

Laboratory System Improvement Program Glossary

The glossary committee developed this glossary specifically for the Public Health Laboratory Systems Performance Standards. Many definitions have been borrowed in their entirety or have been modified from the listed citations. We acknowledge and thank those sources for the work they have done. If readers have questions we advise you to refer to the original source of the definition. **(Indicated here in parentheses).**

Aggregate surveillance: The surveillance of a disease or health event performed by an authoritative body or organization collecting summary data on groups of cases. **(A Dictionary of Epidemiology)**

ArboNET: a comprehensive reporting system that collects, analyzes and reports back to health agencies and the public surveillance data on six arboviral diseases including West Nile Virus, from humans, mosquitoes, birds, mammals and sentinel chicken flocks.

ASC X12/ ANSI ASC X12 - American National Standards Institute (ANSI) Accredited Standards Committee (ASC.): the U.S. national standards body for the development and maintenance of Electronic Data Interchange (EDI) standards including electronic transactions named as standards by the Health Information Portability and Accountability Act (HIPAA). **(Public Health Data Consortium)**

Assurance: The process of determining that services necessary to achieve agreed upon goals are provided, either by encouraging actions by other entities (public or private sector), by requiring such action through regulation, or by providing service directly. **(Institute of Medicine, the Future of Public Health)**

Assure: To make sure or certain **(Webster's)**

Beta testing: the last stage of testing for a computer or instrument product prior to commercial release; normally involves sending the product to beta test sites outside the company for real-world exposure or offering the product

Biomonitoring: The process of measuring environmental chemicals in people, used to determine what environmental factors may influence conditions or diseases such as birth defects, developmental disabilities and cancer. Biomonitoring is also an essential part of the public health response to chemical emergencies whether accidental or terrorist.

CaliciNet: Network of state and local public health laboratories coordinated by CDC that provides electronic laboratory surveillance for norovirus outbreaks by comparing and genotyping norovirus strains based on sequence analysis

Clinical Laboratory Improvement Amendments of 1988 (CLIA): Extensive federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research.

Competencies/Competency Assessment: A process used to assess if individuals are performing their job satisfactorily. The review includes direct observation, monitoring of recording and reporting of test results, review of test results, quality control records, proficiency testing results and preventive maintenance records and evaluation of problem-solving and judgment skills. The review should be performed on a regular basis, such as at six months and with new employee and annually thereafter as required by CLIA. If problems are identified, retraining and ongoing assessment should follow.

Continuing Education (CE): refers to an array of opportunities by which professionals can augment existing knowledge and skills. CE is essential for professional competence, career development, and compliance with licensing rules and other regulations. CE is offered through a variety of auspices, methods, and venues. Advances in instructional technology and electronic communication have further expanded access to CE opportunities.

Continuity of Operations Plan (COOP): A plan that details the how essential functions of an agency will be handled during any emergency or situation that may disrupt normal operations.

Core Functions and Capabilities of Public Health Laboratories: defined public health laboratory functions in support of public health programs. The 11 core functions are disease prevention, control, and surveillance; integrated data management; reference and specialized testing; environmental health and protection; food safety; laboratory improvement and regulation; policy development; emergency response; public health-related research; training and education; and partnerships and communication.

Data Exchange/ Information Exchange: electronic transmission of information involving the process of taking data structured under a *source* schema and transforming it into data structured under a *target* schema, so that the target data is an accurate representation of the source data (Wikipedia)

Data Standards: documented agreements on representations, formats, and definitions of common data. Data standards provide a method to codify in valid, meaningful, comprehensive, and actionable ways, information captured in the course of doing business. (Public Health Data Consortium)

eLEXNET: a secure, integrated network that allows the exchange of information between Federal, State and local food safety agencies.

