National Plant Protection Laboratory Accreditation Program (NPPLAP)

Report of the Planning Committee

21-22 September, 2005

Raleigh, NC

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EXECUTIVE SUMMARY

This report describes a plan to develop a national accreditation system for laboratories to conduct standardized and validated diagnostic tests on plant pathogens or pests of regulatory concern. Tentatively titled the **National Plant Protection Laboratory Accreditation Program (NPPLAP)**, this program will address key components of Homeland Security Presidential Directive-9, which directs the Secretary of Agriculture to develop "*robust, comprehensive, and fully coordinated surveillance and monitoring systems, … for plant disease[s]*"; that "*provides early detection and awareness of disease, pest, or poisonous agents*"; and establishes "*nationwide laboratory networks for food, veterinary, plant health, and water quality that integrate existing Federal and State laboratory resources, are interconnected, and utilize standardized diagnostic protocols and procedures*".

The use of novel molecular diagnostic tools in university, state and federal diagnostic labs is becoming standard practice, allowing the diagnostic process to become more efficient and effective than ever before. A common challenge faced by these laboratories is timely and accurate diagnosis of new and emerging pests, with one or more biological or technical constraints inherent to the pest or pathogen. A national accreditation program that couples technical competence, quality procedures and validated methods will significantly reduce the time necessary for diagnosis while also ensuring the veracity of diagnostic results, which can be used in decision-making by multiple regulatory agencies. Timely and accurate diagnostics utilizing validated and standardized methods are essential for regulatory agencies and other stakeholders to respond successfully to and prevent new pest incursions.

Key stakeholders and clients were represented at this meeting, including: the National Plant Board (NPB); the National Plant Diagnostic Network (NPDN); the USDA's Cooperative State Research, Education, and Extension Service (CSREES); USDA Agricultural Research Service (ARS); State Departments of Agriculture; University researchers and diagnosticians; State Agricultural Experiment Stations, and the National Veterinary Services Laboratory (NSVL). Representation from USDA APHIS PPQ included CPHST, PHP, and PDMP.

The NPPLAP workshop built upon earlier efforts to review other accreditation systems to identify the effective features of each for incorporation into a comprehensive program. The three major tasks of the workshop included:

1. To describe the scope and ultimate charge of the proposed NPPLAP,
2. To develop a comprehensive staffing plan for the NPPLAP,
3. To outline the structure and agenda of the initial NPPLAP Steering Committee.

This will be the first time the US launches a nationwide accreditation program for molecular diagnostics of plant pathogens and pests. Benefits of the program will include: greater standardization of diagnostic procedure between laboratories, increased timeliness, accuracy and capacity of individual laboratories and laboratory networks to process samples, and increased assurances against challenges for international and domestic trade issues.

Introduction

This report summarizes a workshop/planning meeting held to develop the structure and organization of a national accreditation system for laboratories performing molecular diagnostics on plant pathogens and other pests of national regulatory concern to the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ). The envisioned program, tentatively titled the **National Plant Protection Laboratory Accreditation Program (NPPLAP)**, will foster more efficient and accurate sample processing especially when the need exists to simultaneously perform many molecular diagnostic tests in multiple laboratories for a new or emerging exotic pest. The program will also provide more control and accountability to the accredited laboratory. By participation in the program, laboratories will be able to achieve one measure of diagnostic capabilities specific to one or more pests that will be accepted by the USDA, other regulatory agencies and peer laboratories.

Today, a common challenge faced by the USDA APHIS PPQ, State Departments of Agriculture and other diagnostic institutions is timely and accurate molecular diagnostics of new and emerging plant pathogens and pests. Molecular diagnostics are not necessarily done in a rapid fashion due to one or more biological and technical constraints. One solution is to process molecular samples in more than one laboratory; however, this then raises the issue of acceptability of diagnostic results that successfully bridge all concerns of multiple agencies. An accreditation program will provide a highly dependable level of transparency of diagnostics certainty regardless of the actual performing laboratory. Timely and accurate diagnostics are essential for regulatory agencies and other stakeholders to respond successfully to new pests. Delayed diagnostics can result in a pest problem becoming severely problematic in a very short period of time. Lack of efficient regulatory responsiveness may make a once eradicable pest now one to be managed over the long term and at a much higher cost.

Additionally, and perhaps overriding, is the need to address key components of Homeland Security Presidential Directive-9 “Defense of United States Agriculture and Food”. The directive states that “robust, comprehensive, and fully coordinated surveillance and monitoring systems, … for plant disease[s]” will be developed, and “that provides early detection and awareness of disease, pest, or poisonous agents”. The directive further states that “nationwide laboratory networks for food, veterinary, plant health, and water quality that integrate existing Federal and State laboratory resources, are interconnected, and utilize standardized diagnostic protocols and procedures” will be developed.

The representation at this workshop reflects many of the key stakeholders and clients likely to interact with PPQ in the operation of the program: the National Plant Board (NPB); the National Plant Diagnostic Network (NPDN); the USDA’s Cooperative State Research, Education, and Extension Service (CSREES); USDA Agricultural Research Service (ARS); State Departments of Agriculture; University researchers and diagnosticians; State Agricultural Experiment Stations, and the National Veterinary

Services Laboratory (NSVL). Representation from USDA APHIS PPQ included the Center for Plant Health Sciences and Technology (CPHST), Plant Health Programs (PHP), and from Pest Detection and Management Programs (PDMP). A list of workshop attendees is provided in Appendix A.

