



Ronald H. Laessig, PhD

The Current and Future Roles of the Wisconsin State Laboratory of Hygiene

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1980-Present

Ronald H. Laessig, PhD, the Assistant Director and Chief of Clinical Chemistry who had joined the Wisconsin State Laboratory of Hygiene (WSLH) in 1966, was appointed director to succeed Stanley Inhorn, MD. Laessig, whose background is in analytical chemistry, was immediately challenged by increased demand for environmental testing, toxicology services for coroners and law enforcement agencies as well as the rapidly changing health care systems—primarily the emergence of HMOs and reference laboratories. Tremendous changes in laboratory technology, including automation and increased interest in regulations for all types of laboratories, clinical and environmental, led to a major evolution in quality assurance concepts and standards of performance. New contagious diseases continued to remind the world that antibiotics and mass immunizations had not eliminated the need for traditional public health programs. An epidemic of opportunistic infectious diseases in

young men was first recognized in 1981. Initially the diagnosis of “AIDS” was clinical, supported by a panel of tests for various opportunistic infections. This rapidly gave way to sensitive antibody tests and ultimately tests for the viral agent itself. The Wisconsin Division of Public Health (WDPH), charged with controlling this epidemic, found that a new public health partnership had begun to emerge—the CDC, the State Health Department, the WSLH, local clinical laboratories and primary health care providers. Public Health no longer was solely a “state” or “government” issue in Wisconsin—it was becoming a broad-based partnership.

The 1980s were a period of explosive growth in testing as well as in the development of new programs for the WSLH. Staffing grew from 150 to nearly 400 scientists and support staff to keep pace with the demand for services. Governmental support for public health, including laboratory testing, did not keep pace. Basic “state-supported” funding of the WSLH was frozen at 1977 levels; growth had to be supported by laboratory-generated program revenues, grants, contracts, and “fee-for-service” sources. The percentage of program revenues used to operate the laboratory and its programs has grown from zero in the 1960s, to 40 percent in 1977 to 80 percent in 2003.

The growth in demand for WSLH services was driven by the development of highly sensitive and specific tests—tests which aided clinicians in the diagnostic process as well as those needed to support public health studies. In the communicable disease area, the creation of panels of tests for hepatitis, sexually transmitted diseases, prenatal screening, HIV-AIDS, and virus identification improved the WSLH’s diagnostic acumen and greatly aided epidemiological surveillance and monitoring. Tests introduced by, and panels developed at, the WSLH were subsequently adopted by local clinical laboratories. In newborn screening, the number of conditions screened for increased from one, PKU in the 1960s, to four in 1977 when the statute was revised and all testing moved to the WSLH. Currently, the program screens for 26 conditions. The newborn screening technology has evolved from a basic (Guthrie) bacterial inhibition assay test to routine procedures using highly sophisticated tandem mass spectrometry and PCR-based tests. The occupational health laboratory expanded its program from a staff of two chemists serving the WDPH Occupational Health program in 1980 to its current staff of more than 40 chemists serving a national clientele and providing OSHA consultation testing to the federal OSHA programs in 41 states.

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Erik Reisdorf, WSLH advanced microbiologist, loads samples into the LightCycler® real-time PCR instrument. The samples are non-infectious DNA so personal protective equipment is not required in this stage of testing. Photo by Bob Rashid.

Today, this laboratory focuses not only on a healthy workplace, but also the “indoor” environment in schools, public buildings, and homes.

Environmental Testing at WSLH

The era of the 1980s also saw the emergence of a strong Wisconsin Department of Natural Resources (DNR). The demand for environmental laboratory support grew as the state and nation realized that the health of our citizens is irrevocably linked to both public health and environmental health programs. The DNR embarked on an ambitious program to clean up our state’s air and surface waters, safeguard our ground water, and control sources of pollution. The WSLH’s role expanded to include monitoring, generating fundamental scientific data, basic research, and quality assurance support for an extensive program of testing carried out by local and commercial laboratories. Wisconsin led the nation in environmental research focused on measurements of extremely low levels of metals in drinking water, assessing the effects of acid rain on lakes, mercury deposition from burning fossil fuels,

