Quality Certification Services Inc.

Laboratory Advisory Committee (LAC) Meeting

September 8, 2014
Eastern Lab Services
Medina, OH

1. Call to Order – Jere High, Chair, LAC
2. Agenda Review and Repair
3. Appointment of Recording Secretary
4. Minutes from 2013 LAC Meeting – attached
5. Old Business
    a. Milk Pregnancy ELISA Samples Unknown – Steven Sievert & John Rhoads
6. QCS Laboratory Program Update – Steven Sievert, QCS
    a. Review of Current Auditing Schedules - attached
    b. Procedures for New Instruments - attached
    c. Samples Unknown Program
        i. Late Submission of Data - Steven Sievert
        ii. Data Entry Errors – Steven Sievert
        iii. 2015 Unknowns Schedules – Steven Sievert
        iv. Samples Unknown Program revision plans
    d. Potential MUN tolerances for Samples Unknown Program
    e. Addition of New Components (optional) to Unknowns Program
    f. Laboratory Manager and Technician Training
    g. Questions/revisions on current *Auditing Procedures for Laboratories*
7. New Business
    a. What's needed to improve your QC audits?
    b.
8. Election of LAC Chair (Jere High is eligible for another 2-year term)
9. Adjourn

Quality Certification Services Inc.

Laboratory Advisory Committee (LAC) Meeting
September 8, 2014
Eastern Laboratory Services, Medina, OH

1. LAC meeting called to order by Chairman, Jere High at 10:10 a.m.

2. The agenda was approved as distributed.

3. Hearing no opposition from attendees, Jere High appointed Steven Sievert to take minutes for the 2014 meeting.

4. It was moved, seconded and passed to approved the minutes from the 2013 LAC meeting as presented and read at the meeting.

5. Steven Sievert, QCS Program Manager, provided a QC Program update (attached to minutes)
    a. Current auditing schedule distributed and discussed.
    b. Review of procedural steps following on-site laboratory audits.
    c. Report on the late data submission by laboratories.
    d. Discussions on data entry errors in the Samples Unknown program.
    e. Presentation of draft protocol for new instruments and components.
    f. Update on MUN program.

6. There was an extended discussion on the draft 'Approval Protocol for New Laboratory Instrument(s) and Component(s). This discussion focused on the need to balance the laboratory's desire to bring the new instrument(s) on-line as soon as possible and the need to provide an assurance of accurate results being submitted to the Cooperator Database. While the LAC members in attendance agreed on the provisions for notification, training, and routine QC procedures in the draft protocol, there were differing viewpoints on the demonstration of acceptable instrument performance. It was suggested that Steven Sievert incorporate suggestions from the floor into a revised proposal and present this revision during the afternoon session of the NALMA meeting.

7. Steven Sievert offered background on the MUN program and the need to develop tolerances for MUN program. There are no clearly defined tolerances for accuracy or repeatability in the audit guidelines. Further, there have been requests from laboratories on guidance on MUN performance and from outside parties on the data quality. Finally, it was agreed that this would enhance the value of the MUN program. It was agreed that a proposal should be developed and presented during the 2015 LAC meeting. John Rhoads, ELS, and Julee O'Reilly, DHI Cooperative Inc., volunteered to work with Steven Sievert on development of a MUN program proposal. Additional expertise may be solicited in this work area and Steven Sievert will present a draft proposal at the next LAC meeting.

8. There were no other changes to the *Auditing Procedures for Laboratories* proposed during the meeting.

9. Jere High, LAC Chair, was up for election and indicated that he would not be running for another term. Jere was thanked for his 12 years of service to the Laboratory Advisory Committee as Chair.

10. John Rhoads, Eastern Laboratory Services, was elected to the position of LAC Chair for a two-year term by unanimous declaration.

11. Meeting was recessed at 11:45 a.m.

12. Meeting was reconvened at 3:50 p.m.

13. Steven Sievert distributed a revised protocol for new instruments and thanked laboratory managers for their input. This revision (attached to minutes) included two options for providing assurance of instrument performance. It was moved, seconded, and passed by the LAC to send the revised proposal to the Audit Review Committee and subsequently to the Council on Dairy Cattle Breeding for review and addition to the *Auditing Procedures for Laboratories* with a target effective date of January 1, 2015.

14. The meeting was adjourned at 4:00 p.m.

Recorded by:

Steven Sievert
QC Program Manager
Quality Certification Services Inc.

Laboratory Advisory Committee (LAC) Meeting
September 9, 2013
Doubletree by Hilton, Bakersfield, CA

1. LAC meeting called to order by Chairman, Jere High at 10:35 a.m.

2. The agenda was approved as distributed.

3. Hearing no opposition from attendees, Jere High appointed Steven Sievert to take minutes for the 2013 meeting.

4. It was moved, seconded and passed to approved the minutes from the 2012 LAC meeting as presented and read at the meeting.

5. In Old Business, Steven Sievert and John Rhoads provided a brief discussion of SCC Standards and Calibration Ranges. The two components of this discussion included applying the FDA standard for SCC MD of ±15% for SCC <200,000 and ±10% for SCC >200,000 along with the range of calibration standards of 100,000 to 1,200,000. This discussion was initially based on a possible lowering of the SCC limit in the PMO. As this change did not occur, it was recommended by John Rhoads that no action be taken at this time and this item be tabled until the 2014 LAC meeting for further comments.

6. Steven Sievert provided an update in the QCS ELISA Proficiency Program. Tentative plans are for a 12-sample set of unknowns with beta testing in Q4 2013 and launch in Q1 2014. Updates will be posted on the QCS website and program announcement will be distributed to all laboratory managers.

7. Lab QC Program presentation (attached to minutes) by Steven Sievert, QCS Program Manager
    a. Current auditing schedule distributed and discussed.
    b. Review of procedural steps following on-site laboratory audits.
    c. Report on the late data submission by laboratories.
    d. Discussions on data entry errors in the Samples Unknown program.
    e. Discussions on the shift in MUN performance beginning in August 2012 in Chemspec instruments.

8. After extended discussion and reviewing possible options to improve data submission accuracy, It was moved, seconded, and passed to amend the *Auditing Procedures for Laboratories*, page 2, to read:

    Any laboratory that submits either late data or corrected data more than twice in the previous twelve (12) month period without a valid reason will have its respective certification status changed to provisional.

9. There were no other changes to the *Auditing Procedures for Laboratories* proposed during the meeting.

10. Adjourned at 11:50 a.m.

Recorded by:

Steven Sievert
QC Program Manager
Quality Certification Services Inc.

QCS Laboratory Program Update

Steven J. Sievert
Manager, Quality Certification Services, Inc.
Technical Director, National DHIA

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Lab Advisory Committee Meeting
September 8, 2014

Housekeeping

General Auditing Guidelines

- **Service providers are required to notify the auditor of:**
  - **Changes in business name, address, phone, email, contacts**
  - **Changes in authorized personnel – i.e. lab managers, contact person**
  - **Changes in equipment/instrumentation**
- **Notification within 30 days of change.**
- **Changes should be sent to QCS Program Manager – Steven Sievert, not to the Lab Auditor.**
- **Assures accuracy in billing for laboratory fees and samples unknown component fees, website listings, and monitoring instrument performance.**

Renaming of Instruments/Line Identification

- **Notify QCS Program Manager (Steve) of desire to rename instrument:**
  - **Has to be done by QCS staff to merge history files.**
  - **If you only change the name on the Samples Unknown website, it will create a new instrument and start a new history file.**
  - **Please make changes prior to Samples Unknown test week, not during the week. Process takes time and QCS Manager is not always available depending on audit schedule.**
  - **Current program does not allow certain characters to be used in naming such as #, &, @, ( ), { }, or [ ].**
- **QCS will link the history files and email confirmation to lab.**
- **Enter data as normal during the next Samples Unknown trial.**

On-Site Audits

Laboratory Auditing Schedule

Auditing schedule is periodically updated to reflect the current participating laboratories.

