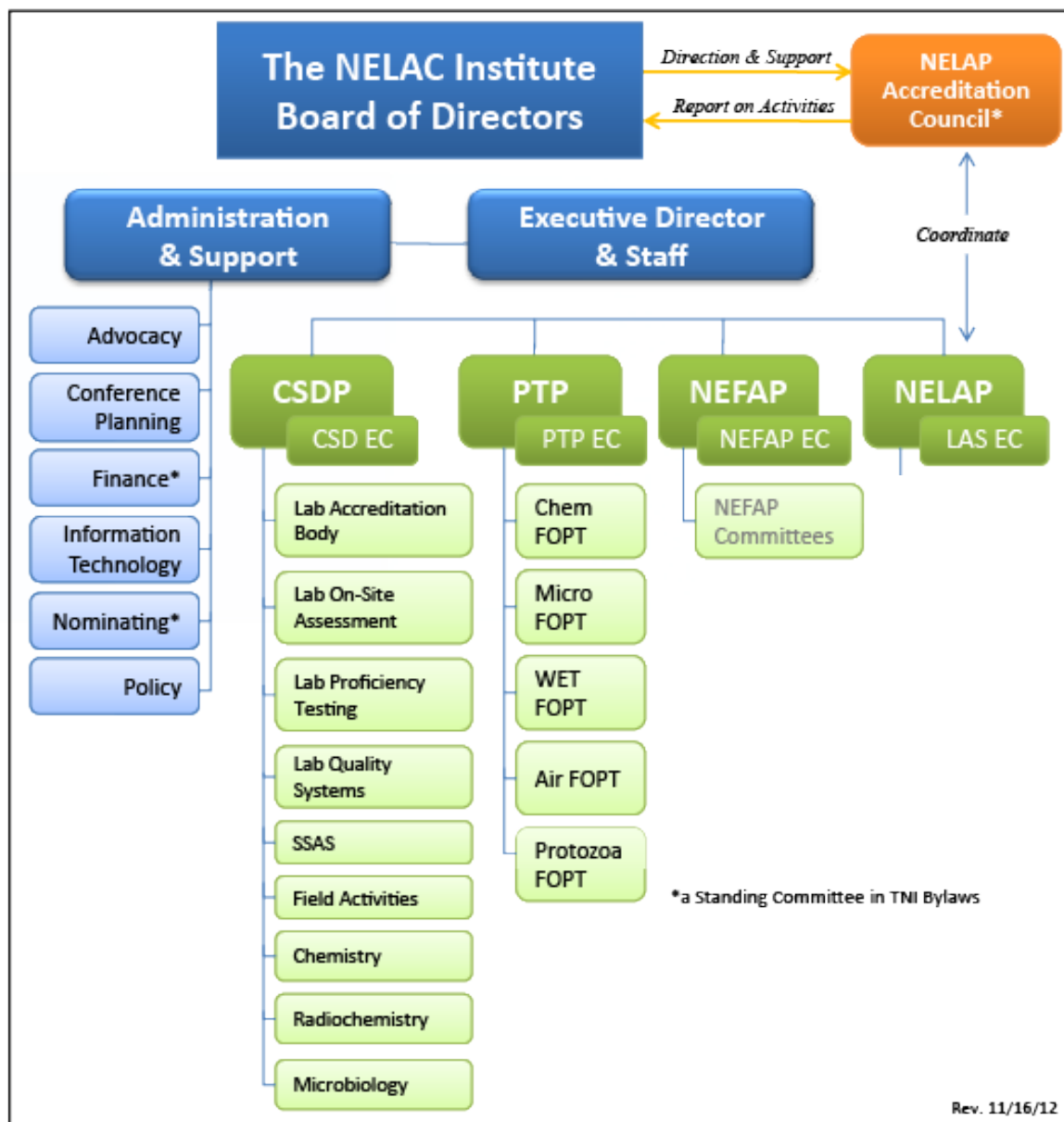




The NELAC Institute (TNI)

The Standards Development and Implementation Process

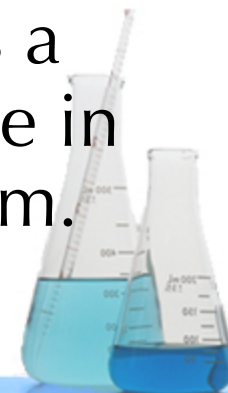






CONSENSUS STANDARDS DEVELOPMENT PROGRAM (CSDP)

The purpose of the Consensus Standards Development Program (CSDP) is to develop standards. The Consensus Standards Development Executive Committee (CSDEC) is responsible for managing this program. The CSDEC consists of the Chair of each Expert Committee plus additional at-large members representing other stakeholder interests. This core program has a support role in assisting the LASEC Committee in developing the laboratory accreditation system.





