

Laboratory Accreditation System Committee

Implementation of the New TNI Standards





Laboratory Accreditation System Program

- Representation of all stakeholders:
 - Accreditation Bodies
 - Laboratories
 - > PT Providers
 - Federal Agencies
 - Data Users, and
 - Other Interests
- Charged in TNI Bylaws to review accreditation standards for suitability for use.



LASC Timeline

- Standards received from CSDB in June 2008
- August 16 2008 TNI Board requested complete review of standards by January 2009
- LASC held many weekly 2 hour conference calls
- Numerous e-mail discussions





THANK YOU!

- It's January in Miami, we made the deadline.
- Many thanks to the dedicated committee members.
- Special thanks to the Expert Committee Chairs and members.
- Standards implementation by August 2009 is possible!



LASC SOP 5-102

- SOP for Review of Accreditation Standards for Suitability
 - It is the responsibility of the LASC to provide a consensus recommendation as to whether or not a standard should be implemented by TNI recognized accreditation bodies in their accreditation programs





LASC Review Process

- The review considered implementation issues that could be faced by accreditation bodies, laboratories, or other stakeholder groups.
- The review looked for significant barriers that would prevent the standard from being implemented timely and costeffectively.



LASC Review Process

- Interim recommendations that could require a change to a TNI standard were provided to the Expert Committee chairs as they were observed.
- Final recommendations will be voted on at the LASC Wednesday meeting, when all responses to comments have been reviewed.



LASC SOP

- Recommendations may include:
 - Adoption by the NELAP Board,
 - Adoption by the NELAP Board once an editorial change, policy, procedure, guidance document or other document has been produced,
 - Adoption by the NELAP Board provided a Tentative Interim Amendment has been used to change the standard using the provision for this purpose in TNI's Procedures Governing Development,
 - That the standard be revised to address concerns brought forth by the LASC.



Tentative Interim Amendment

- The amendment appears to be of an emergency nature requiring prompt action
- Will be used infrequently and only in cases where the amendment is expected to be non-controversial.
- Determination of an emergency nature shall include, but not be limited to, one or more of the following factors:



Tentative Interim Amendment

- the standard contains an error or an omission that was overlooked during the regular standard development or revision process;
- the standard contains a conflict with other language;
- the proposed amendment intends to respond to a new Federal regulation or other development; and/or
- the proposed amendment intends to correct a circumstance that has resulted in an adverse impact that was overlooked during the regular standard development or revision process, or
- was without adequate technical justification for the action.



Tentative Interim Amendment

- Requires 15 day public notice
- Effective 20 days after vote of Expert Committee
- Can remain in effect for two years





Draft Recommendations

Volume	Module	Recommendation	
V1: Lab	M1: PT	To adopt once a guidance document has been produced, and editorial changes have been made to the standard.	
V1: Lab	M2: QS- General	To adopt once editorial changes are made.	
V1: Lab	M3: QS- Asbestos	To adopt once editorial changes are made.	



Draft Recommendations

Volume	Module	Recommendation	
V1: Lab	M4: QS- Chemical	To adopt once a guidance document has been produced, and editorial changes have been made to the standard.	
V1: Lab	M5: QS- Micro	To adopt once editorial changes are made.	
V1: Lab	M6: QS- Radio- chemistry	To adopt once editorial changes are made.	
V1: Lab	M7: QS- Toxicology	To adopt once editorial changes are made.	



Draft Recommendations

Volume	Module	Recommendation
V2: AB	M1: General	To adopt provided a TIA has been used to change the standard.
V2: AB	M2: PT	To adopt once a guidance document has been produced, editorial changes made and a TIA has been used to change the standard.
V2: AB	M3: On- Site	To adopt once a guidance document has been produced, and editorial changes have been made to the standard.



Draft Recommendations

Volume	Module	Recommendation
V3: PT Provider		To adopt provided a TIA has been used to change the standard.
V4: PT Oversight		To adopt once editorial changes are made.





More Details

- Two tables have been developed to provide detail on any recommended changes:
 - Summary of Action Items/Condition

Example:

	Ref to TNI Std	Ref to LASC Review	Editorial Change	Estimated Completion Date
1	V1: M2-M7	QS - 1	Correct inconsistent terms ("mandated method", "reference method" and "standard method".)	Prior to implementation of standard.
2	V1: M3-M7	QS – 2, 2a, 12	ISO language needs to be removed from the non-ISO version of the standard. A reference to this language needs to be added.	Prior to implementation of standard.

 Summary of Comments/Questions and Expert Committee and LASC Responses



What did we learn?

- LASC review should come before voting process
- TNI members participated in their own committees, so it was difficult to look at standards across volumes and modules
- Standards may be accurate on their own, but cannot be implemented without subsequent modules being consistent



The Journey Continues

- Next steps?
- Editorial changes are made and approved by CSDB
- TIAs, guidance documents and/or policies are written
- NELAP Board approves
- Standards are implemented by Accreditation Bodies.





Thank you!