and PCBs entering the food chain through fish. PCBs can be demonstrated in human specimens and represent a classic case where the challenges of public health, environmental health, and laboratory testing involving all types of specimens (food, water and human serum) converge. However, the major “environmental” event of the era came not from a chemical but from a biological agent. The 1993 contamination of the Milwaukee water supply by *Cryptosporidium* created the largest single point source outbreak in the history of public health. More than 400,000 human cases were estimated to have occurred. The laboratory’s role included devising a sample collection system, identification of the organism in the water supply and eventual clearance testing of the restored system. The WSLH was a key collaborator as Wisconsin’s state public and environmental health agencies and the City of Milwaukee Health Department, coordinated by Jeff Davis, MD, of the WDPH, responded to the emergency, which affected more than 10 percent of the state’s population.

In 1999, the WSLH’s Environmental Health Division moved into

a new 76,000 square foot laboratory building designed specifically for environmental testing. This “high-tech” facility is designed to enable Wisconsin to support all of its public and environmental health programs. It is designed to safeguard employees, support highly sophisticated instrumentation, and allow the staff to provide the low-level/highly-specific chemical determinations necessary to meet 21st century public health challenges. Coupled with the remodeled 50-year old Henry Mall building, the WSLH now occupies more than 150,000 square feet (100,000 assignable) of state-of-the-art laboratory space.

New Challenges as the WSLH’s Millennium Approaches

As Wisconsin moved toward the 21st century, public health faced a new set of challenges. The infectious agents Hantavirus and West Nile virus are, today, practically household terms. When they first emerged on the national public health scene public health laboratories were challenged to rapidly develop new diagnostic capabilities. By 2000, Wisconsin’s public health laboratory, along with 50 state public health laboratories, had quietly reorganized themselves. The Centers for Disease Control and Prevention (CDC) remain the primary national (and international) laboratory resource, but through their leadership an effective national laboratory response network (NLRN) has evolved. Through effective collaboration, the capabilities of the 50 state public health laboratories have evolved into an effective national system. If CDC is at the apex of the national laboratory pyramid, the 50 state laboratories are in the middle, and in Wisconsin the 125 hospital and 10 local health department laboratories form the base.

Building on this collective capability and fostering intrastate collaboration, the WSLH began the current system by facilitating the development of a statewide virus laboratory network and a TB laboratory network. Network partners now carry on many of the tests that were formerly done only in the WSLH; we, in turn, focus on quality assurance and collection of statewide laboratory data. The evolution in today's diagnostic testing is technology-driven; slow, expensive culture techniques, still the "gold standard," are being replaced with rapid PCR technologies. Patients benefit from rapid turnarounds, sometimes within hours, of test results, which aid in rapid, definitive diagnoses; epidemiologically, all citizens benefit from surveillance data collected from a broader, more diverse sample of the state's population.

September 11
and Terrorism

For several years prior to September 11, 2001, the public health community, including public health laboratories, had been preparing for an anticipated bioterrorism event. The wake-up call came in early October 2001 when an outbreak of anthrax was detected on the East Coast. Overnight the WSLH became the major anthrax testing facility for the state and became a "24/7" operation. At the local level, the network of hospital laboratories and public health agencies collected human specimens; they also triaged, and then shipped "clinical" and "environmental" specimens to Madison and Milwaukee. Wisconsin's unique "bioterrorism laboratory network" of four partner laboratories—State (WSLH), Veterans (Zablocki), City (Milwaukee Health Department), and Private Sector (Marshfield Clinic)—was activated to meet the

challenge while maintaining a full statewide spectrum of "normal" laboratory services. All of the anthrax specimens were rapidly tested; fortunately, in Wisconsin, none were positive. Nationally, the laboratory response network was also tested. It was far from perfect but it passed its initial test—proving itself to be an effective compo-

ing local (hospital) labs, the WSLH, and the CDC effectively supported Wisconsin's private and public health agencies.