CSDP Membership

- The CSDEC consists of the chair of every Expert Committee
 - Quality systems
 - Proficiency Testing
 - Laboratory Accreditation Body
 - Stationary Source Audit Sample
 - Chemistry
 - Microbiology
 - Radiochemistry
 - Whole Effluent Toxicity
 - Field Activities
- The CSDEC also has 3 members-at-large





Current Board Members

- Bob Wyeth (Exec. Committee Chair; Member-at-large/Other)
- Jessica Evans (Member-at-large/Other)
- JoAnn Boyd (Member-at-large/Accredited Lab)
- Paul Junio (Quality Systems Committee Chair/Accredited Lab)
- Carl Kircher (Accreditation Body Committee Chair/Accreditation Body)
- Tom Widera (Stationary Source Audit Sample Committee Chair/Accredited Lab)
- Shawn Kassner (Proficiency Testing Committee Chair/Other)
- Richard Burrows (Chemistry Committee Chair/Accredited Lab)
- Robin Cook (Microbiology Chair/Accredited Lab)
- Justin Brown (Field Activities Committee Chair/Other)
- Bob Shannon (Radiochemistry Chair/Other)
- Rami Naddy (Whole Effluent Toxicity)
- Program Administrator: Ken Jackson





LASEC Program Objectives

- Work in cooperation with the NELAP Accreditation Council (AC) to assist in implementing this program.
- Work with the Consensus Standard Development Program Executive Committee to ensure that accreditation standards developed for this program are suitable for use by review of standards and by consideration of AB and laboratory needs early in the development process
- Review new or revised standards during development and after approval for the purpose of recommending them to the NELAP AC for adoption
- Manage involvement and assistance of Expert Committees and the PT Executive Committee as appropriate for standards interpretations, guidance documents and related tools
- Develop tools and templates to assist laboratories and accreditation bodies with implementing accreditation programs.
- Support TNI's Educational Delivery System in providing training programs relevant to the needs of the NELAP stakeholder community.
- Ensure that laboratory assessors have a forum to discuss common issues (Assessment Forum)
- Develop a mentoring program to assist both laboratories and accreditation bodies with implementing accreditation programs (Mentor Sessions)
- Provide a voice and solution strategies for small organizations' issues and concerns (small laboratories, especially)
- Provide a peer review mechanism for documents.
- Develop and recommend to the NELAP AC policies and procedures, standards interpretations, guidance documents, and any related tools to implement NELAP





LASEC Membership

Member	Affiliation	Category
Judy Morgan, Chair	ESC Lab Sciences	Lab/FSMO
JoAnn Boyd	Southwest Research Inst.	Lab/FSMO
Barbara Escobar	Pima County, AZ	Lab/FSMO
Betsy Kent	Reedy Improv. District, FL	Lab/FSMO
Kristin Brown	UT Bur. of Lab Improvement	NELAP AB
Bill Hall	NH ELAP	NELAP AB
Carl Kircher	FL DOH	NELAP AB
Kim Sandrock	MN ELAP	NELAP AB
David Caldwell	OK DEQ	Non-NELAP AB
George Detsis	US DOE	Other
Jack Farrell	Analytical Excellence	Other
Mitzi Miller	Dade Moeller, Inc	Other
William Ray	Wm Ray Consultants	Other
Carol Schrenkel	Suburban Testing Labs	Other
Karen Costa	EPA Region 3 Laboratory	Liaison

- **14 Members** – Equally balanced among 3 categories: Lab/FMSO, NELAP AB, Other
- **One EPA Liaison**
- **Six Associate members**
- **One Ex-Officio** – Elizabeth Turner, Small lab advocate.

