Director that PHEP will provide the lab with the recorded drill performance times received from DSLR and consult with the lab to ensure the accuracy of the drill times. If the recorded drill time indicates that they did not meet the time target, both directors understand that they will need to work more closely together to identify the root cause of the failure and implement corrective actions. Ending the 24/7 drill discussion, the PHEP director also discusses incorporating lab staff into future PHEP exercises and considers the possibility of including PHEP staff in lab exercises. They both understand that including the different departments in each other's exercises will provide an opportunity for staff from both departments to work together, which would greatly increase the ability for their state to respond effectively in an emergent situation.

The directors then discuss the Notification to Partners measure (PHEP PM 12.4). Since the Bio and Chem Laboratories operate as one entity, Awardee X only needs to report on this measure once. However, if Awardee X's laboratories did not operate as one entity, it would need to report on this measure twice, once for bio and once for chem lab. The Directors talk over the importance of notifying field partners when testing credible suspect material requiring use of LRN algorithms and assays for both clinical and non-clinical samples. They then review the list of partners listed in the Performance Measure Guidance document (pg 97 and 98) and brainstorm to identify other partners in the field that would be important to notify in case highly pathogenic or virulent agents precipitate a real public health incident. They discuss which partners should be alerted of the *possibility* of a positive result even before a positive result could be processed or, in contrast, notified of negative results. They document their decisions regarding which partners would need to be alerted for what type of significant clinical and non-clinical results. Finally, the directors discuss the importance of developing templates that will appropriately capture all the needed information listed in the data elements (i.e. type of specimen, date and time of result, and the date and time of which partners were notified) before moving on to discuss the next PHEP PHLT performance measure.

The directors move on to reviewing the Sample Quality – First Responders measure (PHEP PM 12.12). Historically, Awardee X's lab has not received many non-clinical (i.e. non-human specimens [food, soil, powder, water or animal products]) samples from first responders. However, the PHEP Director communicates the importance of this measure to support training efforts in the field if needed. The PHEP Director shares lists of online trainings that have been developed by FEMA, the FBI, and others regarding the handling of certain non-clinical samples by first responders such as radiological and other hazardous materials. The lab director decides to conduct awareness training for the lab staff to review the policies and procedures that first responders should follow when submitting non-clinical samples so staff can recognize when an adverse quality assurance (a deviation from policies and procedures)

has taken place. The Lab Director realizes that this measure is important for recognizing whether first responders are following protocols and will help determine whether or not they should advocate for more first responder training for the submission of possibly hazardous non-clinical samples. Since the intent of this measure is to capture the quality of nonclinical samples received on a day-to-day basis, not through exercises, both directors review the data elements necessary for reporting to CDC and decide to develop a template to help them collect all the needed information (Appendix A).

The directors then discuss the last required PHEP PHLT measure, Specimen Quality – Sentinel Clinical Laboratories (PHEP PM 12.13). Since Awardee X's lab receives a high volume of specimens from sentinel clinical laboratories, the lab director recognizes the need for establishing a system to track the quality of these specimens. Fortunately, the laboratory director received some funding to upgrade the Laboratory Information Management System (LIMS), so it now has functionality which includes specimen and sample tracking that can be slightly modified to collect data for the PHEP performance measures. Had there not been a LIMS or similar system in place, the lab director may have had to ask staff to use an Excel spreadsheet or a similar technology in order to manually track specimen quality. The lab director decides that it will be appropriate to develop and institute training for lab employees on when and how to document the needed information in the LIMS system. He also makes a 1-2 year goal to develop a refresher course (for sentinel lab staff) on the proper collecting, packaging, and shipping of specimens and samples to the state public health lab.

Finally, the directors discuss the well-established Pulse Field Gel Electrophoresis (PFGE) performance measures (PHEP PM 12.14 & 12.15). The PHEP director learned from the BP1 performance measures guidance document that in this and subsequent budget periods, the data for this measure will be obtained from CDC PulseNet program directly as well as from data submitted by awardees of the Epidemiology and Laboratory Capacity (ELC) cooperative agreement. Since the PHEP director continues to partially fund (along with the state ELC program) PFGE activities at the state public health laboratory, the PHEP director realizes that she will need to verify the PFGE performance measure data, which will be supplied to her by CDC after the data has been collected at the end of the budget year. She therefore coordinates with the lab director to touch base quarterly on the extent to which the lab is able to submit *E. coli* O157:H7 and *L. monocytogenes* results into the PulseNet database within four working days as called for in the measure. Since the PHEP director actually doesn't know the state ELC program coordinator very well, she makes it a priority to set up a meeting between herself, the ELC coordinator and the state public health laboratory director so they can coordinate their PM data collection efforts as well as strategize collectively about their priorities moving forward.

Appendix A

| Awardee Jurisdiction |                    |   |                                  |   |   |                                  |
|----------------------|--------------------|---|----------------------------------|---|---|----------------------------------|
| Date                 | Sample origination | Collected by type of first responder (i.e. EMS, police) | Total number of samples received | Total number of samples with adverse quality assurance events | Description of adverse quality of assurance event | Description of corrective action |
|                      |                    |   |                                  |   |   |                                  |
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| U.S Territory |                    |   |                                  |   |   |                                  |
|---------------|--------------------|---|----------------------------------|---|---|----------------------------------|
| Date          | Sample origination | Collected by type of first responder (i.e. EMS, police) | Total number of samples received | Total number of samples with adverse quality assurance events | Description of adverse quality of assurance event | Description of corrective action |
|               |                    |   |                                  |   |   |                                  |
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