One hundred years ago, Birge, Harper, and Russell recognized the need for a state public health laboratory. They envisioned a laboratory that would serve all of Wisconsin's citizens through col-

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ment of our state's and nation's response capability for natural as well as terrorism-instigated events. The late 1990s saw an increase in federal funding for bioterrorism. Under the rubric of "dual use," the funds are being used to build new public health capability and capacity for terrorism response as well as to rebuild our country's basic public health infrastructure, including laboratory capabilities. The WSLH has created new biosafety facilities, trained staff, and is acquiring, through the CDC, new technologies including procedures for 12 high priority (select) agents associated with weapons of mass destruction. These new capabilities were again tested, just under the wire, in the 99th year of WSLH's first century, by an international outbreak of "SARS" (Severe Acute Respiratory Syndrome) and a state outbreak of monkeypox. The monkeypox, which emulates to a frightening degree an outbreak of smallpox, was traced to the importation of exotic animals for sale as pets. A collaborative effort, involv-

laboration with state agencies and that would function as a part of our great state university. One hundred years later, their vision is intact. The goal, to provide the benefits of laboratory expertise to the public and environmental health systems of our state, while fostering the "Wisconsin Idea," is not only viable, but has served, and will continue to serve, our state well.

The Future: October 2003
and Beyond

On October 1, 2003, exactly, the State Laboratory of Hygiene embarked on its second century of service as Wisconsin's public and environmental health laboratory. Almost prophetically, this date marked the initiation of a national effort, led in Wisconsin by the Division of Public Health, charged with building the laboratory capacity and capability to address the threat of chemical terrorism. This is for us, for our partner-laboratories, for our state's health and environmental agencies, and for our coun-