Essential Public Health Services: The 10 services identified in the Public Health in America: monitoring health status; diagnosing and investigating health problems; informing, educating, and empowering people; mobilizing community partnerships; developing policies and plans; enforcing laws and regulations; linking people to needed services; assuring a competent workforce; conducting evaluations; and conducting research. (Healthy People 2010, chapter 23-21). (NPHSP)

Environmental Public Health Tracking Program: Environmental public health tracking is the ongoing collection, integration, analysis, and interpretation of data about the following factors:

- Environmental hazards
- Exposure to environmental hazards
- Health effects potentially related to exposure to environmental hazards

The goal of environmental public health tracking is to protect communities by providing information to federal, state, and local agencies. These agencies, in turn, will use this information to plan, apply, and evaluate public health actions to prevent and control environmentally related diseases. (CDC, <http://www.cdc.gov/nceh/tracking/background.htm>)

FoodNet: Foodborne Diseases Active Surveillance Network is a collaborative project under CDC's Emerging Infections Program consisting of surveillance for foodborne diseases and related epidemiologic with CDC, ten sites (California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee), the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA) as partners.

Good Laboratory Practice: Processes that ensure the accuracy and reliability of high quality testing, i.e., quality control, training and competency, quality management

Incident Command System (ICS): A standardized, defined and structured system for the command, control and coordination of an emergency response.

Indicator: A measurement that reflects the statue of a system. Monitoring of indicators reveal the direction of a system (a community, the economy or the environment). **(NPHPSP)**

Information Exchange: See Data Exchange.

Initial Demonstration of Capability (IDC): A defined process to document that a laboratory can achieve acceptable precision, accuracy, sensitivity, and specificity for each method to be used before analyzing samples and reporting results. IDC must also include each analyst and technician who will perform the test. **(Environmental Protection Agency Laboratory Certification Program)**

Institutional Review Board (IRB): A formal committee responsible for approval, reviewing, and monitoring all biomedical and behavioral research involving human subjects that is conducted, supported or otherwise subject to regulation by any federal department or agency. The aim of the IRB process is to protect the rights and welfare of the research subjects.

Jurisdiction: Refers to any area within geopolitical boundaries such as a city a county, multiple counties, a state, a region or nation, within which a governmental agency has legal authority to perform a clearly defined function.

Laboratory-Developed Test (LDT): A laboratory test that is developed, evaluated and offered within a single laboratory. Initially, LDTs were generally relatively simple well-characterized, low-risk diagnostics using Analyte-Specific Reagents (ASR), or were used locally for rare diseases. In recent years however, LDTs have become more complex and more widely available; use elements which may not be FDA-regulated; and are being increasingly used to assess high-risk

but relatively common diseases and conditions by geographically distinct commercial laboratories. FDA has proposed a risk-based application of oversight to regulate LDTs (2010).

Laboratory Services: Includes all the testing and associated activities conducted by public and private laboratories in the support of primary health care, population-based public health and environmental protection; and for the purposes of disease diagnosis, surveillance, prevention and control.

Laboratory Response Network (LRN): An integrated national and international network of approximately 150 laboratories equipped for rapid response to acts of chemical or biological terrorism, emerging diseases, and other public health threats and emergencies. The LRN is made up of government, military and international laboratories; including state and local public health, food, veterinary and environmental laboratories.

LOINC: Logical Observations Identifiers Names and Codes: universal data identifiers for *laboratory results* and *clinical observations*, e.g., vital signs, outcomes management, and research.

Model Standard: An optimal level of performance and capacity to which all State Public Health Laboratory Systems should aspire. Model standards can not only serve as benchmarks by which the system can be judged, but also provide a level of expectation that can be used to advocate for new resources or needed improvements.

National Public Health Performance Standards: Standards that 1) identify optimal level of performance for state and local public health systems and governing bodies and 2) seek to ensure that strong effective public health systems are in place to deliver the ten essential public health services. **(NPHPSP)**

National Public Health Performance Standards Program: A collaborative effort to strengthen state and local public health practice through the establishment and application of public health system standards. **(NPHPSP)**

Necessary System Capacity: Adequate personnel, equipment, and resources to respond to day-to-day operations.