Background

An important resource and essential first step in program development was the National Plant Diagnostic Laboratory Certification Workshop (NPDLCW), which took place in October 2004. At this workshop, a variety of accreditation and certification systems were showcased by their agency developers and the relative merits and pitfalls of each system was discussed at length by the participants. Following the presentations, a list of characteristics considered necessary for a functional accreditation program was generated by the workshop attendees.

Concurrently, CPHST was tasked with the development of a 'provisional approval' process to increase laboratory capacity for molecular diagnostic determinations used in the *Phytophthora ramorum* Emergency Program. The laboratories needed equipment and capacity to effectively perform the molecular diagnostics for *P. ramorum,* and the technical background and experience to smoothly interface with APHIS in a timely and accurate manner. After an outline of the necessary components for such a program was developed, a rudimentary program was created and implemented by APHIS. This provisional approval process sought to facilitate an interactive process whereby laboratories could obtain APHIS approval to perform molecular diagnostics for *P. ramorum*. A primary goal was to define an APHIS acceptance policy for negative diagnostic results provided by approved laboratories, while still requiring all positive results to be sent forward to the federal molecular diagnostics facility in Beltsville for confirmation. A presentation on the experiences and the lessons learned from the provisional approval process was provided to the workshop participants by CPHST.

The NPPLAP workshop built upon these earlier efforts to review extant accreditation systems and identify the best features of each for incorporation into a comprehensive program. The concerns of the workshop participants (stakeholders and partners of PPQ) were elicited and discussed throughout the workshop proceedings. The workshop also examined the 'Provisional Approval Process for Molecular Diagnostics of *Phytophthora ramorum* Samples' for features and characteristics that should be considered when building a more comprehensive and general program.

Justification

In the time between the NPDLCW workshop and the NPPLAP workshop, there have been at least three significant introductions of pests of regulatory concern to PPQ in which molecular diagnostics has played a vital role:

- November, 2004 -- Asian soybean rust was detected in several southeastern states after the passage of Hurricane Ivan. This pathogen was identified by the Agricultural Bioterrorism Act of 2002 as one of the 'Select Agents', with a potential for use as a weapon against food crops in the United States. Although rust spores of the genus are readily identified through morphological means, molecular diagnostic techniques are essential to differentiate the Asian species of the pathogen, *Phakospora pachyrhizi*, from a less aggressive species, *P. meibomiae,* found in the tropical Western Hemisphere (*P. pachyrhizi* has subsequently been removed from the Select Agent list).
- March, 2005 -- sweet potato whiteflies, *Bemisia tabaci*, found on commercial nursery stock in Arizona and California, were determined to belong to the exotic Q biotype. The Q biotype, present in the Mediterranean region of Europe, shows enhanced resistance to the insecticides and management programs currently used by the U.S. nursery, ornamental and cotton industries. Morphological identification is not able to distinguish Q biotype from the non-regulated A and B biotypes. Molecular diagnostic techniques (PCR) are required for the identification of Q biotype whiteflies collected from survey and detection efforts.
- In August, 2005, Huanglongbing, a.k.a. Citrus Greening, was detected in southern Florida. The fastidious phloem limited bacterial pathogen, the causal agent of this serious citrus disease, is non-culturable, and also a Select Agent. Taxonomically, the bacterium is classified as a *Candidatus* Liberibacter species. Molecular diagnostics are required not only to detect this pathogen but also to distinguish between the three similar species of the organism, and also to make regulatory determinations. Wayne Dixon, Bureau Chief of Diagnostic Services in the Florida Department of Agriculture and Consumer Services and co-organizer of this workshop, updated workshop participants on the current situation in Florida and the use of molecular diagnostics for survey and regulation of this pathogen.

Common to these three newly detected exotic pests is the critical need for timely and accurate taxonomic identification that form the basis for appropriate regulatory decisions. Each new pest challenged the capabilities of several laboratories to process a large number of suspect samples. A key issue was having one or more laboratories with the needed expertise and equipment to conduct the complicated molecular diagnostics.

These incursions will continue and further underscore the need for a national laboratory accreditation and certification system. Such a program will enhance the ability of APHIS PPQ to respond to and manage intentional and incidental introductions of plant diseases and pests by: increasing the speed of response, increasing the reliability of diagnostic tests and adding surge capacity in the event of an extraordinary emergency. It will ensure that the highest quality tests are performed consistently across accredited laboratories using validated methods. It will serve to increase national laboratory diagnostic capacity, capabilities, quality, and will facilitate rapid and accurate detection, leading to a quicker response by regulatory agencies and stakeholders. Ultimately, it will reduce the potential negative impact of introduced pests or pathogens.

Goals

The NPPLAP workshop was designed to:

1. Foster an understanding of the need for a national accreditation program;

2. Develop the scope and the structure of a national accreditation program;

3. Define the next steps in the program building process and move toward the formation of a laboratory accreditation steering committee.

NPPLAP Workshop Outcomes

The meeting followed an agenda (Appendix B) although modifications were made throughout the workshop to maximize time management and goal achievement. There were a total of 29 participants (Appendix A) with representation from the NPDN, State Departments of Agriculture, University and USDA-Agricultural Research Service researchers, as well as APHIS personnel from the various programs within PPQ and Veterinary Services. The participants represented the regulatory and diagnostic community within the U.S., and are vital to PPQ's safeguarding mission. The participants share interests in the coordination of molecular diagnostic tools and procedures, and the need for building diagnostic capacity ranging from triage laboratories to overflow/surge capacity. General accreditation and standardization of protocols can also raise awareness of laboratory roles and provide justification for IT and scientific equipment and staffing needs for each laboratory pursuing accreditation.