Member	Affiliation	Category
<u>Ex Officio</u>		
Elizabeth Turner	Small Lab Issues	North TX Mun. Water District
<u>Associate Members</u>		
Aaren Alger	PA DEP	NELAP AB
Carol Barrick	FCC Environmental	Lab/FSMO
Myron Gunsalus	KS Lab Accred.	NELAP AB
Christelle Newsome	C2N Associates, Inc.	Other
Gale Warren	NY ELAP	NELAP AB

Program Administrator
Lynn Bradley





Standard Development Process

Expert Committees at the request of or in response to stakeholders, and/or on their own initiative, in a consensus process, develop and propose standards or changes in standards.

The process follows SOP 2-100 “Procedures Governing Standards Development”

To date 3 versions of this SOP have been used. Each version required modifications to the overall process.





SOP 2-100 Rev 1

- Expert Committee Develops WDS
- WDS Presented/Response to Comments
- Persuasive Comments...Revised WDS
- Revised WDS eventually moves to VDS
- VDS presented/Response to Comments
- VDS Becomes TNI Standard **or** MVDS
- Eventually MVDS becomes a TNI Standard





Issues with SOP 2-100 Rev1

- ❑ Slow and arduous process
- ❑ Generally failed to involve all stakeholders in development process
- ❑ Represented consensus of expert committee but did not address potential conflicts with other parts of the standard
- ❑ Did not address implementability by ABs





Draft of Revision 2 of SOP 2-100

In attempts to resolve the issues seen with Rev 1 of SOP 2-100, the CSDEC began the process of re-writing this SOP.

A number of improvements were introduced including:

- An Interim Standard (IS) following the VDS
- A Standards Review Council (SRC)





Draft of Revision 2 of SOP 2-100

- The intent of the Interim Standard was to provide an additional level of review primarily for resolution of potential implementation issues.
- The intent of the Standards Review Council was primarily to ensure lack of conflict with other parts of the TNI Standard. This Council was also charged with final review relative to editorial and grammatical changes needed in the IS.





Draft Rev 2 SOP 2-100 Process

- Expert Committee Develops WDS
- WDS Presented/Response to Comments
- Persuasive Comments...Modified WDS
- MWDS eventually moves to VDS
- VDS presented/Response to Comments
- VDS becomes **Interim Standard** or MVDS
- Eventually MVDS becomes **an Interim Standard**





Draft Rev 2 SOP 2-100 Process (Continued)

- IS Presented/Response to Comment
- Stakeholder input actively sought
- SRC review
- Persuasive Comments...MIS
- IS without persuasive comments ...TNI Standard
- MIS eventually becomes TNI Standard





Draft of Revision 2 of SOP 2-100

- While these additions and other procedural changes within the SOP were approved by the CSDEC, it remained in a provisional status pending Board approval and an ANSI audit of TNI.
- The Provisional version was utilized in some instances and where possible but without formal Board/ANSI approval Rev 1 was still the “order of the day” which only added additional confusion to the process.





Draft of Revision 2 of SOP 2-100

The use of the provisional draft of SOP 2-100 continued to prove problematic relative to efficient and timely Standard Development.

Issues included:

- Too slow; still arduous
- Somewhat improved stakeholder involvement but too late in process
- Did not adequately address potential conflicts and/or implementability





Final Revision 2 of SOP 2-100

Realizing the issues with the draft Revision, most notably the lack of stakeholder involvement and potential problems with implementability, the CSDEC embarked on yet a new and distinctly different approach to the process for Standards Development.

The development of this final Revision of the SOP was vetted through a BOD appointed Task Force.





SOP 2-100 Rev. 2

This final SOP 2-100 Revision 2 calls for significantly more “up-front” involvement of all stakeholders including the LASEC and the AC.