NREVSS: a laboratory-based system that monitors temporal and geographic patterns associated with the detection of respiratory syncytial virus (RSV), human parainfluenza viruses (HPIV), respiratory and enteric adenoviruses, and rotavirus. Data are collected from collaborating university and community hospital laboratories, selected state and county public health laboratories, and commercial laboratories. <http://www.cdc.gov/ncidod/dvrd/nrevss/>

Newborn Screening (NBS): A program of testing blood from newborns prior to discharge from a hospital or birthing center for certain endocrine, and metabolic disorders that can affect long-term health or survival. The objective of NBS is early detection, diagnosis, and intervention to prevent death or disability, and enable children to reach their full potential. Most NBS programs are coordinated by state government and many include testing for hearing loss.

Objective: Defined as results of specific activities or outcomes to be achieved over a stated time. Objectives are specific, measurable, and realistic statements of intention. Objectives state who will experience what benefit or change and how much change is to be experienced in what time. **(NPHPSP)**

Partner organizations: Groups formed by partners with similar interests such as county organizations, a regional group of laboratories or a regional physician group.

Partnership: A collaborative relationship of individuals and/or organizations within which partners determine to collaborate.

Performance standard: A generally accepted, objective form of measurement that serves as a rule or guideline against which an organization's level of performance can be compared. **(A Proposed Model for a Voluntary National Accreditation Program For State and Local Public Health Departments)**

Policy Development: The means by which problem identification, technical knowledge of possible solutions and societal values converge to set a course of action (Institute of Medicine. **(The Future of Public Health)**). As such policy development is an outgrowth of the assessment and monitoring activities described with respect to all other Essential Services. Policy development is not synonymous with the development of laws, rules, and regulations. Laws, rules, and regulations may be adopted as tools among others to implement policy. Policy development is a process that enables informed decisions to be made concerning issues related to the public's health. **(NPHPSP)**

Population based: Pertaining to a general population defined by geopolitical boundaries; this population is the denominator and/or the sampling frame. **(A Dictionary of Epidemiology)**

Professional Societies: Organizations for laboratory science professionals to promote specific activities, e.g., American Society of Clinical Pathologists, American Society of Microbiologists, College of American Pathologists.

Public Health: "...the science and the art of preventing disease, prolonging life, and promoting physical health and mental health and efficiency through organized community efforts toward a sanitary environment; the control of community infections; the education of the individual in principles of personal hygiene; the organization of medical and nursing service for the early diagnosis and treatment of disease; and the development of the social machinery to ensure to every individual in the community a standard of living adequate for the maintenance of health." **(Man and Epidemics)**

PulseNet: a network of National and regional laboratory networks dedicated to tracking foodborne infections world-wide, that utilizes standardized genotyping methods and sharing information in real-time. To provide early warning of food and waterborne disease outbreaks, emerging pathogens, and acts of bioterrorism.

Public Health Emergency: An occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or novel and highly infectious agent or biological toxin, that poses a substantial risk of a significant number of human fatalities or incidents of permanent long term disability. **(The Model State Emergency Health Powers Act)**

Public Health Laboratory (PHL): A scientific facility with the equipment and staff needed to conduct testing related to ongoing public health assessments and to respond to emergency public health issues. **(APHL)**

Quality Assurance: A program for systematic monitoring and evaluation of various aspects of a project, service, or facility to ensure standards of quality are followed and met. **(Webster's)**

Quality Improvement: Maximizes the managerial goals of operational efficiency, effectiveness and adaptability by synergistically combining quality planning, quality monitoring, quality teamwork, quality improvement and quality review within an integrated quality system. **(Modified from CLSI publication Continuous Quality Improvement Integrating Five Key Quality System Components)**