Task 1: Develop a list of overarching issues that are important to the development of a NPPLAP. The following list represents the results of the discussions held by the workshop participants. The items that were discussed in detail within this workshop are identified in red with the remaining items for discussion and resolution by a steering committee, when established:

- CHARTER/MISSION Statement
- Scope of pests/pathogens that will be covered by NPPLAP
    - Prioritization of pathogens/pests
    - Resolution of laboratory results in disagreement
- Triage/ surge capacity
    - Multi-event planning
- Communication structure; mechanism for information flow; directory of 'approved' labs
- Internal and external communications
    - Information management
    - Chain of communication and notification
- Strategy for technical development, deployment and industry involvement

    - Streamlining methods development
- Continued stakeholder input
- Stakeholder buy-in
    - APS, ESA, other professional societies
- Need for a transparent process
- Continued and Coordinated funding
    - Avoiding unfunded mandates
    - Investigate possibility of subcontracting various components
- Role and function of technical working groups
    - Validation criteria
- Quality Assurance
- Training
- Clarify bio-containment levels for plant pathogens
- Develop PAS (Potentially Actionable Suspect) sample policy
    - Define policies for confirmation of positive samples (including who and where)
- Structure of Steering Committee
- Possibility of an 'Approving Body' and its structure and composition
- Who might be opposed to NPPLAP?
    - Agricultural Experiment Stations
    - Land Grant University Department heads
    - Commodity groups
    - State Departments of Agriculture
    - Foreign Regulatory entities
- Legal considerations at all levels

Additional points that were brought up for discussion, but not listed, include the need for a 'white paper' to cover the concepts of diagnostic method validation for plant pathogens. This is of paramount importance, to clarify a general misunderstanding within the plant sciences community of what validation is and how it is accomplished. Once a white paper is developed, it could be showcased on the APS website or other suitable venue.

There was considerable discussion during the workshop on the relative merits of seeking a comprehensive accreditation system or developing a streamlined approval process. As a full accreditation process is pursued, should the program seek official ISO-recognized accreditation, use an ISO-based accreditation system but not seek official registration, or use an accreditation program that is based on another system like GLP that is not an ISO system? Related issues include the costs of the program, especially if the outside laboratories need to pay to keep the program running and for ISO registration fees, not to mention the required internal and external periodic and/or annual auditing of the entire system.

Task 2: Revise the initial organizational chart so that each of the personnel on the plan can perform their duties in a highly efficient and flexible manner. The

organizational chart proposed at the beginning of this workshop was the result of consideration by USDA program leaders and with some participants in the NPDLCW. However, it was clear from comments and suggestions in this workshop that the current staffing plan would need to be further refined. Some of the main comments on the organizational chart are paraphrased below.

As a result of extensive discussion on the organizational structure of NPPLAP, a revision that attempts to integrate the various components is presented below and in Appendix C and D. However, there are now two charts. Figure 1 reflects lines of communication, while Figure 2 represents the administrative structure. These charts attempt to capture the suggestions of the NPPLAP participants as to the relationship of the Steering Committee to the National Coordinator and NPPLAP, as well as the role(s) of Technical Working groups. Consensus was that the Technical Panels could be assembled by a number of sources including the Steering Committee or the National Coordinator.

