Laboratory Mentor Session
Monday, January 29, 2007

1. Introduction – John Gumpper
   - Handouts were provided.

2. Topic #1: Documentation – written and standard operating procedures.
   - The topic was introduced by John Gumpper with a short PowerPoint presentation. This was followed by a discussion session.
   - Questions asked:
     - How do people document SOP reviews? Suggestions:
       - Review during annual method audits and system reviews.
       - Review during annual management review.
       - Databases are used for monitoring.
     - Comment from EPA
       - G6 guidance document is coming up on the 5 year review. It was sent out looking for comment. Send comments in to Margo Hunt, hunt.margo@epa.gov.
       - G8 is coming up this year. You can send comments to her on that one too.
     - What should go in policy, SOP, QA manual etc?
       - There are 23 elements that need to be addressed (or referenced) in an SOP.
       - Additional suggestions:
         - Analytical and administrative SOPs can be separated
         - SOPs should be archived and dates used included so the history of the method can be reconstructed
         - You can purchase electronic quality management system. It allows you to keep an electronic record of the SOPs and their review. It is designed to replace paper based systems. There is a cost and IT support is needed.
         - If you have a policy for something you need a procedure to describe how to implement the policy.
     - Do analysts need to have a copy of the SOP at the bench?
       - It must be readily available to the analyst; e.g., have computers available where the analysts can look SOPs up.
     - What do you do about training? Suggestions:
       - Have a training binder for each method in use.
       - Try to break SOPs into modules for training. Each module has groups of SOPs that analysts have to master before doing the procedure.
     - Who reviews the SOPs before they go to the analyst? Suggestions:
       - Do observational audits and write an audit report on the observation
       - Make the analyst doing the analysis revise the procedure each year – i.e., do the annual review

        - When there is a new analyst using a new procedure – ask for the new analyst to provide comments on the procedure.
        - Consider these factors:
            - Historical reconstruction. You should plan on archiving (SOPs, training) for at least 5 years
            - This entire program is to generate known and documented data – how you document is up to you
            - If it is not documented – it is not done.
            - Say what you do and do what you say
            - For a one time method – documenting what you did in a notebook provides adequate documentation. You need to focus on the ability to recreate.
    - Discussion points on compliance:
        - All agreed all test methods need to be documented in an SOP
        - Most agreed all sample receipt procedures should be documented
        - Level of detail is usually the issue during an assessment.
    - What signatures are required on the SOPs?
    - Is one signature is enough?

3. Topic #2: Analyst Proficiency
    - John provided a short presentation on the topic. This was followed by a discussion session. Attendees were asked if they were from a small or a large lab.
        - Large lab (12)
        - Small lab (24)
    - Questions asked:
        - What can be used for on-going analyst demonstration of competency? Suggestions:
            - Use the computer system to track.
            - Doing a single PT is not a good way to demonstrate capability.
            - Review the PT data and make sure the SOP criteria are met in determining the PT acceptability.
            - Continuing proficiency is currently in the TNI draft working standard
            - You should have bench data to support the tests
            - You have to keep in mind what you are trying to accomplish. The data should demonstrate the lab can put out the quality of data it says it can.
            - Look at control charts for the analyst as a mechanism to demonstration of continuing proficiency.
            - An effective internal audit program may be an effective method of demonstrating proficiency.
            - If you use a control chart, be careful of the range of acceptable data. Don't just accept everything.
        - What systems are used to track continuing demonstration of analyst proficiency?

- Does the back up analyst have to do a demonstration of competency prior to allowing them to do the test? .
- Four consecutive LCS; does that mean for one analyst?
- Are marginal exceedences allowed in continuing demonstrations of analyst's proficiency?
- How do you track training and proficiency for each analyte? Suggestions:
  - The laboratory scope of accreditation is a way to track up to date training and proficiency for each analyte and method.
  - Utah has developed a database to track this type of data. They may be willing to share this.
- Shouldn't we clarify the standard about how frequent "annually" is? .

4. Parking lot issues
   - Data review for PT tests
   - LOD
   - DOCs for extractions – is this by technique or by method?