Reportable disease: Health conditions which are required through statute, ordinance, or administrative rule to be reported to a public health agency when they are diagnosed in individuals. **(NPHPSP). (National Notifiable Diseases Surveillance System).**

Research: Investigation, experimentation, or evaluation aimed at the discovery and interpretation of information, or the practical application of such information to the field of public health. Research may be categorized as applied, basic, clinical, systems and services, or translational. **(Comprehensive Laboratory Services Survey 2010 Glossary)**

- Applied- Solves problems rather than to acquire new knowledge. Such research might be used to improve a process.
- Basic - Tests a hypothesis or answer a scientific question. The motivation for such research is to acquire new knowledge.
- Clinical - Determines the safety or efficacy of medications, devices, diagnostic products/procedures and regimens. Often carried out for the prevention, treatment or diagnosis of a disease or condition.
- Systems and Services - Examines the organization, financing and delivery of public health services in communities, and assesses the impact of these services on public health.
- Translational - Translates the findings in basic research and applies them to meaningful health outcomes which broadly affect a population or community.

Retail Laboratory: Laboratories which are not associated with hospital or physician offices and perform non-waived patient requested testing. These laboratories can be found in retail pharmacies, shopping centers or big box stores.

Safe Drinking Water Information System (SDWIS): EPA's Safe Drinking Water Information System (SDWIS) databases store information about drinking water. The federal version (SDWIS/FED) stores the information EPA needs to monitor approximately 156,000 public water

systems. The state version (SDWIS/STATE) is a database designed to help states run their drinking water programs.

Sentinel Health Event: The detection in one or more sentinel laboratories of a microbial agent in one or more Sentinel Clinical Laboratories that poses a potential public health threat.

Social media/ social marketing: A discipline that addresses an issue with particular regard to those affected by it (target audience), considering their perspectives and perceived wants and needs to develop strategies toward change. **(National Cancer Institute. Making health Communication Work) (NPHPSP)**

Stakeholders: All persons, agencies and organizations with an investment or “stake” in the health of the community and the local public health system. This broad definition includes persons and organizations that benefit from and/or participate in the delivery of services that promote the public’s health and overall well-being **(NPHPSP)**

Standard: A level of quality or excellence used as a criterion by which actual attainments are judged.

State Public Health Laboratory (SPHL): A governmental facility that performs analytical testing for personal health and/or environmental health surveillance and disease prevention and control.

State Public Health Laboratory System: A partnership between public health laboratories and other state agencies, private laboratories, and other organizations and health care providers to assure laboratory services essential to the health of the public.

State Laboratory Training Coordinator: A laboratory professional who develops and coordinates training of state and local public health laboratory staff and, where appropriate, clinical laboratory staff, to promote use of best laboratory practice throughout the state to further public health, with particular regard to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies. Usually designated as working closely with APHL and CDC.

Succession Planning: development and implementation of education and recruitment strategies to accelerate the acquisition of laboratory leaders with vital scientific, technical, and managerial skills, in view of impending shortage of qualified candidates to fill top positions in public health laboratories.

Surge Capacity: the ability to respond in an emergency by redirecting personnel, equipment and resources.

Surveillance: the ongoing systematic collection, analysis, and interpretation of data (e.g., regarding agent/hazard, risk factor, exposure, health event) essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control. **(NPHPSP)**

SNOMED: Systemized Nomenclature of Medicine: - comprehensive, defined and controlled clinical terminology created for the indexing of the entire medical record, under the International Health Terminology Standards Development Organization. **(Public Health Data Standards Consortium)**

Training: systematic instruction and exercise in some art, profession, or occupation, with a view to proficiency in it. **(Oxford English Dictionary)**

Translational Science Research: a research approach that seeks to move “from bench to bedside” or from laboratory experiments through clinical trials to actual point-of-care patient applications **(Wikipedia)**