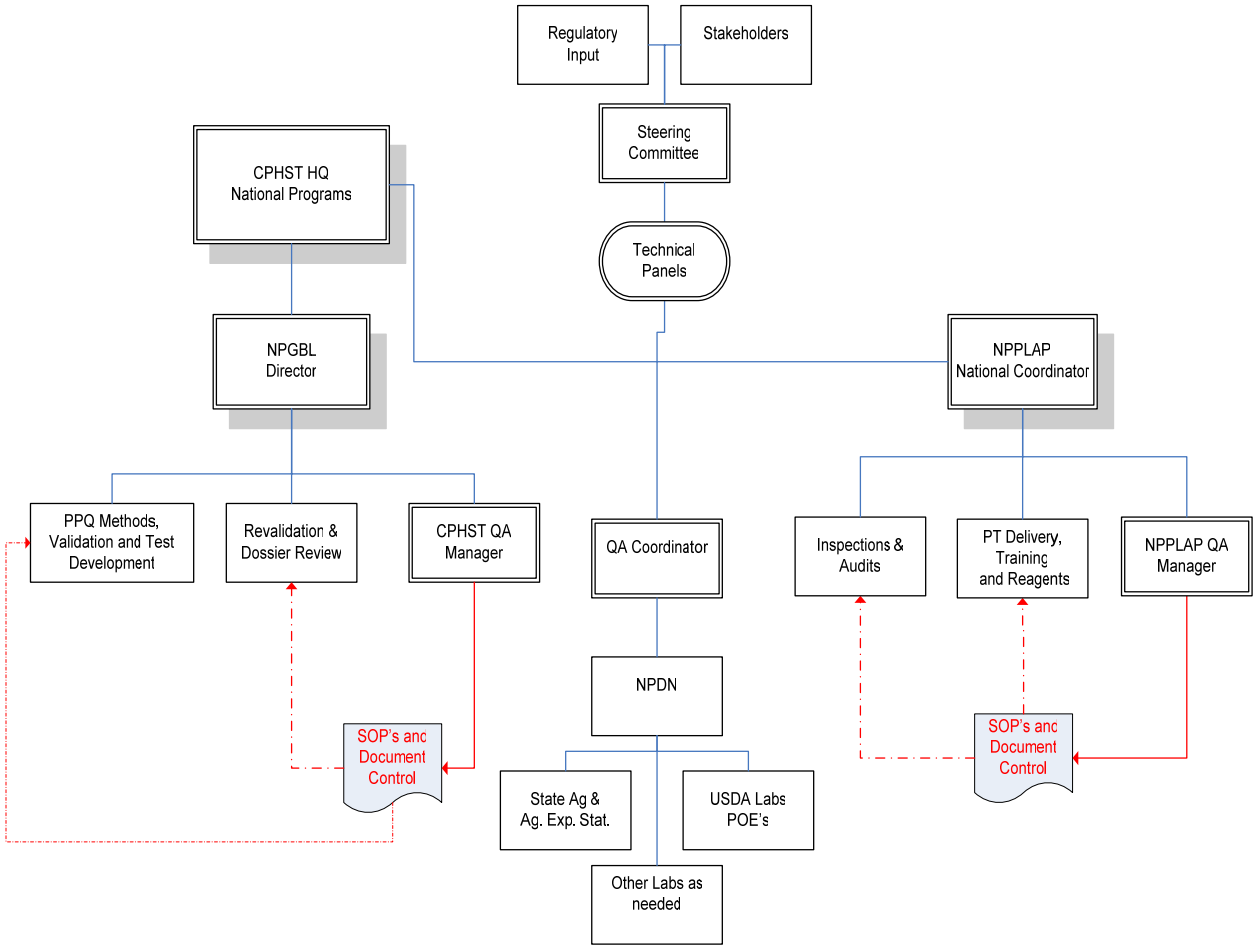

Figure 1. NPPLAP Communications and Interactions

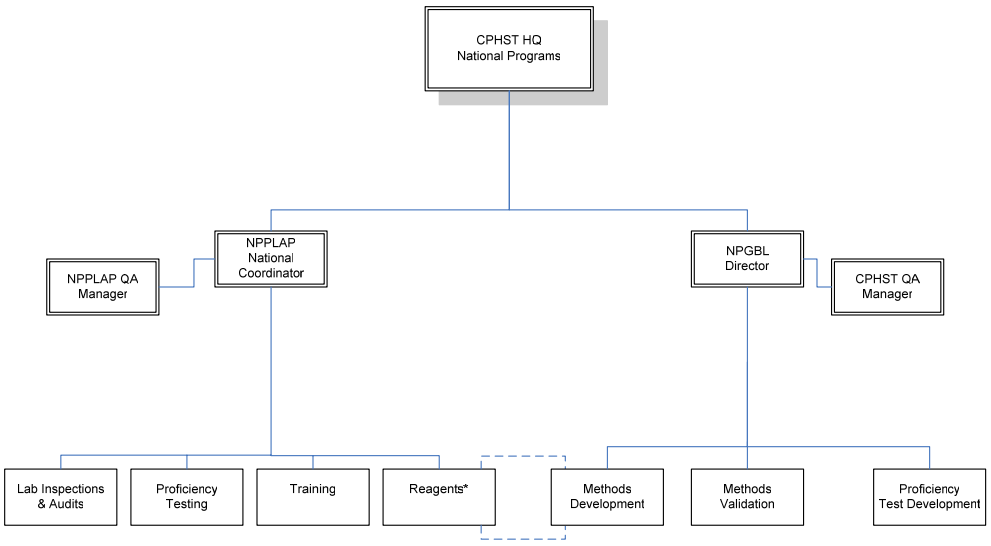

Figure 2. NPPLAP Administrative Structure

* Reagents have components that cross over between NPPLAP and NPGBL

The function of the personnel that will populate the organization is critical to its design. First, the 'Methods Development' grouping in the organizational chart is staffed by the current scientists and technicians at the NPGBL. In addition, the National Coordinator position has been advertised and the incumbent will have a key role in the implementation of the program. The Quality Assurance Coordinator position funded by CSREES will serve as a communications liaison between the PPQ components of the program and NPDN laboratories outside of PPQ that will participate in the accreditation process.

Another consideration discussed was the scope of the accreditation process. Although regulated pathogens that are both highly significant and require molecular diagnostics for final determinations, e.g., Select Agents and *P. ramorum* are certain for inclusion, the limits of what diagnostic processes require accreditation needs to be addressed and is a dynamic process. There was some concern expressed on being forced to require accreditation for diagnostics that would amount to 'unfunded mandates' by the participating laboratories. The NPPLAP workshop participants agreed that accreditation would be strictly voluntary. If established laboratories wished to have federal acceptance of their molecular diagnosis then they would need to be accredited; if they don't wish to have federal acceptance then there is no need for accreditation. Furthermore, no federal accreditation is needed at the state level for state regulatory responses. Therefore, the scope of the program will be limited to high impact pests of national regulatory concern. The inclusion of arthropod, mollusk, and weed pests are due for consideration, but were beyond the scope of the current workshop tasks. However, there was considerable discussion over the relationship of NPPLAP and the National Seed Health System (NSHS). The existing NSHS accreditation program operates as a result of Federal

rulemaking, and is intended to address laboratory tests of domestically produced seed for export in order to meet foreign phytosanitary requirements. The NPPLAP is aimed at safeguarding US agriculture, and is not related to nor intended to affect the NSHS. The NSHS exists for the purpose of supporting issuance of phytosanitary certificates for seed intended for export. NPPLAP is for diagnostic determination of agents exotic to the US or of only limited distribution in the US and under regulation.

