

Preparing for the New ELAP Regulations

A short look at where ELAP is Going

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BACWA Lab Committee meeting October 8, 2019

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Topics for This Presentation

- What is known so far
- Issues created by ELAP choices
- Issues created by incorporating TNI
- Some suggested first steps
- Other info

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What is Known

- Based on the 3rd draft ELAP regulations
- ELAP sets requirements for certification process; applications; fees; reporting; sale/transfer; and defines terms
- Incorporate TNI -2 for PTs and QMS

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Issues with ELAP's Portion

- Certification process cited in two different places and they have different requirements
- Applications ask for info that is undefined.
- Fees are arbitrary and not in keeping with the requirements in H&SC 100837.(a)
- Added in requirements contrary to statute
- Places Fields of Accreditation as a list on a webpage.

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Issues with Incorporating TNI

- Licensing agreement with ANSI (ISO) all ISO (italicized) language cannot be shared but purchased
- TNI copyrighted the entire standard, it cannot be shared but purchased
- Purchasing is by individuals unless you purchase a site license (annual fee).
- Several court cases might not allow incorporation under these conditions

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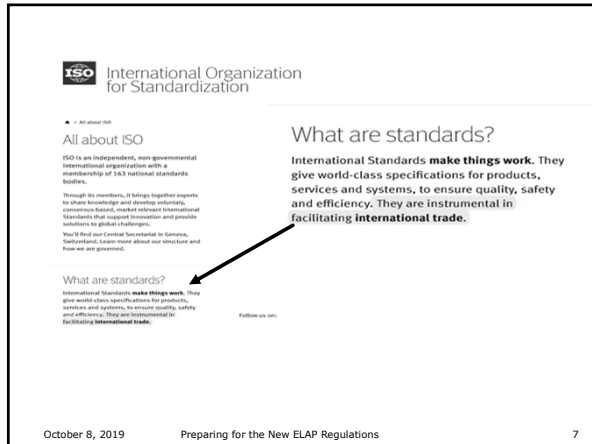
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TNI Creates Issues

- Commercial lab focus
- Division of technical and management functions
- Assignment of duties
- Outside business functions

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ISO International Organization for Standardization

• All about ISO

All about ISO

ISO is an independent, non-governmental international organization with a membership of 163 national standards bodies.

Through its members, it brings together experts to share knowledge and develop voluntary consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

You'll find our Central Secretariat in Geneva, Switzerland. Learn more about our structure and how we are governed.

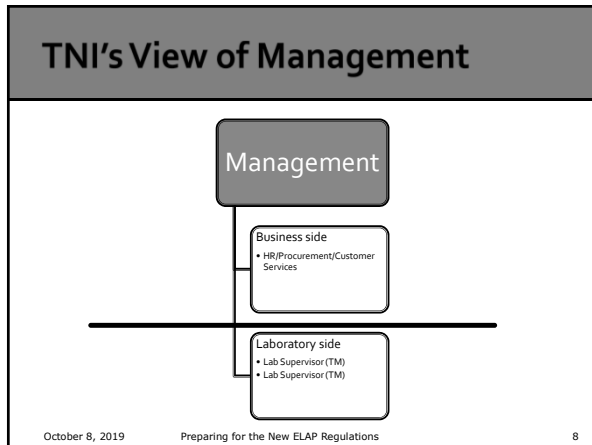
What are standards?

International Standards **make things work**. They give world-class specifications for products, services and systems, to ensure quality, safety and efficiency. They are instrumental in **facilitating international trade**.

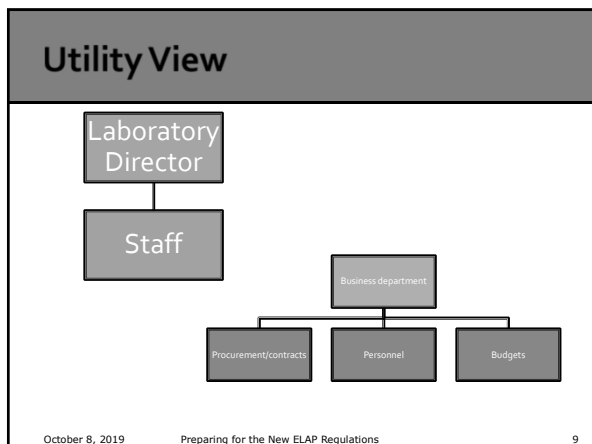
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Personnel Issues not Resolved

- Is Laboratory Director = to Technical Manager or Management
- If Management, then NO Qualifications but who would be Technical Manager in 1-person lab
- If Technical Manager who takes on Management duties/responsibilities/ authorities

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Lab Business Issues to Resolve

- Business functions in another department/agency – lab has no control
- Some business functions such as job classifications/procurement controlled by unions or local/state law

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A Request Walks into a Lab

- Requests handled informally and with a predictable outcome
- Under TNI V1M2 4.4
- Depends on who is defined as a "customer"
- Request will create a contract (4.4.1)
- Records of discussions with requestor (4.4.2)
- Includes subcontracting work (4.4.3)
- CA QMS also places responsibility for work on the applicable lab (CCR 64814.b.4) vs. V1M2 4.5.3)

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What can Any Lab do Now

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First Level Planning

- Determine Now whether to create stand-alone documents or incorporate them into the Quality System Manual
- WHY??
- Don't create a document control nightmare

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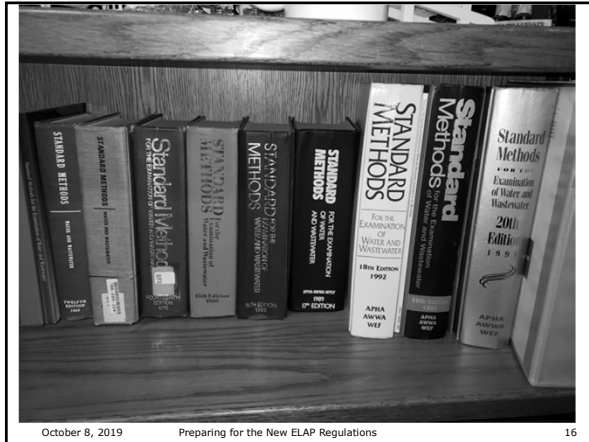
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V1M2 4.3 Document Control

- All documents must be controlled
- Only current version are available
- Obsolete (archived) documents cannot be generally available
- Drafting revisions is a structured process

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Plan Now – Consider This

- Work on analytical method SOPs now
- Prepare Sample Collection; Sample Receipt-Handling-Acceptance; Training-Demonstrations of Capability; and Limits of Detection-Quantitation Policies/Procedures
- Draft any additional stand-alone P/Ps
- Draft Quality System Manual

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CA QMS

- Solved many of the issues created by ELAP and TNI
- Added requirements under Transparency
- Language worked on with cooperation of labs and even an agency partner – but not ELAP
- Needs daylighting to whole lab community

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Questions?

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