- **Updates are published on QCS website when changes occur.**
- **Work to have a balanced audit schedule/workload**
  - **23 labs in even-numbered years**
  - **22 labs in odd-numbered years**
- **There is one laboratory expected to close in 2015 (from the even year group)**

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Availability of Samples During Audit

- Laboratory MUST have samples to run the day of the audit.
- If no samples are available, the audit will be terminated and will be rescheduled.
- Laboratory is responsible for all costs (time and travel) associated with the subsequent audit.
- Will negatively affect your certification status (i.e. Provisional).
- Certification expiration date cannot be extended and the auditor's schedule may push subsequent audit date past expiration date. Net result is decertification of the laboratory until the on-site audit can be completed.

After your lab audit…

1. Paul provides a summary list to lab with non-compliant items, usually before leaving the laboratory.
2. Paul sends summary, audit report and certification status recommendation to QCS for review. The lab auditor does not determine certification status.
3. QCS reviews recommendation along with payment history, on-time submission requirements and other factors.
4. QCS prepares summary letter and full report and sends to laboratory, general manager and board president (as applicable).
5. QCS updates website with certification status.
6. QCS places follow-up items on calendar based on timetable (30 days, 6 months, etc.) stated in audit report.
7. QCS and Paul work cooperatively to secure required follow-up if laboratory does not respond in a timely fashion.
8. Failure to respond, either partly or fully, will negatively affect your certification status.

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Noncompliant Items from Previous Audit

It is normal that certain noncompliant items identified during the course of the on-site audit are designated with a completion timeline of 'by the next audit'

- **If a lab fails to address these noncompliant items by the subsequent audit, the laboratory will have its certification status changed to 'Conditional.'**
- **The auditor will recommend to QCS a time-frame for completion that will not exceed six (6) months.**
- **Failure to address these items within the time-frame designated will result in the laboratory certification status to be changed to 'Provisional.'**
- **May bypass the 'Conditional' status if additional serious noncompliant issues are identified during the course of the subsequent audit.**

Samples Unknown

Review of Monthly Samples Unknown Results

1. **Paul provides a list of labs not satisfying the guidelines and recommendation each month:**

   - **Immediate contact with laboratory**
   - **Watch closely next month**
   - **Out of tolerance, but issue has been addressed**

2. **QCS sends an email to each lab listed as immediate contact requesting a response within 7-10 days to both Paul and QCS.**

3. **QCS and Paul work cooperatively to secure required follow-up if laboratory does not respond in a timely fashion.**

4. **Failure to respond <u>will</u> negatively affect your certification status.**

Review of Monthly Samples Unknown Results

During the analysis of the July 2014 QCS Samples Unknown trial, lab auditor Paul Sauvé made the following comments regarding [redacted] DHIA laboratory.

[redacted]	1	Fat	MD out in two of last three trials. July MD=.079.	Recommend contact with lab regarding this issue.

Please review internally and then provide feedbacks and steps taken to correct these issues on or before July 29, 2014. Please include both Paul and myself on this communication.

Best regards,
Steven

Steven Sievert
Manager, Quality Certification Services
Technical Director, National DHIA & DHIA Services

Samples Unknown – Data Entry Errors

- **Huge increase in number of data entry errors in Samples Unknown:**
  - **Transpositions – 3.18 instead of 3.81**
  - **Minor data entry errors – 4.30 instead of 3.30**
  - **Switching rows & results – i.e. protein & MUN switched**
  - **Major data entry errors – entered the wrong data (previous months data, total protein instead of true protein, or wrong instrument)**
- **Paul and Steven correct obvious errors – but should we?**
  - **Labs should be responsible for the data they submit**
  - **If QCS does not correct mistakes, labs may potentially be 'out of compliance.'**
- **Batch entry confirmation report is available – each lab should print and double check the data entered.**
- **Corrected data is late data as discussed and agreed during 2013 LAC Meeting**

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Samples Unknown – Data Entry Errors

During the review of the July 2014 Samples Unknown trial, Paul Sauvé noted the following data entry error for [redacted] DHIA.

- In reviewing the July samples unknown, I discovered a data entry error in your results – L2, FAT, Sample #11 changed from 3.43 to 4.43.

Previous data entry errors during the last twelve months for [redacted] DHIA have been noted in the following samples unknown trials:

- May 2014
- September 2013
- August 2013

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Batch Entry Confirmation

Alpura Delicias

Delta CombiScope
FTIR

	Fat		Pro		SCC		MUN	
	Rep1	Rep2	Rep1	Rep2	Rep1	Rep2	Rep1	Rep2
1	2.810	2.840	2.970	2.980	41	43	13.90	15.40
2	3.530	3.550	2.890	2.880	441	441	12.20	12.30
3	3.670	3.700	3.020	3.000	165	171	13.70	14.50
4	4.530	4.570	2.890	2.870	258	252	8.30	9.10
5	4.950	4.980	2.870	2.860	192	198	11.10	12.70
6	4.110	4.130	3.250	3.250	315	315	14.70	15.20
7	3.950	3.940	3.630	3.610	1,219	1,224	11.10	10.80
8	4.280	4.280	3.180	3.180	107	113	11.80	12.80
9	3.860	3.860	3.020	3.020	207	218	14.20	14.60
10	3.330	3.340	2.810	2.800	459	484	16.10	16.80
11	3.410	3.420	2.810	2.820	249	238	21.50	21.90
12	4.030	4.030	3.240	3.240	263	248	17.50	16.20
Hash Totals	46.460	46.640	36.580	36.510	3,916	3,945	166.10	172.30

Late Entry of Samples Unknown Results

- **Laboratory Guidelines changed in 2009 – any lab submitting data late (unexcused) twice or more in a 12 month period will have certification status changed to provisional.**
  - **6 Labs have been made provisional**
  - **19 labs have 'one strike' today**

August 2014

- **3 late labs – 10 instruments, 40 components**
- **Two labs with data entry errors**

Late Entry of Samples Unknown Results

What is Valid?

