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A2LA TNI PT Oversight Program

The Forum on Laboratory Accreditation

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Laboratory Accreditation (A2LA)

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Overview

- One issue – “assigned value”
- Oversight Activities
- Database Now Active, 4thQ09, 1stQ 10
 - 174 studies uploaded
 - Nearing sufficient data for comparisons
- Plans for 2010/2011



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Assigned Value

- Defined effectively the same in TNI Vol 3 and in ISO/IEC 17043
- Used differently for those analytes where
 - Consensus mean is used as expected mean
 - a b regression coefficients used to determine the expected mean
- Confusion in application of footnotes
- Confusion in application of some 17043



Oversight Reviews

- 1st year: focused on getting successful uploads PTPs and then reviewing flags
 - Illegal units; non-TNI studies; additional post-study results; idiosyncrasies of each PTP
 - Required active oversight from A2LA, including review of flags and formats
 - Required special encouragements (some providers)



Automatic Screens

- All submitted studies are screened:
 - Analytes in proper groups, use proper units
 - Analytes in TNI range
 - Evaluation limits calculated per FoPT
 - Verification mean close to assigned value
 - Homogeneity within accepted limits
 - Stability within accepted limits



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Initial activities

- Clean up formatting in reports before flags could be used
- Review individual approaches by PTPs
- Error detection and correction
 - Incorrect assigned values for calculating limits
 - Failure to apply 10% and 110% limits
 - Incorrect FoPT coefficients



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1st year process improvements

- Revised some flag limits;
- Designed revisions to streamline input options, and interpretation of flags
- Reporting specific problems and other findings to the renewal assessment teams



PT Study – Ongoing Monitoring

- 174 Studies Uploaded, from all providers
- All parts of database working for nearly all providers, most of the time
- Some PTP input processes are stable, some not.



Oversight Analyses

- Database now (8/2010) has a practical minimum numbers of studies for extended analyses
 - Uniform concentration ranges (12-20 per PTP)
 - Unacceptable rates (3 per PTP, 50 for %tiles)
 - Recovery (6-12 per PTP, 50 overall)



Uniform Concentration

- Look for sample concentrations to span range of PT testing
 - 12-20 samples per analyte per provider
 - 4 equal quartiles of concentration range
 - Chi-Square analyses (expect 3-5 samples per quartile)
 - Conducted semi-annually



Unacceptable Rates

- For every analyte, for all PTPs, calculate distribution of unacceptable rates for all studies with $n > 50$.
- Accumulate 3-5 consecutive studies for each analyte
- Calculate all-PTP distribution (not average)
- Flag unaccept = 0%, <5% tile or > 95% tile
- Conducted semi-annually



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Unacceptable Rates

- For all analytes in a group, and all PTPs, calculate distribution of combined unacceptable rates for all studies.
- Calculate for all analyte groups
- Flag unaccept $< 5\%$ tile or $> 95\%$ tile
 - Conducted semi-annually



Recovery

- Regression of study mean vs. expected mean (assigned value or calculated)
- Flag slope $\neq 1.0$ or intercept $\neq 0.0$
- Data query to study recovery vs. expected and vs. all PTPs
 - Conducted monthly



Imminent changes

- Changes soon (this week?):
- First set of revisions, to streamline data for analytes determined to be stable and analytes not tested for homogeneity
- Modified flagging criteria
- Corrections for excluded analytes (BOD, COD, phenols, etc.)



2010/2011 Changes

- Implement new FoPT Tables – maintain multiple levels of tables, as PTPs implement new requirements.
- Change Experimental to Listed analytes
- Develop review analysis templates
- Streamline flags



PT Study Monitoring

- Will start planned monthly and semi-annual analysis reviews in Sept, 2010, when 2nd Qtr results are uploaded
- Not enough data to update FoPT tables, but will have by next year at this time
 - Identify analytes with poorest agreement
 - Identify opportunities for fixed limits



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Slide 17, 18 and 19 were examples of the data base. They were deleted because they included specific provider data.



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Questions?



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