Task 3: Develop the concept of the Steering Committee in terms of its function, structure, and composition. The consensus of the workshop participants is as follows:

Functions

- Propose policy
- Review and make recommendations regarding scope of program
- Recommendations regarding funding issues and initiatives
  - -Recommend prioritization of funding expenditures
- -Review operational components of program
- -Convene Technical Working Groups
- -Assist in setting long-term priorities and goals
- -Liaison with stakeholders

Structure

The structure of the steering committee should be designed so that balanced input will be obtained from the key stakeholders and the groups that form the clientele will be able to provide feedback for continual improvement of the program. The structure will be such that the Steering Committee will serve as a 'barometer' to gauge the program among different and sometimes competing interests.

With this structure and with inputs from the scientific community, the Steering Committee can advise on the scope and the priorities of the program, communicating these priorities directly to the NPPLAP National Coordinator. In addition, the Steering Committee will be able to facilitate the formation of Scientific Technical Panels.

Additional elements to the structure of the Steering Committee also discussed:

- APHIS Veterinary Services as a committee component, as well as perhaps a tie-in to the Integrated Consortium of Laboratory Networks (ICLN).
- Making the Chair of the committee a rotational position and having the NPPLAP National Coordinator as the Executive Secretary of the committee.
- Other structural components discussed were on appointment and approval of committee members, terms of office, and committee chair eligibility. No specific recommendations were made.

Composition:

As a point of comparison, Kathryn Moser, APHIS Veterinary Services (VS), described the composition of the analogous committee used by VS in their laboratory approval program. It is as follows:

- National Animal Health Laboratory Network (NAHLN) Coordinator
- VS Associate Deputy Administrator – not on steering committee, attends all meetings and acts as our liaison to the VSMT
- National Veterinary Services Laboratory (NVSL) Director
- NVSL Chief
- CSREES - National Program Leader and 2 others
- American Association of Veterinary Laboratory Diagnosticians (AAVLD) – President Elect, President, Past President
- AAVLD - 3 Laboratory Directors
- 2 State Veterinarians which represent - U.S. Animal Health Association (USAHA) and
- National Assembly of Animal Health Professionals
- 2 NAHLN IT Specialists - sit in on meetings, but aren't a part of the steering committee Ex Officio

It should be noted that there are important differences between the VS program and the laboratory accreditation program that is being developed here. Many of the laboratories that APHIS VS is approving are commercial labs; however, the NPPLAP program is not designed for commercial labs at this time.

The steering committee needs to consist of most or all of the following stakeholders, although some could possibly represent more than one group each. This should receive serious consideration because the Steering Committee must be small enough to reach timely and effective decisions.

Regulatory – Federal

Center for Plant Health Science and Technology (National Science Program Leader and National Plant Germplasm and Biotechnology Lab Director)
Plant Health Programs (National Identification Service)
Pest Detection and Management Programs
Eastern Region/Western Region
Veterinary Services

Regulatory – State

National Plant Board
National Association of State Departments of Agriculture or State Departments of Agriculture

Non-Regulatory

National Plant Diagnostic Network
Professional Societies: American Phytopathological Society, Entomological Society of America, American Society of Mycologists
USDA-Agricultural Research Service
USDA- Cooperative State, Research, Education, and Extension Service -National Program Staff
Agriculture Experiment Stations
University Extension

Potential At Large members:

- Additional technical resources: e.g., USDA-Office of the General Counsel
- International agencies, e.g., (Central Science Lab, Canadian Food Inspection Agency, etc)
- North American Plant Protection Organization, European and Mediterranean Plant Protection Organization, International Plant Protection Convention

Although the specific people to serve on the committee were not named, it was generally agreed that the people present at this workshop represent most of the groups mentioned above. Therefore, the committee could be a subset of this workshop/planning committee, and would be small enough to make timely decisions to continue the formation of the program.

Conclusions and Future Direction

Workshop participants successfully completed the three major tasks of the workshop. The group was able to describe the scope and ultimate charge of the proposed NPPLAP. This was accomplished by enumerating and defining overarching issues that will face the NPPLAP as it is formed and proceeds to function. The workshop results are underpinned by the broad spectrum of scientific expertise assembled for the workshop, especially diagnosticians from a variety of institutions and experiences in making regulatory determinations. It is now possible to illustrate a new and comprehensive staffing plan for the NPPLAP.

This will be the first time the US launches a nationwide accreditation program for molecular diagnostics of plant pathogens. *An underlying principle is that more rapid and more accurate diagnostics will result in reduced impact of the pest or pathogen.* The benefits of this program to US agriculture will include: greater standardization among laboratory diagnostics; increased timeliness, accuracy and capacity of individual laboratories and laboratory networks to process samples; and increased assurances against challenges for international trade issues. An added bonus of building and maintaining the NPPLAP will be additional recognition and increased visibility of the work that is done by plant disease diagnosticians.

The next stage of the NPPLAP process is to convene the inaugural session of the NPPLAP Steering Committee. The group identified five functions that could be accomplished by the Steering Committee:

1. Identify experts and recruit to the Steering Committee
2. Workshop/meeting of the Steering Committee
3. Draft mission statement
4. Deal with discussion list
5. Post Steering Committee decisions to website (TBD)

It was agreed that the Steering Committee would be mostly comprised of the representation listed above, and that many at this workshop would be among the representation. However, it was also agreed that the Steering Committee would be (much) smaller than the current workshop attendee list since the decisions that need to be made are more geared to the immediate function of the NPPLAP. The committee has to be small enough to provide timely decisions on the direction and operation of the NPPLAP.