- **Acceptable Reasons**
  - Instrument problems
  - Waiting on parts and/or manufacturer technician to arrive
  - Samples arrived spilled or out of condition
  - Samples arrived late

- **Unacceptable Reasons**
  - Vacation
  - Forgot the samples were in the cooler
  - Did not get around to running the samples
  - Forgot to enter the results
  - Ran out of time on Friday

Samples Unknown Programming Plans

- **QCS is working on a rewrite/refresh on the Samples Unknown Website with focus on:**
  - **Data entry compatibility with newer browsers as well as tablets and other touch screen devices**
  - **Ability to add new components**
    - **BOHB, casein, FFA, lactose, etc.**
  - **Address instrument naming concerns**
  - **Internal data handling and editing needs**
  - **Exploring options for interface for result submission**
    - **Challenges - different instruments with different output and labs handle unknowns differently**
    - **Goal – QCS will have a STF (Standard Transfer Format) that labs will have to use**

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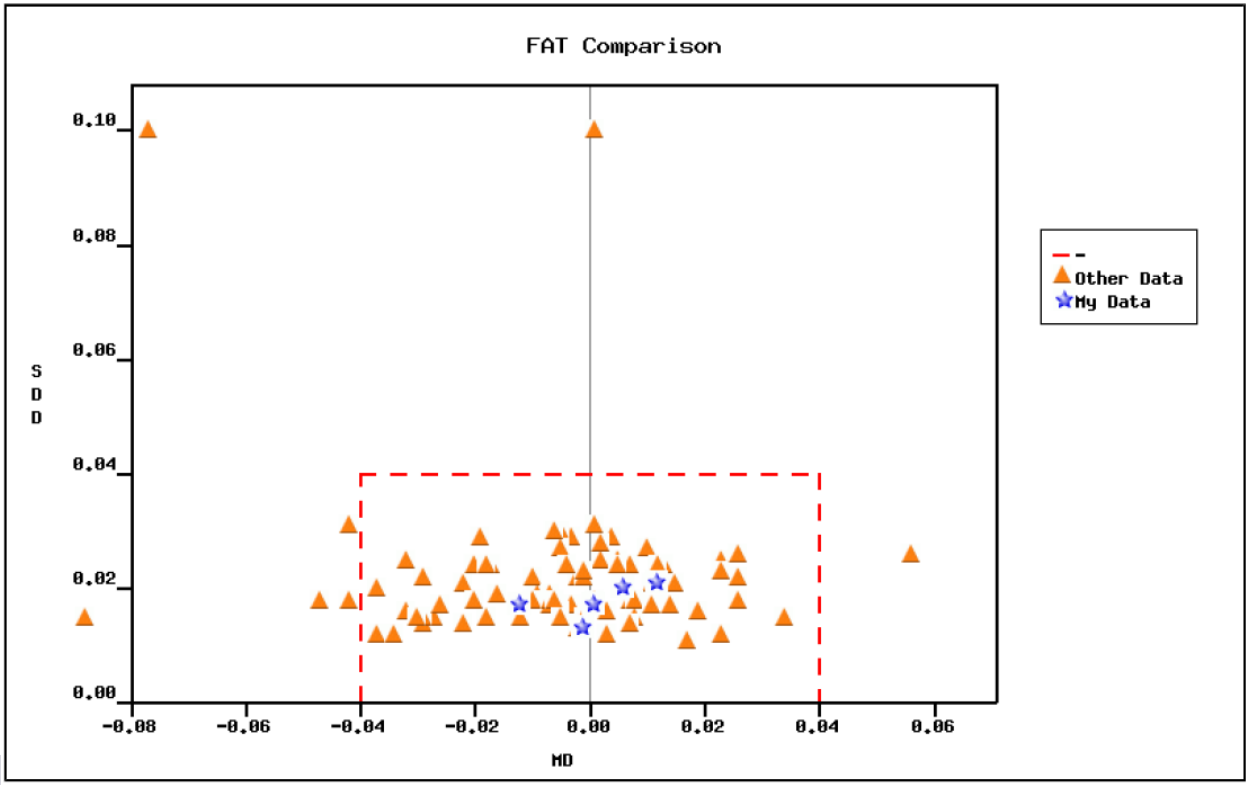
Samples Unknown–Batch Comparison Report

Allows you to compare performance with other labs

- Only know the identity of your lab
- Identify trends by looking at all instruments in your lab
- Build value in DHI programs and use as sales tool



Adding New Instruments & Components

Procedure for New Instruments

- **Proposed addition to the Auditing Guidelines**
  - **Applies to new, used, and refurbished instruments**
  - **Technically this proposal adds a detailed procedure to the auditing guidelines to help labs through the process**
  - **Designed to be cooperative as QCS recognizes the desire to have new instrument fully operational as soon as possible**
  - **Provides an assurance that data submitted to GEP and used by the industry is accurate and repeatable**

Procedure for New Instruments

What are the costs of removing component results from a non-compliant lab or instrument from the database?

- Identifying which herds & cows were run on the instrument during the time period in which it was out of compliance
- Removal of component results and reprocessing test days by DRPC
- Resubmission of format 4 and 14 to CDCB by DRPC
- Notification of third party users of data
- Decrease in DCR (Data Collection Rating) for components in affected herds
- Possible incomplete lactations for cows without a test day result in the first 90 days of the lactation

Procedure for New Instruments

- **Notify QCS Program Manager of new instrument:**
  - **Make, Model and In-Service Date**
  - **Components to be analyzed**
  - **Instrument to be taken off-line (if applicable)**
- **If the laboratory and technicians are not familiar with the make and/or model of the new instrument(s), manufacturer training is required and subsequent documentation sent to the QCS Program Manager**
- **Perform appropriate and routine QC checks**
- **Calibrate the instrument using suitable reference control samples**
  - **Pilot samples and Samples Unknown sets are not suitable for calibration**

Procedure for New Instruments

- **Laboratory adds instrument on Samples Unknown website. The Samples Unknown website will create a new history file for the instrument.**

- **Component results for herds with data going to the GEP should not be submitted to DRPC until satisfactory instrument history is established:**

  - **3 monthly Samples Unknown trials within component tolerances, or**
  - **1 'official' Samples Unknown trial plus 2 special weekly sets of unknowns all within tolerances**
  - **Data from special unknowns is emailed to QCS Program Manager and to Paul Sauvé**
  - **Must meet current guidelines for all instruments – three of the last four trials within tolerance for MD and SDD for all components analyzed**

- **Submission of data to Industry Cooperator Database after written approval from QCS Program Manager**

Observations from New Instrument Start-Ups

- **Issues noted with new instruments**

  - Calibration mistakes – usually 2nd or 3rd week of full operation
    - Calibrated to total protein vs. true protein
    - Errors in calibration
  - Sample handling issues related to new instrument capability
    - Sample heating - shorter time in water bath
    - More samples in water bath and water does not reach proper temperature
  - Solution/reagent preparation
  - Environmental – humidity, temperature, vents/fans
  - Software/data flow issues

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Procedure for New Components

- **Proposed addition to the Auditing Guidelines**
  - Applies to existing instruments when a lab begins analyzing a new component
  - Generic language that would apply to additional components if deemed valuable in the marketplace
    - BOHB, casein, FFA, lactose, etc.
  - Set up the new/additional component in the Samples Unknown system
  - Meet the same performance criteria as with all instruments submitting data to the Industry Cooperator Database

MUN Update

Shift in Milk Urea Nitrogen (MUN) Results

1. **CL-10 is the international reference method for MUN.**

2. **QCS documented a noticeable change in Chemspec performance beginning with the August 2012 Samples Unknown trial.**

   - **Increased SDD for all Chemspecs**
   - **All Chemspecs had a negative MD except for one instrument**

3. **This shift in MUN performance became more pronounced through the balance of 2012.**