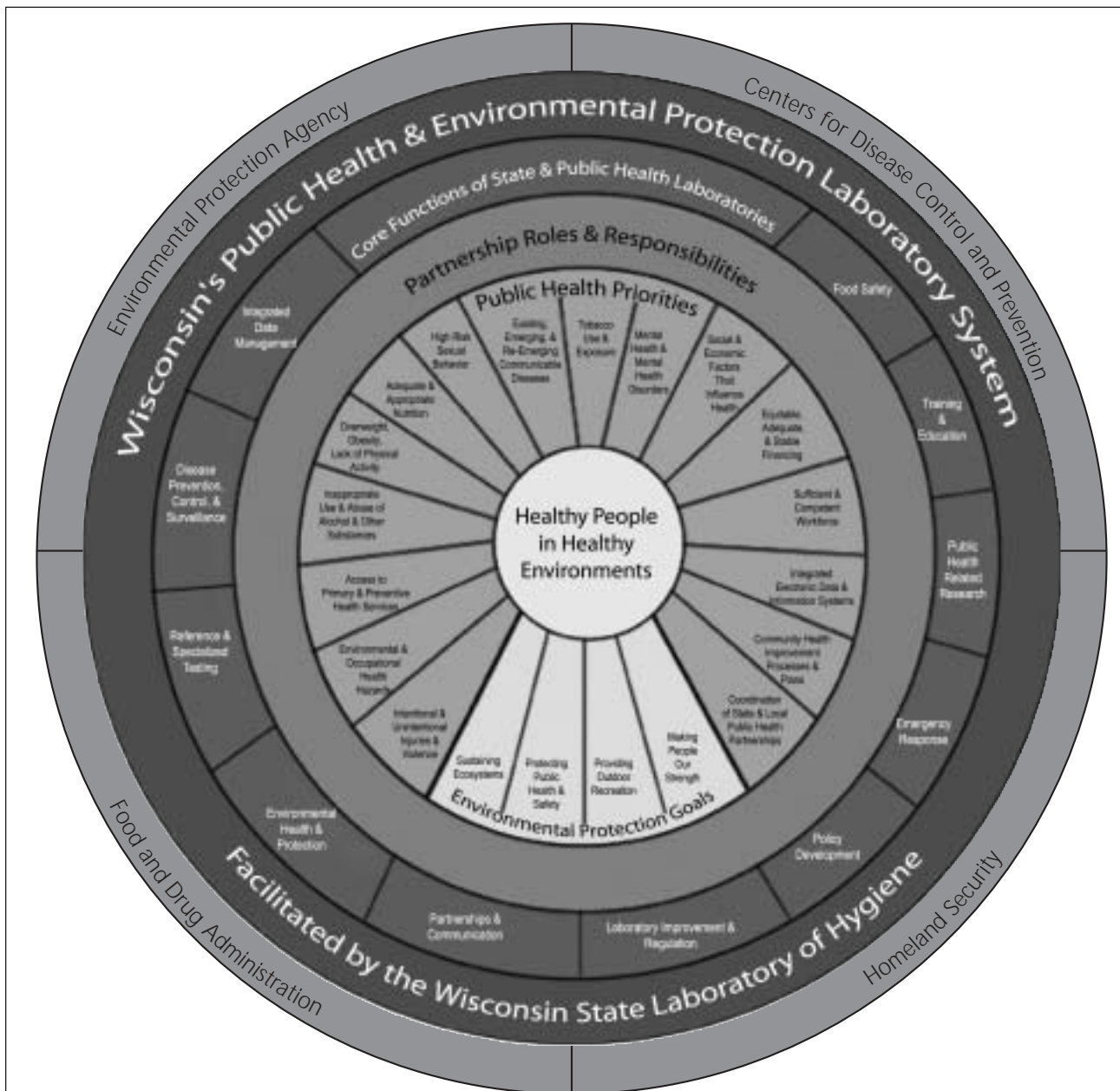


Figure 1. Wisconsin's Public Health and Environmental Health Laboratory System.

try, an entirely new undertaking. Chemical terrorism also serves as a metaphor for the future and the role we envision for the Wisconsin's state public and environmental health laboratory.

In a chemical terrorism event, the laboratory will have a pivotal role, working beside clinicians, epidemiologists, environmental specialists, first responders, and law enforcement in the process of detecting, diagnosing, assessing,

surveying, and containing threats to the health of the public. We will do this with incredibly sensitive and specific tests and methods. These procedures will be based on highly sophisticated instrumentation and/or on cutting edge techniques. Routine detection of micro-nanopico and even femtograms of analytes or single copies of biological agents is tomorrow's reality. The line between traditional "environmental" and "public" ("clini-

cal") health will disappear. The laboratory will be a key player, as the importance of relationships between environmental exposures and human health are better understood. In any future scenario, the public health laboratory will have to maintain a highly sophisticated armamentarium of methods and equipment, and be ready to respond, in an instant, to a heretofore-unknown threat. This will require not only a highly dedicated

but also a highly skilled staff that, conceptually, is quite different from the chemists and microbiologists of today. Under the dual use doctrine, they still must be able to perform the most highly complex, sophisticated procedures with skill, great insight and intuition, rapidity, and with a degree of precision that permits results to be interchanged on a national basis. The 2001 assessment of the anthrax threat by 50 state laboratories enabled the CDC to “manage” this national public health crisis because laboratorians could meet the above demands. The national laboratory response network, even in its earliest stages, proved the viability of the concept. The future public health laboratory scientists must be able to do all of these things and more.

Dual Use Capability and Capacity

In the last years of the 1990s, the federal government recognized the threat that biological and chemical terrorism posed to our nation. It was recognized that this threat would have to be addressed through our public and environmental health system at the national, state, and local levels. Led primarily by the CDC, an ambitious federal preparedness effort was instigated through a series of federal-state cooperative agreements. The concept was brilliant in its simplicity: build the capacity to deal with the threat of terrorism by re-building the infrastructure of the public health system.

In the preceding 30 years, the funding for public health programs of all types, at all levels, had been in steady decline. The events of September 11 and the anthrax attacks caused our nation to launch a war on terrorism. Today, resources are being provided to all parts of the infrastructure including, of

course, the public and environmental health laboratory system.

The “dual use” concept has provided public and environmental health programs at all levels with a badly needed influx of resources. The SARS and monkey pox outbreaks have demonstrated a renewed level of capacity in the public health system. However, these recent successes are not a long-term cure. If a public health system is overly focused on building the capacity and capability to respond to threats of terrorism—and there are none or only a few real instances—policy makers will rapidly lose interest and sources of funding will dry up and the effort will be lost. As a state laboratory, we will therefore be challenged to put the “threat” resources to routine use. These could include using chemical terrorism capabilities for monitoring our most valuable resource, our groundwater, for contaminants at extremely low levels, measuring a host of “environmental” chemicals, including endocrine disruptors, at near molecular levels in both environmental and human specimens and using our detection capabilities for “select agents” to detect, diagnose and control “natural” epidemics such as SARS, pandemic influenza, or West Nile Virus.