It is anticipated that the National Coordinator position will be filled in the near future. The person that is selected for this position will be the key contact for all the functioning components of the program and will be the primary shaper and mover of its fully functional phase. One of the first tasks will be to coordinate and assist in designing the facility additions at Beltsville needed for the new staff to function.

Based on input from the workshop participants and PPQ requirements, it is possible to develop other key positions within the NPPLAP organization, such as the Quality Assurance Manager, and some of the functional teams. It is likely that the new National Coordinator will lead the interview and hiring process for these positions. The National Coordinator will also need to keep the Steering Committee informed of progress and needs to complete key tasks. It is estimated that the NPPLAP may be fully functional in about 18 months.

Planning Committee:

Phil Berger, co-chair	APHIS PPQ CPHST
Pat Shiel	APHIS PPQ CPHST
Matt Royer	APHIS PPQ PDMP
Tim McNary	APHIS PPQ – WR
Mike Kenney	APHIS PPQ PHP
Mary Palm	APHIS PPQ PHP
Laurene Levy	APHIS PPQ CPHST
Vessela Mavrodieva	APHIS PPQ CPHST
Kathryn Moser	APHIS VS NVSL
Bob Martin	USDA ARS
Doug Luster	USDA-ARS
Kitty Cardwell	USDA CSREES
Wayne Dixon, co-chair	Florida Department of Agriculture
Carrie Harmon	University of Florida/SPDN
Carla Thomas	University of California Davis/WPDN
Gail Ruhl	Purdue University
Jennifer Falacy	Washington Department of Agriculture
Ken Eastwell	Washington State University.
Matteo Garbelotto	University of California Berkeley
Steve Marquardt	North Dakota State Seed Department.
Elizabeth Bush	Virginia Tech
Sue Tolin	Virginia Tech
Tom Creswell	North Carolina State University.
Karen Snover-Clift	Cornell University/NEPDN
Umesh Kodira	California Department of Food and Agriculture
Tim Tidwell	California Department of Food and Agriculture
Victoria Smith	Connecticut Agricultural Experiment Station
Jim Stack	Kansas State University/NPDN
Tom Harrison	Ohio SPRO

The National Plant Protection Laboratory Accreditation Program (NPPLAP)

Overall Objective: The purpose of the NPPLAP is to accredit laboratories in the National Plant Disease Network (NPDN), State Departments of Agriculture, and private or commercial sectors to carry out diagnostic tests on plant pathogens or pests of regulatory concern under defined standards for facilities, equipment, personnel training, and certified methods. These determinations will provide USDA APHIS with scientifically certain results to assist in regulatory decisions and actions.

Goal: To enhance the ability of APHIS PPQ to respond to and manage intentional and unintentional introductions of plant diseases and pests by increasing the speed and reliability of diagnostic tests.

- Ensure that the highest quality tests will be performed, using validated methods
- Increase laboratory capacity, capabilities, and quality for federal agency utilization
- Facilitate rapid and more accurate detection for a more rapid response which will lead to a reduced impact of pest or pathogen

What do we want to accomplish in this meeting?

1. An understanding of why this is needed and communication with stakeholders.
2. Consensus around general principles of structure and operation.
3. Define the next steps and form a steering committee.

Tentative Meeting Agenda

DAY 1

08:30	Welcome and Introductions	Berger/Dixon
08:40	Review of Agenda, Ground Rules, Charge of Committee	Dixon
08:45	Need for Accreditation: PPQ Mission and Needs	Dunkle
09:15	Definitions and Terms	Berger
09:30	The Life of a [Regulatory] Sample	
09:45	APHIS PPQ View of NPPLAP discussion	

10:55 Break

11:15 "What IS Method Validation"? A Foundation of the Accreditation and Certification System

12:00 Working Lunch

01:00 Review of accreditation programs and ISO: applicability and challenges.
Quality Assurance as an Overarching Principle
What Is ISO And How Is It Being Used In The PPQ World
How Will This Apply To External Labs

01:20 The *P. ramorum* Provisional Approval Program and lessons learned: Elements of Accreditation and Certification (or what it feels like to be thrown to the wolves…)

- Background
- Establishing Requirements for Accreditation
  - Infrastructure, etc.
  - SOPs: Sample Control
  - Training
  - Proficiency Test Panels
  - Quality Management
  - Audits
- Implementation — Berger
- Observations of Lab inspections — Shiel
- Development and Deployment of Proficiency Panels — Levy
- Legal Documents to Seal the Deal — Berger

Q&A/Discussion

02:45 Break

03:05 Stakeholder comments, perspectives and perceptions: (5-10 min ea)

NPB/NASDA	Dixon, Kodira and others
NPDN	Cardwell, Thomas, Stack and others
ARS	Bob Martin, Doug Luster
APHIS Plant Health Programs	Palm, Kenney, McNary and others
APHIS Pest Disease Management Programs	Royer and others

04:05 Organizational Structure and Staffing Needs — Berger
- Methods Development
- Methods Validation
- Proficiency Test Development and Deployment
- Training – development and deliver

Audit – Quality Management System
Information Technology

Q&A/Discussion

05:30 Adjourn (dinner on your own)

DAY 2

08:30 Review of day 1
Is there consensus on structure and function? If not, then where are disconnects?
If there is general consensus, then elaborate.

