



Laboratory Mentor Session

Topic 1: Documentation





Welcome to our grand experiment!!



Purpose

To discuss issues about the Environmental Laboratory Accreditation process in:

- an open discussion format;
- a neutral environment;
- a manner that accesses any TNI committee;
- a productive environment where all unresolved issues are brought to the appropriate TNI committee for action.





TNI Training Disclaimer

- The material presented in this session is for informational purposes only. It is designed to promote understanding, consistency and clarification of technical and accreditation requirements. It should not be considered a change or alteration of the Accreditation standards, the published methods, a regulatory agency requirement or a position of TNI.
- The opinions expressed by the learned speakers, trainers or panel participants are their own and are not necessarily intended to infer an official decision or interpretation by TNI or an accrediting authority. Interpretations of requirements are solely in the purview of the accrediting authorities and TNI board of directors.
- Questions and issues raised may be referred to the appropriate TNI committee or decision making body for consideration or action as appropriate.



Mentors

- John R. Gumpfer
ChemVal Consulting, Inc.
- Ilona Tauton
TestAmerica
- David Caldwell
State of Oklahoma
- And everyone else here!



Ground Rules

- Mentors will recognize the speaker by passing the microphone to them.
- The Mentors role in the discussion will be to:
 - Help clarify specific implementation points,
 - Guide the discussion to pertinent topics, and
 - To provide links between people and solutions
- Mentors are resources, but not encyclopedias!



PARKING LOT flip chart

Use this for things that you would like to address but:

- 7) You are too shy
- 8) It is off subject
- 9) You'd like a separate discussion on this topic.



Use the microphone to enter into the discussion.

Please wait to be recognized.

Sidebars are considered the “good stuff”. Please share.





First Session Topics

- Procedures, Written Procedures, & Standard Operating Procedures
- Records



Definitions

- *Note: All definitions are from the non-existent glossary*
- **Standard Operating Procedures (SOPs):**
a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.
(QAMS)



Definitions, cont.

- **Procedure:** Specified way to carry out an activity or a process. Procedures can be documented or not. (ISO 9000: 2000 and Note 1)
- *Note: There is no definition of “Policy”*



Required SOPs

- **5.5.4.1.1 Standard Operating Procedures (SOPs)**

Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods.

- Additional requirements on hand-out



Where to Write?

- Quality Manual or Stand-alone SOP?
- John's Opinion:
- For laboratory methods, it makes the most sense to have them as stand-alone documents, since they are designed to be used at the bench one at a time.
- For other documents, the place for them is determined by where they need to be available and how often they might change.



Example 1

- In most labs over about 8-10 people, sample receiving starts to become a specialized activity, often performed by less technically experienced personnel. In that case, the sample receiving procedures should be split off into a stand-alone SOP for ease of use by sample receiving personnel



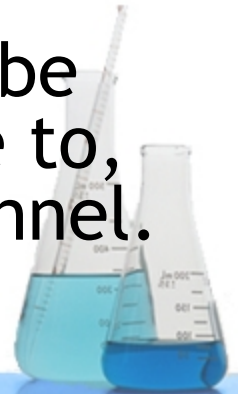
Example 2

- In most laboratories, Corrective Action is a static process. Unless it is one that is trained more frequently than other quality system processes (and it may be), I would recommend including it in the Quality Manual rather than as a stand-alone SOP.



Whether to Write?

- **5.4.2.1** The laboratory shall establish implement and maintain a quality system based on the required elements contained in this chapter and *appropriate to the type, range and volume of environmental testing activities it undertakes. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the environmental test and/or calibration results.* The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.



Reasons to Write

- The necessity depends on
 - Whether the procedure is performed frequently enough, and/or
 - Is simple enough to be easily remembered
 - If training is a laboratory issue, whether it can be easily transferred through verbal training.



Records

- There is an extremely long list of items that need to be recorded. See handout for guidance.

