



Memorandum

Effective Date: March 9, 2011

To: PT Providers and PTPAs

From: The TNI Proficiency Testing Program's PT Executive Committee

Regarding: Experimental Fields of Proficiency Testing tables

The PT Executive Committee recently distributed a memo notifying the TNI Community of the removal of the Experimental FoPT tables from the website. To assist PT Providers and PTPAs with this transition, this memo is generated to provide responses to comments and questions that have arisen from this action.

Comment #1 – When will the Experimental analyte tables be removed from the website?

Response #1 – The Experimental analyte tables were removed from the website on March 3, 2011.

Comment #2 – When a change is made to the TNI PT FoPT tables, either removal or addition of analytes, the change needs to include an effective date. The policy that details the change should clearly state that all PT studies that start after the effective date must comply with the new PT FoPT tables. The policy issued on February 24, 2011, did not include this distinction.

Response #2 – Paragraph three of the 2/24/11 memo states that the change is effective when the Experimental FoPT tables are removed from the website. This change immediately applies to both current and future studies. It is acknowledged that this is a somewhat different approach than the one typically utilized for routine FoPT table updates.

Comment #3 – The removal of the Experimental analytes may cause some currently available PT product lots to not be in compliance with the rule for the minimum number of analytes that have to be in a PT. Time is needed to evaluate whether this would be an issue and for determining how to design, manufacture, package and verify standards that are compliant with the new requirements.

Response #3 – The PT Executive Committee grants PT providers a transition period, where any PT product lots that, due to the removal of the Experimental tables, now fail to meet the rule for the minimum number of analytes as described in section 6.3 of the 2009 TNI Standard Volume 3 may continue to be used and distributed to laboratories. The

transition period is until June 30th, 2011. This transition period does not apply to any PT product lots that did not meet the minimum number of analytes requirement prior to the removal of the Experimental FoPT tables from the website. As of July 1, 2011, all PT product lots distributed to laboratories must again meet the rules as described in section 6.3 of the 2009 TNI Standard Volume 3.

Comment #4 – Will uploads of PT data from PT Providers to PTPA PT databases be changing? Will former Experimental analyte data no longer be collected by the PTPA and will the PTPA systems require that only Accreditation analyte data be uploaded?

Response #4 – The TNI Standard does not prevent the upload of non-FoPT analytes into a PTPA PT database. Given that a number of the former Experimental analytes will become Accreditation analytes in the coming months, the PT Executive Committee's preference is that a PTPA would continue to collect former Experimental analytes in their PT database until such time as new DW, NPW and S&CM FoPT tables are approved and made effective later this year. The PTPAs will make the final determination on whether or not they will continue to collect former Experimental analyte data in their PT databases until such time as new DW, NPW and S&CM Accreditation FoPT tables are approved and made effective later this year, and the PTPAs will notify their accredited PT providers of that decision by March 31, 2011.