Acronyms

AAR/IP	After-Action Report/Improvement Plan
ANSI	American National Standards Institute
APHL	Association of Public Health Laboratories
ASC X12	Accredited Standards Committee X12
BT	Biological Terrorism
CDC	Centers for Disease Control and Prevention
CE	Continuing Education
CLIA	Clinical Laboratory Improvement Amendments of 1988
COOP	Continuity of Operations Plan
CT	Chemical Terrorism
DOT	United States Department of Transportation
eLEXNET	Electronic Laboratory Exchange Network
EPA	Environmental Protection Agency
FDA	Food and Drug Association
FERN	Food Emergency Response Network
HIPAA	Health Insurance Portability and Accountability Act
HL7	Health Level Seven
HPIV	Human Parainfluenza Virus
ICS	Incident Command System
IDC	Initial Demonstration of Capability
IRB	Institutional Review Board
IT	Information Technology
LDT	Laboratory-Developed Test
LIMS	Laboratory Information Management System
LOINC	Logical Observations Identifiers Names and Codes
LPA	Laboratory Program Advisor
LRN	Laboratory Response Network
MSDS	Material Safety Data Sheet
NBS	Newborn Screening
NLTN	National Laboratory Training Network
NPHPSP	National Public Health Performance Standards Program
NREVSS	National Respiratory and Enteric Virus Surveillance System
OSHA	Occupational Safety and Health Administration
PFGE	Pulsed Field Gel Electrophoresis
PHL	Public Health Laboratory
RSV	Respiratory Syncytial Virus
SOTA	State-of-the-art
SDWIS	Safe Drinking Water Information System
SNOMED	Standardized Nomenclature for Medicine
SPH	State Public Health
SPHL	State Public Health Laboratory
USDA	United States Department of Agriculture

Bibliography

A Proposed Model for a Voluntary National Accreditation Program for State and Local Public Health Departments [cited December 2006]. May 16 2006. Available from: URL: <http://www.exploringaccreditation.org/>.

CMS State Operations Manual, Chapter 6. Special Procedures for Laboratories (Rev.1, 05-21-040 6036). Centers for Medicare and Medicaid Services.

Continuous Quality Improvement: Integrating Five Key Quality System Components, Approved Guideline. Second Edition (GP22-A2). Clinical Laboratory Standards Institute; 2004.

Core functions and Capabilities of State Public Health Laboratories, Centers for Disease Control, Association of Public Health Laboratories Available at URL <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5114a1.htm>

Environmental Protection Agency Laboratory Certification Program. Available at URL: <http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm>

Gostin, L and J Hodges. The Model State Emergency Health Powers Act. Draft dated October 23 2001.

Institute of Medicine. The Future of Public Health. Washington, DC: National Academy Press; 1988.

Laboratory Response Network. Centers for Disease Control and Prevention [cited December 2006]. Available from: URL: <http://www.bt.cdc.gov/lrn/>.

Last, J. A Dictionary of Epidemiology. USA: Oxford University Press; 2001.

National Cancer Institute. Making Health Communication Programs Work. Washington, DC: United States Department of Health and Human Services; 1989.

National Notifiable Disease Surveillance System (NNDSS). Available from: URL: <http://www.cdc.gov/epo/dphsi/PHS/infdis.htm>.

National Public Health Performance Standards Program (NPHPSP) [cited December 2006]. Available from: URL: <http://www.cdc.gov/ocphp/nphpsp/>.

Public Health Data Standards Consortium. Available from URL: <http://www.phdsc.org/>

United States Department of Health and Human Services. Healthy People 2010. Washington, DC: United States Department of Health and Human Services; 2000.

United States Food and Drug Administration. Medical Devices: In-Vitro Diagnostics.

Webster's New Collegiate Dictionary. Springfield, MA: G and C Merriam Co; 1975.

Winslow, C and A Edwards. Man and Epidemics. Princeton, NJ: Princeton University Press; 1952.