4. **Not all labs were affected to the same magnitude.**

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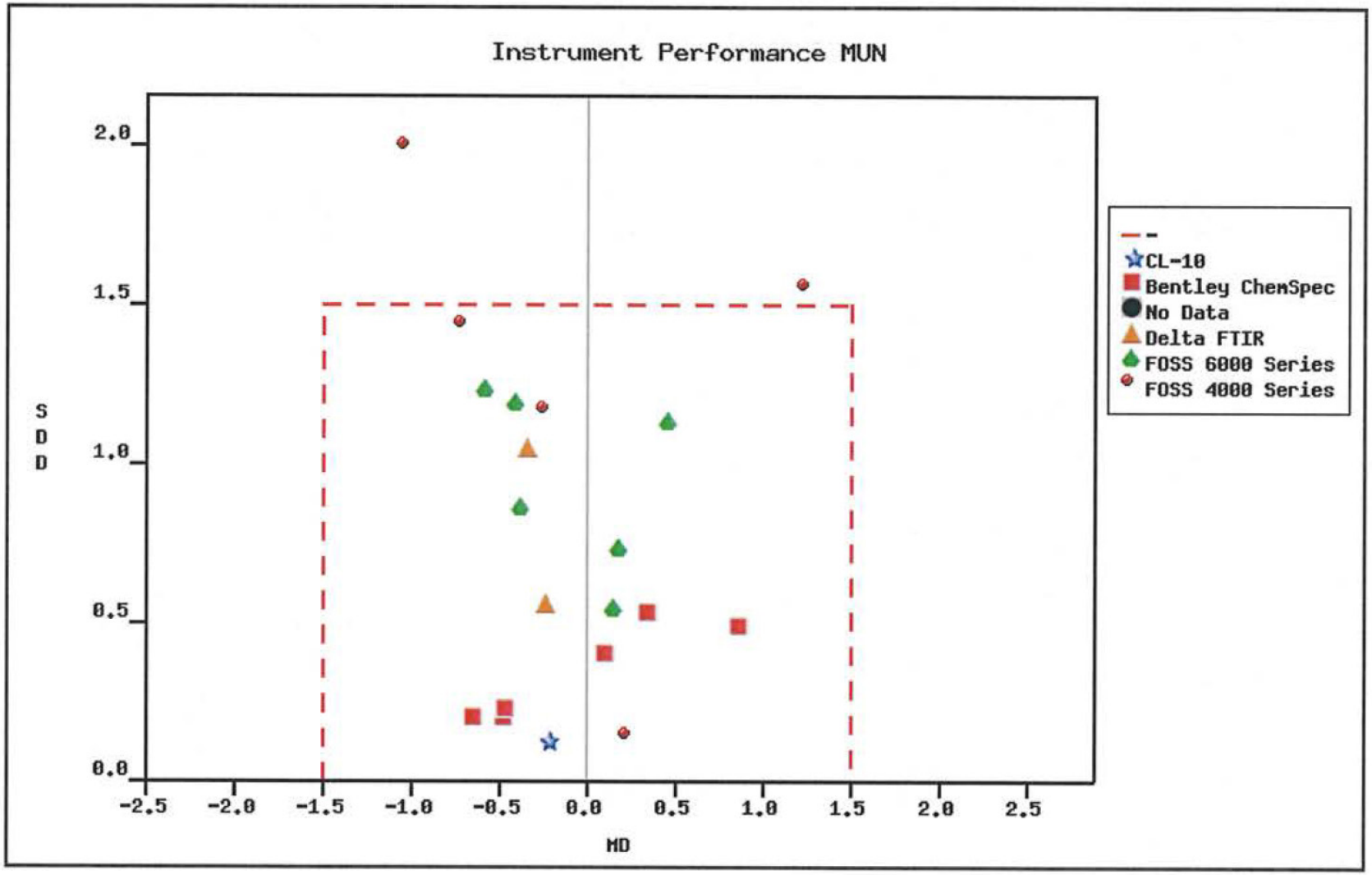
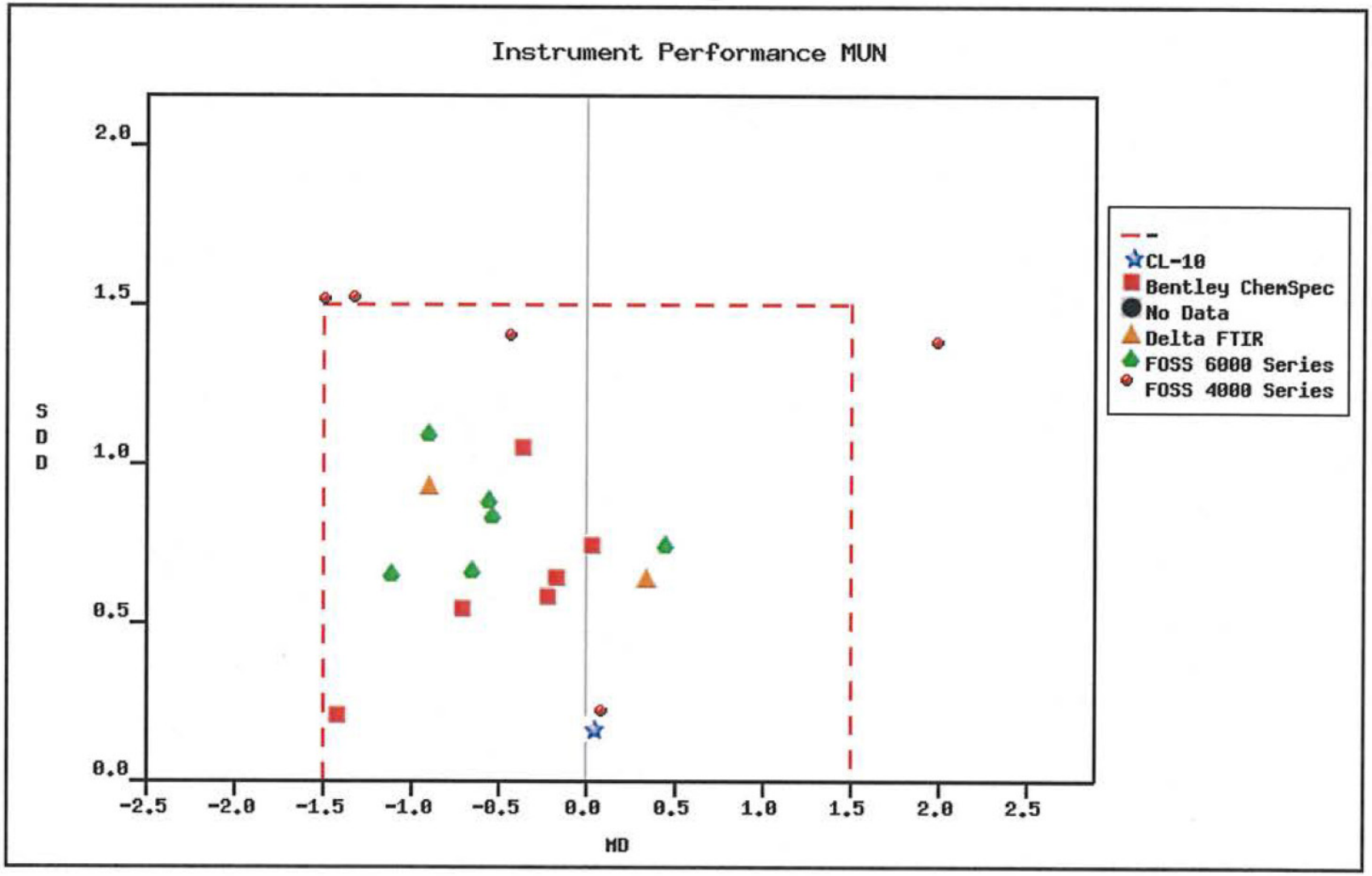
MUN – July 2012