Development of report of Planning Committee outline/report

09:45 Discussion: Methods for Standard Communications
Between laboratories and NPPLAP
Role of NPDN, LGU's, State Depts. of Ag
Technology transfer from NPPLAP to laboratories

10:30 Discussion: Function and organization of Steering Committee Berger/Dixon
Membership numbers
Credentials
Representation (Fed, State, Univ.)

11:00 Break

11:20 Appointment of Steering Committee and development of charge.
Set dates for meeting of steering committee

12:00 Lunch (provided)

01:00 Charge and Formation of Breakouts (as necessary) Berger/Dixon
Further development of report of Planning Committee outline

5:30 Review of Day 2 and adjournment

Some FAQs

1. What will it cost a lab to become accredited?

At present, NPPLAP is conceptually structured in such a way as to not cost participating labs anything. Labs may have expenses for obtaining needed equipment/instrumentation. We have discussed an accreditation fee. Perhaps the planning or steering committees could deliberate this point further. However, we don't want labs to cavalierly join the NPPLAP, so a fee might weed out those who are not seriously interested. Also, current thought is have labs operate under ISO guidelines but not put them through ISO accreditation (which is how Canada is doing this). This would not only lessen paperwork, but also save funds.

2. What is the downside of not being accredited?

We are not sure if there is a downside. Unaccredited labs cannot perform tests for regulatory pests/pathogens in a federal capacity. Some laboratories rarely encounter samples such as these, and it would be more expedient to simply send the sample(s) to an accredited lab or to APHIS. Diagnostic labs that don't interact with APHIS very often would probably not want to make the effort to be accredited under this system.

3. What about arthropods?

Although most insect diagnoses of regulatory significance don't require molecular technologies at the present time, it is likely that there will be increased use of these expanded capabilities in the future, and we have seen an increase in the number of arthropod samples that require these sorts of tests. Diagnostic labs should at least be cognizant of the accreditation process.

4. Who’s in Charge?

(We often ask ourselves that question.) Seriously, the way NPPLAP is conceptually structured now is that APHIS PPQ CPHST is the managing program. It could remain there indefinitely or not. The planning and/or ‘steering’ committees may want to weigh in on this. Note that the National Seed Health system is federal, as a result of rule making (to be avoided, if possible), and rule making may need to be done in the future. Note that NSHS has delegated quite a bit of process to Iowa State University. Remember, however, that the NSHS is only responsible for phytosanitary certificates for export. In order to function, this NPPLAP will have to follow PPQ policy as proscribed by law under the Plant Protection Act. Whatever oversight is used to govern the process will have to recognize this as they make decisions.

5. Problem resolution mechanism for diagnostic results, procedures, etc.?

This is still an issue and will need resolution. However, it also seems that a result is subject to 'further review', and a new sample might be needed to resolve discrepancies.

In any case, this is also something for steering committee and others to consider. One consideration is that since PPQ has a charge prescribed by law, the steering committee will need to determine a mechanism for resolution that is consistent with that.

6. What about improvement processes (communication up and down the food chain)?

This should be inherent in any good Quality Management System, which is contemplated as a key component of NPPLAP. That said, also areas for steering committee to contemplate. Question: Do others have a system already?

