Detection and Quantitation Guidance Document Sub-Committee Meeting
September 17, 2009

1. Roll Call: Subcommittee chair, Richard Burrows called the meeting to order at 1:00 PM EDT. Subcommittee members present included Richard, Brooke, June, Jack, Gail, and Prabha.

2. Approval of minutes: Not done

   Richard clarified that we are trying to provide guidance on how to provide LODs and LOQs, we aren't saying it's the only way. If we restrict ourselves to the language provided in the standard, then there wouldn't be any point in having this committee since it is intentionally vague.

   The only requirement in the TNI standard is that you detect something for an LOD verification. That verification result could be meaningless if you spike high enough because you would surely detect it. We can't stop a lab from doing that, but we can explain the basis of detection and quantitation and explain a meaningful way to accomplish verification.

   Jack – There are a lot of labs that just want to minimallycomply with the standard. He thinks we should show them how to comply minimally, and give technical details as an aside. He is concerned that we are saying the way we think it should be. We aren't providing guidance on how to comply with the standard.

   Richard – We can make clear what the minimum standards are – they are pretty simple. Richard would like to point out that doing the minimum may result in meaningless verifications. Jack and I are on the same page.

   > Brooke went through the LOD verification slides showing the various pitfalls of choosing certain spike levels.

   Richard – The slides show that spiking at 4x LOD is useful when recoveries are low. Slides are designed to explain a good way to do LOD verifications. A preamble (not yet developed) would describe the minimal requirements.

   Prabha - Marlene prefers to use "signal" rather than recovery. Concerned about using the term recovery inside the LOD verification discussion.

   Richard – Recovery is not part of the TNI LOD verification. The term is only used in the slides to show that you won't be able to see your LOD verification spike if the analyte you are verifying is prone to having low recovery (as known from your LCS results). You do not calculate recovery for a TNI LOD verification sample. You use the knowledge of the recovery about an analyte to choose a higher spike concentration when an analyte is

likely to have poor recovery. That way you'll be better assured that you'll see the verification spike.

Richard - The problem with using signal instead of a quantitated value, is that if you look at just the signal, it may be buried under the instrument censoring threshold, so you can't measure the signal.

Jack – Suggested providing a table of poor performers and their LCS recovery limits.

Richard – say "low recoveries" are expected based on LCS performance. So we don't confuse recoveries as a required part of the LOQ.

June – first present standard language, then slides.

Jack – most simple relationship between LOD and LOQ is to say the LOQ is higher.

Prabha – many programs require LOD reporting.

Richard asked the committee about the document he provided that a lab could write into their SOPs (if they want to get the most out of their LOD determinations).

Jack asked if we were going to provide examples for all methods? Richard said we only have a difference for GCMS.

Jack - are we going to be talking about suggesting signal to noise and what detected means for inorganics.

Richard – we aren't going to suggest a certain level for signal to noise because in some instances it is very difficult to measure the noise. eg Cyanide. The result should be able to be distinguished from a blank. Your LOD spike should be greater than your noise.

Jack – the preamble should have examples of how labs currently meet the requirements.

Richard – ours is a best-practice approach. We can point out that LOD is not required if you don't report below the LOQ.

June – Worried that auditors will use this document and audit to it. Jack agrees and wants to call this a tool set.

Richard – Asks committee if document and slides are a good way, if we add a preamble, and we emphasize that is guidance only, can this form the basis for a recommended procedure on what we have so far (it's not complete – we can add to it)?

> Brooke – yes, we need to have input on comments on the slides so we can keep moving forward.

Jack – comfortable conceptually, wants to see whole thing and wants to resolve Marlene's points. Thinks this is only ONE way of dealing with it.

Gail – no matter what we do, the lab has to know how to communicate it to their clients. She thinks what we have is only an option.

June – We have provided enough to move onto LOQ.

Prabha – Has problem with recoveries with LOD , wants to call it detected , not recovered.

Richard – we have consensus to move on. Next teleconference, Oct 8 at 1:00 eastern.

Homework – How are going to come up with what ought to be the recovery criteria for LOQ spike?