MUN – August 2012



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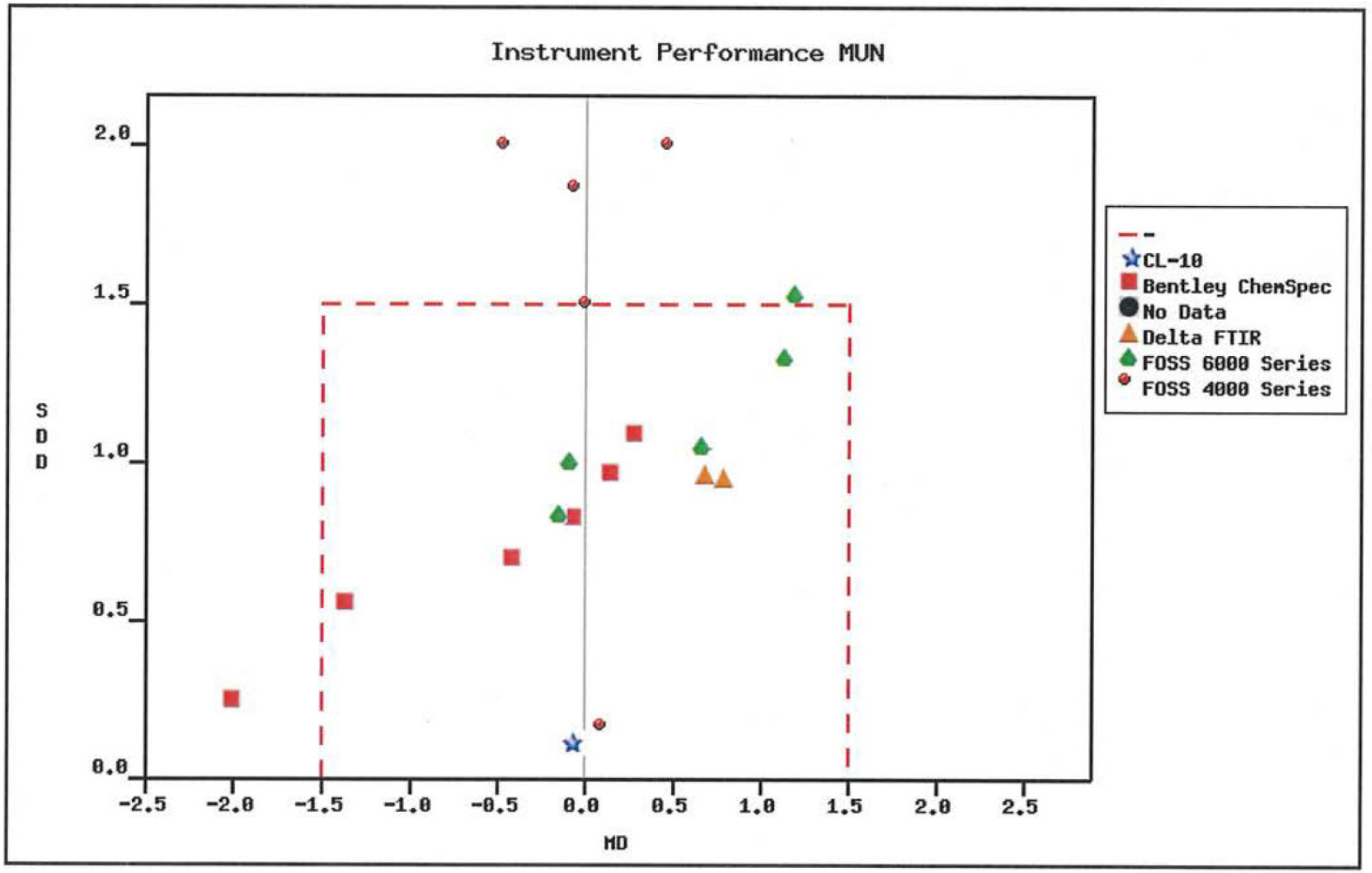
MUN – December 2012



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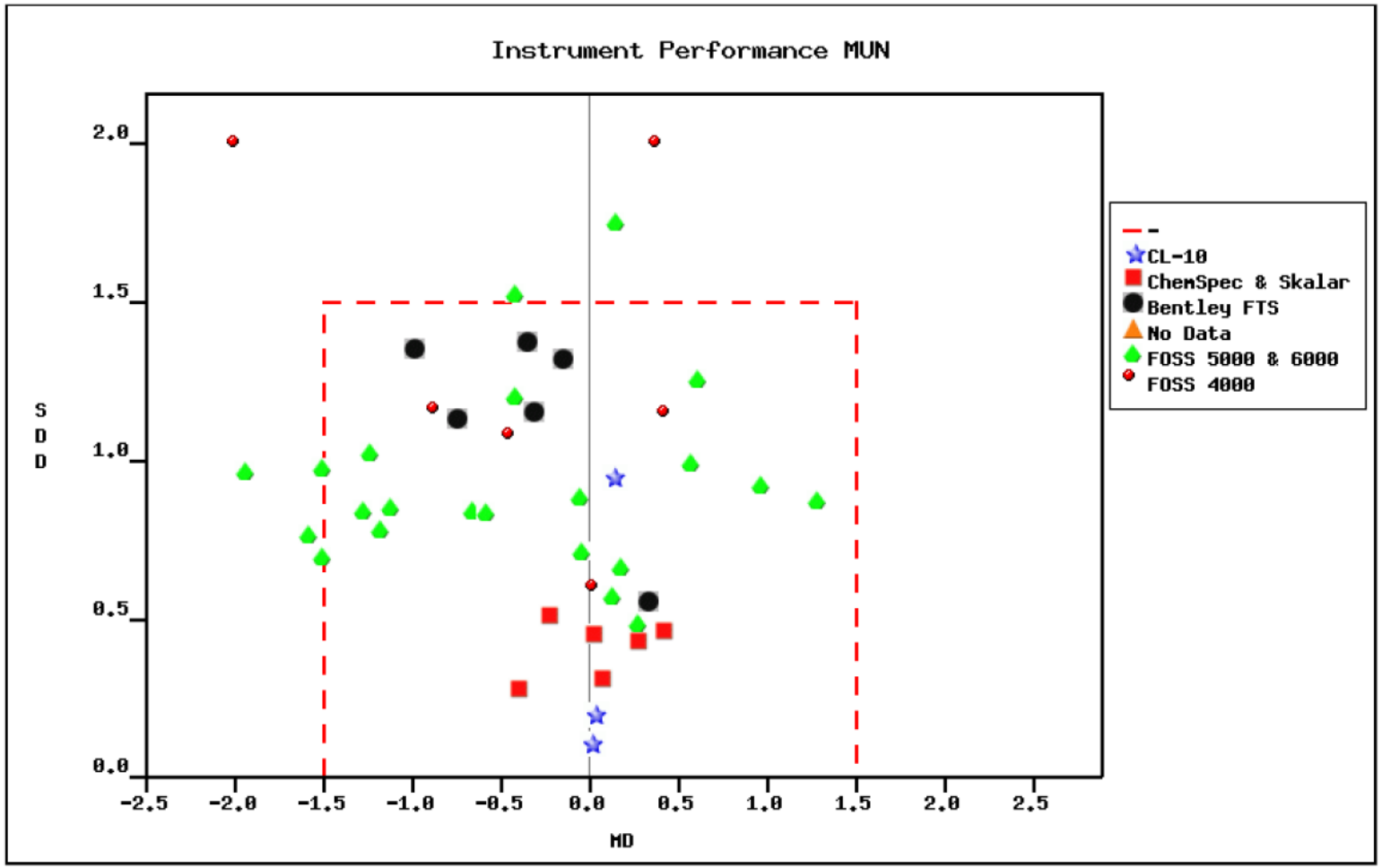
Milk Urea Nitrogen (MUN) Results

