



The NELAC Institute

**Quality Systems Expert
Committee**

August, 2008



Ground Rules



TNI Consensus Standards

- Volume 1, Modules 2 to 7
- Final Standards Published June 2008
- Appeal Process closed.
 - 1 Appeal
- Ready for Implementation – No further changes are allowed



What is Consensus?





Consensus is a decision-making process that not only seeks the agreement of most participants, but also to resolve or mitigate the objections of the minority to achieve the most agreeable decision.





What is a Standard?





A **standard** is an established norm or requirement. It is usually a formal document that establishes uniform engineering or technical criteria, methods, processes and practices.





Quality Systems Expert Committee Activities

The TNI Quality Systems Expert Committee is involved with the implementation process.

The LASC, NELAC BOD and Technical Committee will ask for implementation guidance documents.

The Quality Systems Expert Committee has been busy with a crosswalk document to the NELAC 2003 Checklist.



Quality Systems Expert Committee Activities

■ Checklist

- Language is still NELAC 2003
- TNI References were added
- Next Step is a new checklist with TNI Language



Quality Systems Expert Committee Activities

■ Presentations

- Assessment Forum – Tuesday Morning at 9:00 AM – New TNI Standards
- NEMC – Thursday Morning at 9:30 AM – Development of a Consensus Standard for Quality Systems in Environmental Testing Laboratories



Quality Systems Expert Committee Activities

- Quality Systems Expert Committee
 - Membership
 - Applications due September 1, 2008
 - Committee will select new members for Jan 2009
 - Technical Experts Needed
 - Toxicology
 - Radiochemistry



Quality Systems Standards Improvements

- Module Concept
- ISO/IEC 17025:2005 Structure
 - Placement of additional NELAC Requirements
 - Redundant language removed
- Clarifications
 - M5 1.7.5.b)
 - M2 4.2.8.3
 - M2 4.2.8.4



Quality Systems Standards Improvements

- Technical Modules Structure
 - Same structure in all technical modules
- Demonstration of Capability (DOC)
 - Technical Modules section 1.6
 - General Requirements
 - Initial DOC
 - Ongoing DOC



Quality Systems Standards Comments on Hold

- All comments placed on Hold will be reviewed in the next revision cycle.
- Types of Response limited by TNI policy (3)
 - New concept not discussed
 - Restudy entire language
 - Not enough time to complete



Quality Systems Standards Comments on Hold

<i>Quantity</i>	<i>Comment Category</i>
1	Use VIM Definitions
1	Quality Managers must be member of Staff
1	Do not make this a interim standard
1	Preparation Batch > 20
9	Format: Placement of Additional Requirements Placement of a Section
1	Combined Standard Uncertainty Needed
1	Technical Module 7 Clarification
15	Total On Hold



Quality Systems Standards Open Mike

- Focus on Improvements Needed for next revision cycle.
 - Quality Systems Expert Committee
 - All Other Experts