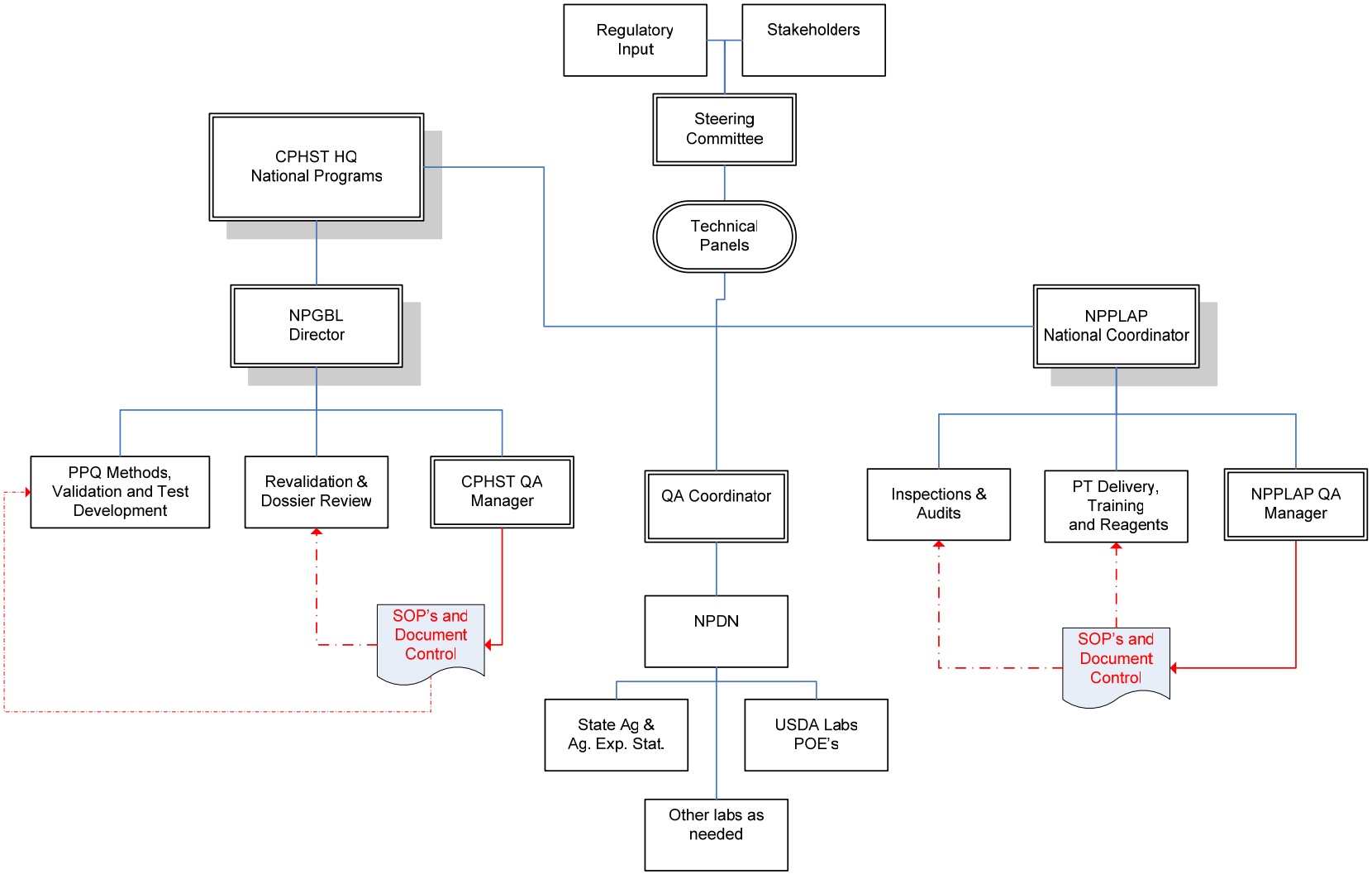

Figure 1. NPPLAP Communications and Interactions

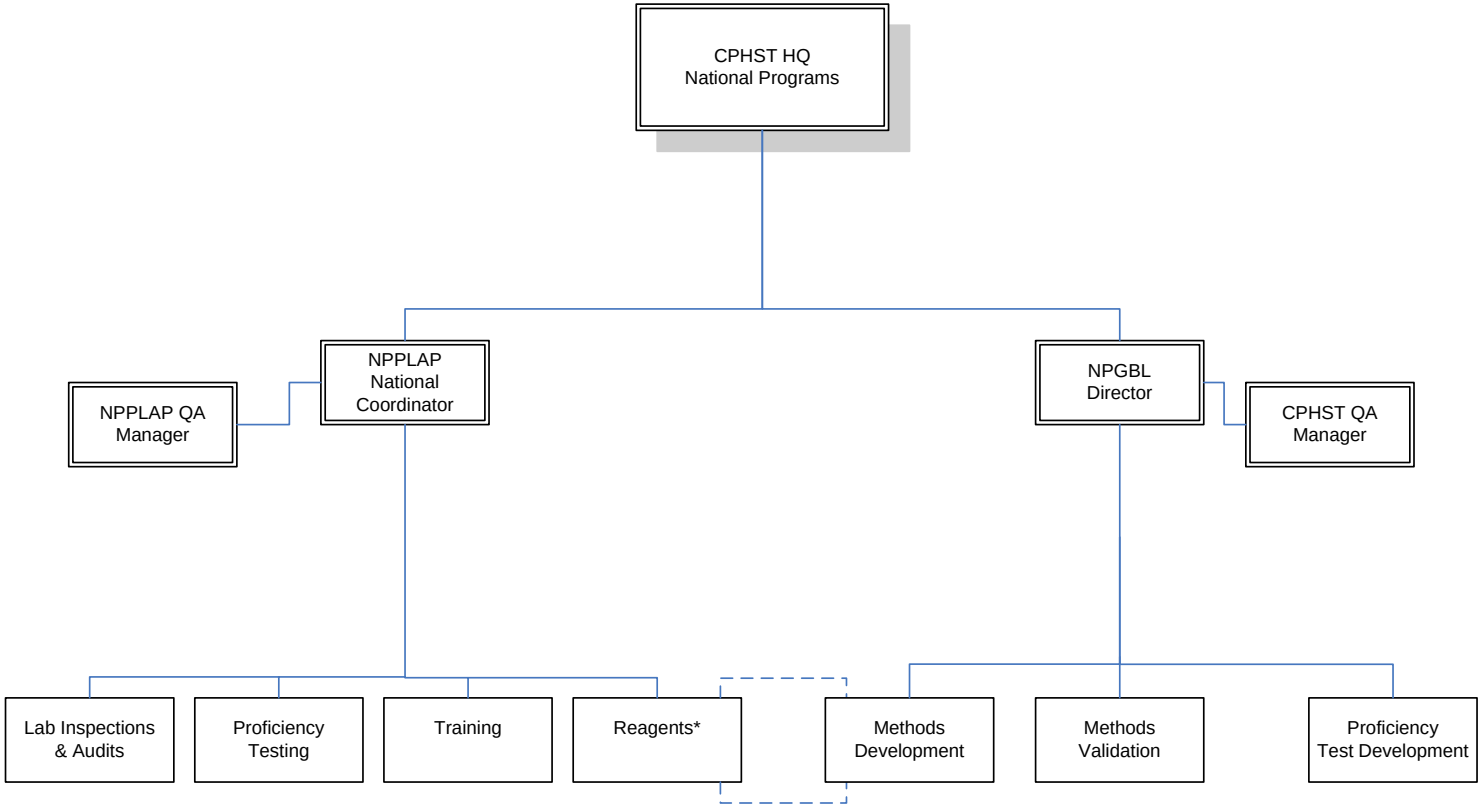

Figure 2. NPPLAP Administrative Structure

* Reagents have components that cross over between NPPLAP and NPGBL