1. **Discussions with Bentley, CL-10, and ELS have occurred.**
   - **The slopes for the Chemspec and CL-10 are no longer well correlated in Paul's opinion.**
   - **Changes in chemical packaging at Bentley in 2012.**
   - **Change in reagents for the CL-10 causing the reference reading to be lower than the US average.**
   - **Labs calibrating to ELS standards saw different results than those calibrating to Bentley UHT sample.**
   - **Concerns were noted from labs outside the DHI system.**
2. **Results in July and August 2013 have improved and have maintained in 2014 YTD.**
3. **QCS and Lab Auditor have reviewed and continue to monitor results monthly as well as work with manufacturers and standards suppliers.**
4. **ELS has added additional CL-10 reference labs reporting results to the Samples Unknown program**

MUN Performance – August 2014



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MUN Tolerances

- Multiple requests to define tolerances for MUN in the Samples Unknown program
  - Labs with new instruments desire direction
  - Third parties using MUN data would like an assurance of accuracy
  - Support and marketing of MUN program
- Considerations when defining tolerances
  - Results from all instruments have improved
  - As herds use the same lab for MUN over time to measure changes, repeatability may have to have tighter tolerance than single cow accuracy
  - Can our tolerances be tighter than the instrument capability?
  - Our sample set needs to be in the range of all instruments
  - The variation in the lab has to be smaller than the variation between cows

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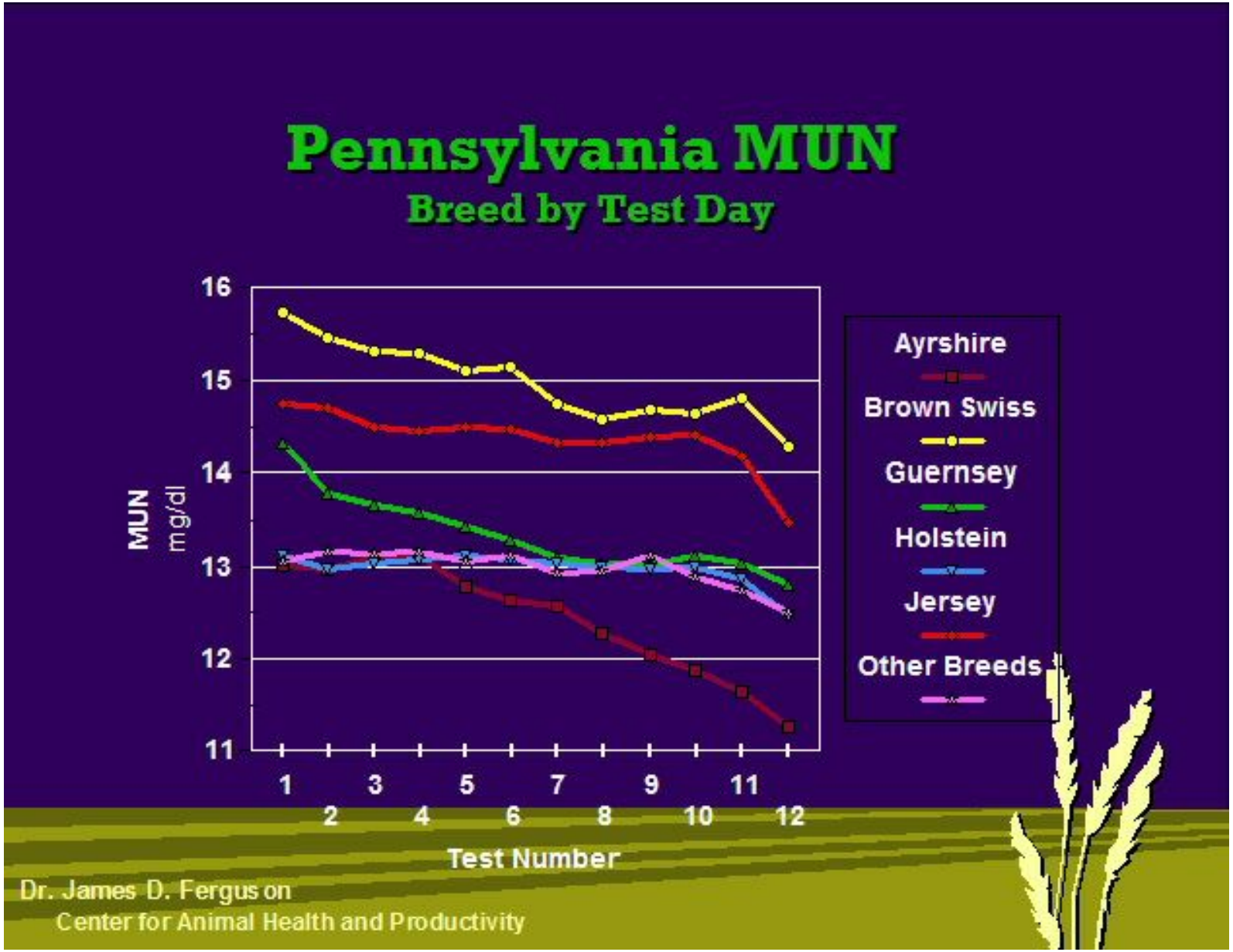
Pennsylvania MUN
Breed by Test Day
MUN
mg/dl
16
15
14
13
12
11
1
2
3
4
5
6
7
8
9
10
11
12
Test Number
Ayrshire
Brown Swiss
Guernsey
Holstein
Jersey
Other Breeds
Dr. James D. Ferguson
Center for Animal Health and Productivity

MUN Interpretation

Table 1: Interpretation of MUN for Group-Fed Holstein Herds[1]				
Stage of Lactation	MUN (mg/dl) < 10	10-12	13-14	> 14
Early (0-30 days)	Lack Dietary Protein Intake & milk yield may be sub-optimal	OK		Excess Dietary Protein Check RDP, RUP and / or adjust NFC
Peak & Post-peak (31-150 d)		Most desirable	May be acceptable	
Mid to Late (>151 d)				

[1] For Jerseys and Brown Swiss herds, add 1.5 units to all MUN value

Laboratory Training Modules

Laboratory Manager & Technician Training

- Both Paul and QCS have identified a strong need to improve and standardize training for DHI laboratory managers and technicians.
- Discussion on development of online training modules for various components (i.e. purging efficiency) of laboratory quality control.
  - Who, what, why, how, timing
  - Calculations, forms, record keeping
  - Troubleshooting
- Designed for both laboratory managers and employees
- Modules would be designed to be approximately 15 minutes with quiz
- Would help meet the training requirements in *Auditing Procedures for Laboratories*

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THANK YOU!

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Centering Period Months for Laboratories – Even Years

Laboratories are subject to biennial, on-site audits. Below is a schedule of target months for the on-site audits scheduled to occur during even-numbered years.