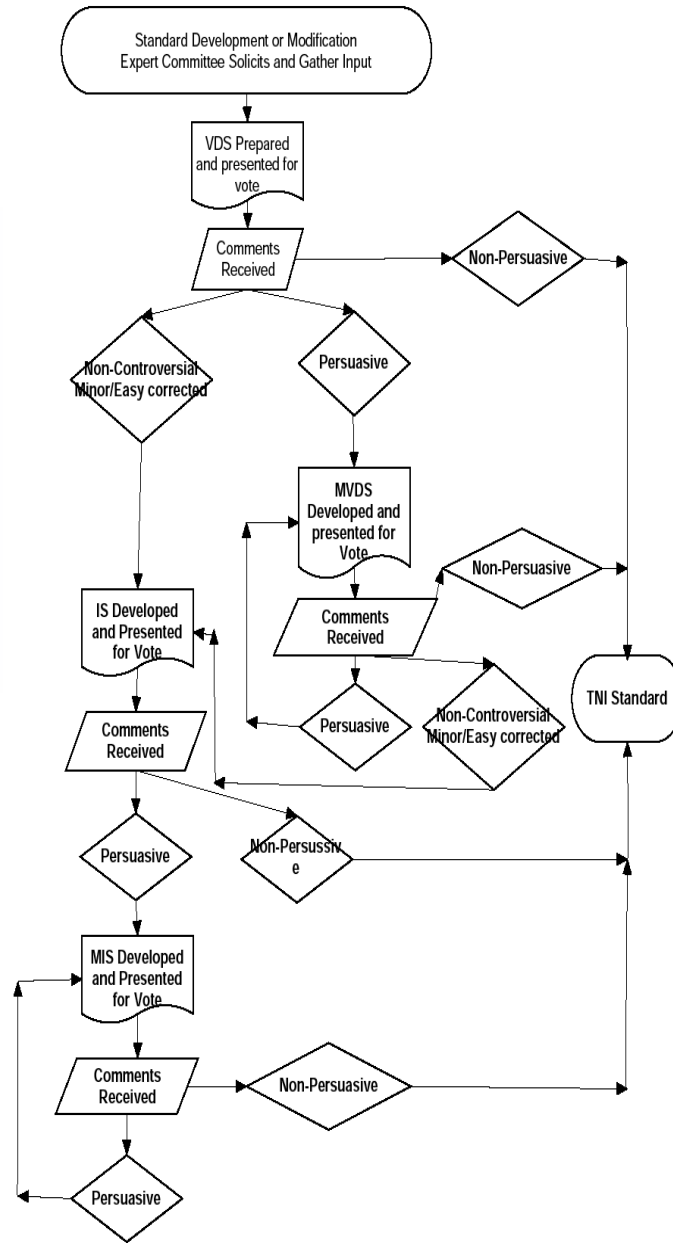
Before the EC begin standards development, a website and e-mail notification to all expert, executive and standing committees will be made expressing the nature of and the need for the new standard or the change in an existing standard.

Input will be specifically requested from the stakeholders prior to development of the VDS.



PROPOSAL FOR ESTABLISHMENT OR MODIFICATION TO TNI STANDARD						
Expert Committee or group requesting the establishment or change to the Standard		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Proposal Date</td> <td style="width: 30%; text-align: center;">_/_/</td> <td style="width: 30%;">CSDEC approval</td> <td style="width: 30%; text-align: center;">_/_/</td> </tr> </table>	Proposal Date	_/_/	CSDEC approval	_/_/
Proposal Date	_/_/	CSDEC approval	_/_/			
TNI Volume	Module	Section (s)				
Nature of the standard to be established or the change to the existing standard proposed:						
Justification or need for the standard or the change to the standard:						
How is the proposal an improvement over the existing standard:						
Any potential conflicts developed upon development of the standard or the proposed change to the standard?		Yes (Y) or No (N)				
Any potential obstacles to implementation by AB's?		Yes (Y) or No (N)				
Signature of proposal representative		Date				







LASEC Involvement and coordination with EC/CSDEC

- LASEC is notified by the respective EC of a need to revise the standard
- The EC will prepare a list of proposed items to be addressed in the revision
- A joint discussion will determine if the items are needed and justifiable
- Standard revision will take place based on these decisions and follow the process as stated in SOP 2-100
- The LASEC will review the final standard for suitability according to SOP 3-106 and make recommendations
- The NELAP AC will determine acceptance according to SOP 3-103