Wisconsin’s Public and Environmental Health Laboratory System

Our vision of the future state public health laboratory can be described by referring to the diagram shown in Figure 1. In our second century, Wisconsin’s state public and environmental health laboratory will play a key role by continuing to help safeguard the state’s and the nation’s quality of life. The distinction between traditional clinical public health (infectious diseases in humans) and environ-

mental health will blur as we continue to demonstrate that insults to the environment, accidental or intentional, are ultimately played out as adverse health effects. Likewise, threats from infectious agents, whether new or re-emerging, as well as those modified by man to become weapons of mass destruction, cry out for a traditional public health solution. The framework of this solution will emerge as we define the future role of Wisconsin’s State Laboratory in yet another new context.

We examine the future by focusing on the second of the outermost rings. Wisconsin’s Public and Environmental Laboratory System will be one of 50 such state systems joining together to provide a true national laboratory capability and capacity. States will look to CDC, EPA, and Homeland Security for leadership, resources, and the highest level of technical support. Federal agencies will, in turn, look to Wisconsin and the 49 other state systems for laboratory capacity and capability. During the SARS outbreak of 2003, the NLRN was challenged to do precisely this, and succeeded. A SARS determination performed in Augusta, Madison, Sacramento, or at the CDC in Atlanta yielded precisely equivalent results and could be interpreted, literally, on a national basis as the United States mobilized to contain the epidemic. The national NLRN was a key component of the effort. The immediate future will see the mission of the NLRN extended from its original objective of dealing with threats from natural infectious agents and bioterrorism to incorporate chemical terrorism as well. The second circle in the diagram also suggests that within the state there will be a system of local laboratories linked to national partners and facilitated by the WSLH. Webster renders the word as fol-



Terry Kurzynski, WSLH advanced microbiologist, performs Pulsed Field-Gel Electrophoresis testing for a foodborne outbreak. Photo by Bob Rashid.

lows: “fa-cil’i-tate v.t. To make easy or less difficult.” We recognize our responsibility to be just that: a key laboratory in the actual testing processes but likewise engaging other Wisconsin partner laboratories—clinical, environmental and local public health—in the process as well. Looking inward, the diagram suggests how we will accomplish this task.

Core Functions of State Public Health Laboratories
The actual core functions, the attributes that constitute the mission of a state laboratory, are detailed in the third circle. They differentiate the state public and environmental health laboratory of the future from our partners in clinical (hospital) and environmental (private sector) laboratories by looking at those functions unique to public and environmental health laboratories. The responsibilities that will define the State Laboratory of Hygiene’s future include the following.

Integrated Data Management

State Public and Environmental Health Laboratory (SP&EHL) data will no longer flow into the system from a single laboratory source. The SP&EHL role will include assuring quality of the data, and, once it is integrated from many sources, assessing its technical suitability for use by multiple Wisconsin programs.

Disease Prevention, Control and Surveillance

Testing of target populations or the environment both through routine monitoring and for control of outbreaks by the SP&EHL will augment and complement routine diagnostic testing by hospitals and clinics and compliance monitoring by environmental laboratories throughout Wisconsin.

Reference and Specialized Testing

SP&EHL will continue to expand the current reference laboratory role. This will include confirmatory testing, quality assurance and standardization of procedures. Some types of tests, i.e. *Salmonella* serotypes or PCB congeners, because of highly specialized applicability or high costs or both, will remain the purview of the WSLH.

Environmental Health and Protection

SP&EHL will be key partners as state agencies, clinicians, and researchers establish the links between environmental exposures and effects on human health. Routine monitoring of the environment, without establishing health links will be carried out largely in private sector and local health agency laboratories.

Partnerships and Communication

Based on their increasing capabilities, primarily through PCR-based methodologies, local clinical labo-

ratories will be engaged to do much of the routine population monitoring, particularly through large HMOs. Likewise, environmental testing capabilities will increase to the point where the SP&EHL will de-emphasize primary testing. In turn, the WSLH will initiate partnerships to communicate data rapidly and effectively into a statewide system.

Laboratory Improvement and Regulation

SP&EHL will continue to work with both clinical and environmental laboratories to improve performance through training, consultation, and quality assurance. Programs like our nationally accredited Wisconsin Proficiency Testing Program, which enables hospital and clinic laboratories to meet CLIA or EPA requirements, will increase in importance as technology advances.