January .....Dairy Lab Services
..... Stearns DHIA Central Laboratory
.....Minnesota DHIA - Zumbrota

February .....Fresno DHIA
..... Kings County DHIA
.....Central Counties DHIA
.....Southern Counties DHIA
..... Tulare DHIA

March .....Puerto Rico DHIA

April .....Lancaster DHIA
.....Dairy One Cooperative Inc. – Hagerstown
.....United Federation of DHIAs

August ..... Asociación Holstein de México, Santiago de Querétaro, Querétaro, México
.....Alpura, Edo. de México, México, México
..... Inledesa (Alpura), Cd. Delicias, Chihuahua, México
.....Alpura, Gómez Palacio, Durango, México
.....Texas DHIA – Stephenville
..... The Dairy Authority LLC
.....Langston Laboratory

October.....Integrated DHI – Dimmitt
.....Texas DHIA – Canyon
.....Circle H Headquarters LLC
..... ADM Laboratories LLC

Centering Period Months for Laboratories – Odd Years

Laboratories are subject to biennial, on-site audits. Below is a schedule of target months for the on-site audits scheduled to occur during odd-numbered years.

January .....Heart of America DHIA
.....Mid-South Dairy Records

February .....Dodge County DHIA
.....Eastern Wisconsin DHIC
..... Gallenberger Dairy Records
.....NorthStar Cooperative DHI Services – Wisconsin

March .....Southeast Milk, Inc.
.....Tennessee DHIA

April .....AgSource Cooperative Services/CRI – Menomonie Laboratory
..... Barron – Washburn DHIC
..... Marathon County DHIA

June .....DHI Cooperative Inc.
.....Eastern Lab Services
..... Universal Lab Services

September .....Tillamook DHIA
.....Willamette DHIA
..... Washington State DHIA

October.....Northwest Labs, LLC
.....High Desert Dairy Lab
.....Rocky Mountain DHIA
.....Arizona DHIA

December ..... Dairy One Cooperative Inc. – Ithaca

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ELISA Proficiency Program

2015 Samples Unknown Schedule

Trial Number	Date Samples Shipped to Labs	Due Date for Results
161	January 12	January 30
162	January 31 (from NVSL-tentative) (NOTE: results should be entered on both NVSL website and QCS website)	February 27
163	March 16	March 31
164	April 13	April 30
165	May 11	May 29
166	June 8	June 30
167	July 13	July 31
168	August 10	August 31
169	September 14	September 30
170	October 12	October 30
171	November 9	November 30
172	December 14	December 31

Quality Certification Services
PO Box 930399 Verona WI 53593-0398
Phone: 608.848.6455 Fax: 608.848.7675 Email: sjsievert@dhia.org Web: www.quality-certification.com

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DHI Component Laboratory -

2015 Samples Unknown Schedule

Batch Number	Week Starting	
206	January 12	
207	February 9	
208	March 16	One week later due to National DHIA 50th Annual Meeting March 9-13
209	April 13	
210	May 11	
211	June 8	
212	July 13	
213	August 10	
214	September 14	
215	October 12	
216	November 9	
217	December 14	

Quality Certification Services
PO Box 930399 Verona WI 53593-0398
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Approval Protocol for New Laboratory Instrument(s) and Component(s)

DHI laboratories certified under the CDCB *Auditing Procedures for Laboratories* are required to demonstrate acceptable analytical performance on all lines of test instruments (also known as analyzers) on a routine basis. The monthly Samples Unknown program administered by the QC Program Manager serves this role for existing laboratory instruments.

Certified laboratories replace or add new line(s) of instruments on a routine basis. This procedure applies to new, used, and refurbished instruments. Results from these new instruments may not be submitted to the Genetic Evaluation Program (GEP) until demonstration of satisfactory instrument performance is completed.

New Instrument Approval Protocol

1. As outlined in the *General Auditing Guidelines*, the new instrument(s) must be reported to QC Program Manager and subsequently enrolled in the monthly Samples Unknown program. For each new instrument, the following information should be provided:

    a. Manufacturer,
    b. Model,
    c. Condition (new, used, refurbished),
    d. Serial number,
    e. Components to be analyzed (fat, protein, SCC, MUN, other),
    f. Instrument(s) to be replaced/taken out of service (where applicable).

2. If laboratory management and instrument technicians are not familiar with the make and/or model of the instrument, appropriate installation and training by the respective instrument manufacturer must be provided. Written evidence of this training must be forwarded to QC Program Manager.

3. Appropriate and routine QC checks must be completed and the instrument must be appropriately calibrated using suitable reference controls. Samples Unknown sets and pilot samples are not suitable reference controls for calibration of any instrument.

4. The laboratory will remain certified provided the laboratory completes one of the following options.

    a. Laboratory submits documentation to the QC Program Manager that includes the documentation listed below. Submission of data to the GEP from the new instrument(s) may begin immediately when using this option.

        - Completed manufacturer's training checklist,
        - Results from one set of Samples Unknown run by the laboratory during the instrument installation,
        - Documentation of calibration check validation during the first three consecutive weeks of operation, and

- Log files/reports for daily and hourly checks of multiple ranges of components, SCC, and zeroes during the first three consecutive weeks of instrument operation.

b. Laboratory establishes a satisfactory performance record by analysis of a minimum of three sets of unknowns provided by Samples Unknown provider. This process may be expedited by ordering and analyzing three consecutive weekly sets of unknowns. The tolerances for mean difference (MD) and standard deviation of differences (SDD) as outlined in CDCB *Auditing Guidelines for Laboratories* must be met for all components analyzed. Submission of data to the GEP cannot begin when using this option without approval from the QC Program Manager. The cost of these additional samples sets are the responsibility of the laboratory.

5. Laboratory management is responsible for contacting the QC Program Manager and for providing all of the required information as outlined in this protocol.

6. Failure to follow this protocol may be result in the change of the laboratory's certification status to provisional until such time satisfactory instrument performance is documented. Further, data submitted to the GEP that was generated from new instrument(s) may be removed from the database if warranted.

New Component Approval Protocol

1. As with new instruments, a laboratory that desires to analyze an additional component using an existing instrument should follow a similar protocol. The additional components(s) must be reported to QC Program Manager and subsequently enrolled in the monthly Samples Unknown program.

2. The laboratory will remain certified provided and may submit data to the GEP provided the laboratory provides documentation of instrument performance using one of the options outlined in the '*New Instrument Approval Protocol*.'

3. Laboratory management is responsible for contacting the QC Program Manager and for providing all of the required information as outlined in this protocol.

4. Failure to follow this protocol may be result in the change of the laboratory's certification status to provisional until such time satisfactory instrument performance is documented. Further, data submitted to the GEP that was generated for the additional component(s) may be removed from the database if warranted.

10 Best Practices of Good Laboratories

Lessons from a Laboratory Career

BY ROBERT L. ZIMMERMAN JR.

Beyond the simple chemistry lab directions of "Don't taste the chemicals; don't sniff the chemicals; don't look too closely at the chemicals – and wear your safety glasses!" are best practices that apply to test organizations across all scientific and engineering disciplines.[1]

There are 10 practices that laboratories, test organizations and individual analysts should keep in mind when performing daily analytical tasks. Many professionals may see these 10 practices as no-brainers. That's a good thing. However, all of us who are willing to tell the truth will admit there have been times when we might have slipped a bit on one or two. These "slips" can affect test result validity.

The importance of accurate results cannot be overstated. Test results change people's lives. This is eminently true in the medical and forensic fields. It is also true for those of us who test products, sometimes mundane products. Getting the right answer matters. To good laboratories, these best practices become routine procedures; to good analysts they become habits. The goal is to produce quality results.

