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 cost-effectively.
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

<table>
<thead>
<tr>
<th>Volume</th>
<th>Module</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1: Lab</td>
<td>M1: PT</td>
<td>To adopt once a guidance document has been produced, and editorial changes have been made to the standard.</td>
</tr>
<tr>
<td>V1: Lab</td>
<td>M2: QS-General</td>
<td>To adopt once editorial changes are made.</td>
</tr>
<tr>
<td>V1: Lab</td>
<td>M3: QS-Asbestos</td>
<td>To adopt once editorial changes are made.</td>
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</tbody>
</table>
## Draft
### Recommendations

<table>
<thead>
<tr>
<th>Volume</th>
<th>Module</th>
<th>Recommendation</th>
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</thead>
<tbody>
<tr>
<td>V1: Lab</td>
<td>M4: QS-Chemical</td>
<td>To adopt once a guidance document has been produced, and editorial changes have been made to the standard.</td>
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<tr>
<td>V1: Lab</td>
<td>M5: QS-Micro</td>
<td>To adopt once editorial changes are made.</td>
</tr>
<tr>
<td>V1: Lab</td>
<td>M6: QS-Radio-chemistry</td>
<td>To adopt once editorial changes are made.</td>
</tr>
<tr>
<td>V1: Lab</td>
<td>M7: QS-Toxicology</td>
<td>To adopt once editorial changes are made.</td>
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</table>
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<tr>
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<th>Module</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>V2: AB</td>
<td>M1: General</td>
<td>To adopt provided a TIA has been used to change the standard.</td>
</tr>
<tr>
<td>V2: AB</td>
<td>M2: PT</td>
<td>To adopt once a guidance document has been produced, editorial changes made and a TIA has been used to change the standard.</td>
</tr>
<tr>
<td>V2: AB</td>
<td>M3: On-Site</td>
<td>To adopt once a guidance document has been produced, and editorial changes have been made to the standard.</td>
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</tbody>
</table>
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<th>Module</th>
<th>Recommendation</th>
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</thead>
<tbody>
<tr>
<td>V3: PT Provider</td>
<td></td>
<td>To adopt provided a TIA has been used to change the standard.</td>
</tr>
<tr>
<td>V4: PT Oversight</td>
<td></td>
<td>To adopt once editorial changes are made.</td>
</tr>
</tbody>
</table>
Two tables have been developed to provide detail on any recommended changes:

- Summary of Action Items/Condition

Example:

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

- 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!