Policy Development

Policy development is the responsibility of state and federal public and environmental health agencies (in Wisconsin, the DHFS and the DNR). However, much of the health policy of the future will be based on utilization and interpretation of laboratory data. The expertise of the laboratory and its personnel will make the SP&EHL an invaluable agency partner for creation of policy and enforcement of legislation.

Emergency Response

No matter what the event, the SP&EHL will have to be prepared to instantly redirect its resources as needed to respond to any state emergency. While traditional clinical and environmental testing, teaching, and research will continue to be the mainstays of the WSLH’s existence, preparing for and responding to emergencies will, more

than any other factor, characterize our future. Maintaining seldom-used emergency capabilities will be one of the most critical challenges facing the future state laboratory.

Public Health Related Research

Research in public and environmental health will include a major focus on laboratory identification of diseases and health conditions and/or environmental factors that affect them. Documentation of improved health outcomes or the environment, because of intervention, prevention, or changed policies, will require laboratory-based documentation. The Wisconsin SP&EHL, with its strong university connection will be a key player in all phases of research.

Training and Education

Effective partnering among the state's laboratories will require post-graduate training and re-training as technology continues to advance. Wisconsin's SP&EHL, uniquely a part of the University of Wisconsin (UW), has and will continue to provide this training, as well as university courses and graduate research opportunities in public and environmental health.

Food Safety

In Wisconsin, the SP&EHL is complemented by the State Veterinary Diagnostic Laboratory (also part of the UW) and the Department of Agriculture, Trade and Consumer Protection Laboratory. The "Ag" Laboratory plays the key role in primary food safety while the other two collaborate on the "human" and "animal" components of food safety. The threat of terrorism has intensified this collaboration, especially as we embark on efforts to deal with combinations of chemical and biological threats to Wisconsin's population through the food supply.

Partnership Roles and Responsibilities

As Wisconsin's state public and environmental health laboratory envisions its future, our 11 core processes will define our role. To accomplish our mission in our second century, we must, of necessity, engage local hospital and environmental laboratories in the processes of public health. Their mission is patient and client-focused, primary testing. One of our primary responsibilities will require us to facilitate integrating their data into the Wisconsin Public and Environmental Laboratory databases. The broad spectrum of laboratory "partners" will continue to focus on their individual primary responsibilities but in partnership with the DHFS and DNR. We will have the unique responsibility to encourage all of the state's laboratory resources to work toward Wisconsin's strategic plans for health and the environment. The Wisconsin DHFS facilitated creation of the mandated 10-year state health plan "Healthiest Wisconsin 2010." The plan for Wisconsin's environment is embodied in the DNR Strategic Plan. These plans set, collectively, 11 health priorities, four environmental protection goals and five "overarching" infrastructure priorities for Wisconsin. While we view our future role from a laboratory-centric perspective, our efforts must dovetail with the state's strategic plans for health and environment. As laboratory capabilities have become more powerful, the problems faced by Public Health have become more complex. Examples include new or re-emergent drug-resistant infectious agents that require highly sensitive and specific diagnostic information to maximize the efficacy of treatment which can take the form of designer drugs or even gene-based therapeutic agents. On the environmental

side, PCBs require not only quantification of minute levels but also differentiation from among the 209 different congeners. This differentiation has environmental implications related to tracing them back to the source but also predicting health effects as they move from the environment, through water, air or fish, to humans.

Healthy People in Healthy Environments

The state public and environmental laboratory of the future, cognizant of the public health priorities and environmental protection goals must, ultimately, focus on the bull's eye (Figure 1). The *raison d'être* of our existence is Healthy People in Healthy Environments. As we have stressed, the two are, in the 21st century, irrevocably linked. Achieving one is not possible without the other. Whether one assumes a "creationist" or an "evolutionist" view, the emergence, after 100 years of successful service, of a fully integrated State Public and Environmental Health Laboratory suggests that the WSLH is on the correct course. Likewise, as part of the UW, in the past century, the concept of a true "state's" laboratory has matured along with the Wisconsin Idea. Just as we have evolved, we look to our future, to our second one hundred years, with optimism, with strength, and with a renewed commitment to the citizens of Wisconsin and the agencies who serve them.



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