The overarching rule for all these practices is: If you didn't document it — you didn't do it. Documentation is

critical. If documentation doesn't exist, create it; otherwise … re-read the rule.

For laboratories and test organizations that are considering applying for accreditation, following these 10 practices will be a significant step toward achieving that goal.

1. ESTABLISH AND FOLLOW PROCEDURES

Develop basic procedures, for example, to receive, identify, assign, cue, test, report and dispose of samples. For some organizations, a comprehensive quality system with an electronic laboratory information management system is appropriate. However, what is necessary can be a simple, orderly, faithfully followed process.

Samples should not languish unassigned in a receiving area; they should be logged in, given a unique identifier and assigned to an analyst or analytic team within one to two working days of arrival at the laboratory. Although some LIMS developers will rightly claim that the unique identifier need not contain specific sample information, information such as a customer code or arrival date is often useful in sample handling. Depending on the laboratory, sample assignment to a particular analyst or team may be based on the sample type, workload or other criteria. To allow analysts to plan their work, once assigned, samples should be moved to a queue zone for the team or analyst. While first in-first out is often the rule, holding a few days to allow for "batching" may be in order for some types of samples.

Post-analysis sample disposition should also follow an orderly process. Inventory records should include details that account for environmental and safety rules. Where legal action may ensue, chains of custody must be kept valid, and samples may have to be retained or returned to the submitter. Legal actions can be very lengthy. Therefore, when a laboratory retains samples, orderly storage is needed.

2. MAINTAIN YOUR PROFICIENCY

Analysts must have the education, training and experience, acquired through formal education or on-the-job training, sufficient to perform assigned analytic duties. Education and apprentice training provide the foundation for and give a snapshot of an analyst's capability, but they do not guarantee a sustained capability. This best practice assists analysts in maintaining and documenting capability.

Periodically, analysts should participate in proficiency testing, which shows that the analyst maintains capability over time. That gives customers and

stakeholders a greater level of assurance that the laboratory is maintaining its ability to perform a test method in a manner that produces valid results. (For accredited laboratories, periodic proficiency testing is required.)

If a laboratory decides to expand its capabilities, staff analysts will need training on the new tests. Continuing education affords an analyst the opportunity to expand capability in a current or a new technology area. When purchasing a new instrument, laboratories should give strong consideration to including the training package offered by the manufacturer. The laboratory should plan for proficiency tests in the new area.

3. VALIDATE METHODS

Method validation needs and techniques will change as the group using a particular method changes. Laboratories that work in fields with methods in widespread use, e.g., environmental and clinical laboratories, have more established techniques than fields with a smaller community of interest. Research laboratories that develop new test methods may offer their work for others to reproduce, and thus, validate.

For testing and calibration laboratories, the goal in selecting a test method is to choose one that produces an accurate result within an acceptable uncertainty that can be reproduced by multiple analysts. Test methods originate from various sources: standards development organizations, equipment and instrument manufacturers, universities, consortia and other organizations and individuals. Individual laboratories will develop new or modify existing methods to fit specific test needs they encounter. With the possible exception of SDOs that use a rigorous consensus development process, the validity of methods developed in any other venue cannot be assumed.

It is not necessary that every laboratory use the same method to test the same

ASTM International contributes to best laboratory practices through a number of programs that address testing, training and more.

Proficiency Testing Programs

Laboratories worldwide can compare, check, and if need be, improve their performance by participating in the ASTM International Proficiency Testing Programs.

With offerings in electrical insulating liquids, engine coolants, metals, plastics and much more, ASTM's PTP statistical quality assurance programs provide samples for each test cycle, method instructions and electronic submittal forms. The resulting reports, which code lab test results for confidentiality, contain statistical data analysis, charts plotting test results and more.

The programs help laboratories monitor their strengths and weaknesses, compare test results and statistical parameters with other participants and demonstrate proficiency for laboratory accreditation.

Technical and Professional Training

From coal chemistry to corrosion and petroleum to plastics, the ASTM International Technical and Professional Training program offers courses for lab technicians and other professionals to better understand and perform ASTM test methods and work with ASTM standards. Courses are held in various locations or at a client's site.

Certification Programs

ASTM International is currently ramping up a program that will offer certification services for products and personnel. Responding to requests from stakeholders for third-party demonstration of compliance to ASTM standards, ASTM staff anticipates that the first certification program will launch in 2011.

Cement and Concrete Reference Laboratory

The Cement and Concrete Reference Laboratory provides services that assist more than 1,100 laboratories in maintaining their capabilities. CCRL offers inspections for laboratories that test cement, concrete, aggregate, steel reinforcing bars, pozzolan and masonry using ASTM International standards in these areas, and reviews the lab's procedures, practices, equipment and facilities. CCRL also offers Proficiency Sample Programs based on tests performed by participating laboratories that can be used to check testing consistency, to help identify equipment or procedural problems, and to evaluate test quality between laboratories. The programs support accreditation by outside groups.

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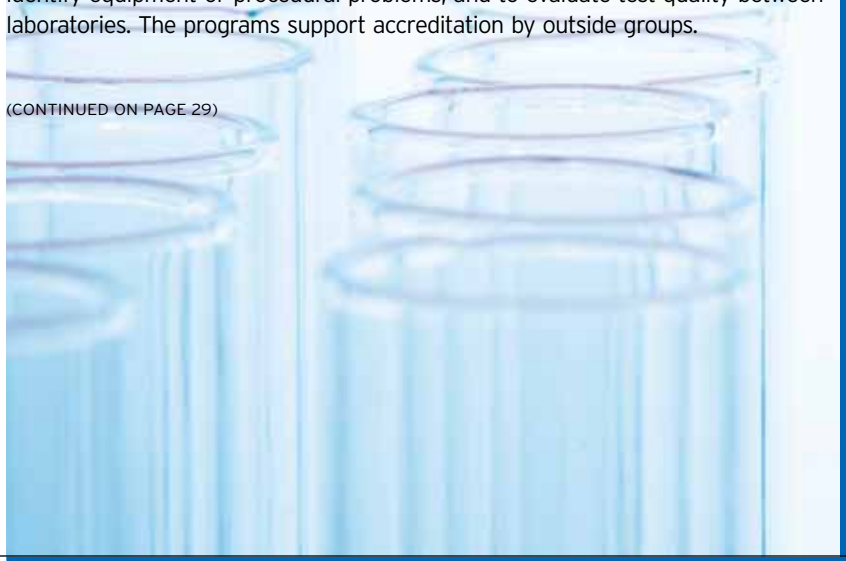

object. However, every laboratory must be able to defend its chosen method as capable of giving accurate results, which is achieved through method validation by multiple organizations and/or analysts who run the method using the same test object that has a predictable result. If one exists, a traceable standard reference material from the National Institute for Standards and Technology or an established test artifact with a known result should be used. Successful validation requires that the results of multiple runs are all within an acceptable uncertainty value, that is, a statistically acceptable margin of error.

For methods where multiple laboratories are few, or nonexistent, validation can be problematic. A potential validation process would be: 1) to have different analysts at the same laboratory run the method using the same SRM or test artifact and/or 2) to create relevant control charts where test results from one or more analysts are tracked over time. On the rare occasion when only one proficient analyst is available, that analyst should perform multiple independent runs of the protocol over time using the best SRM available. Control charts can be used to measure the reproducibility, accuracy and uncertainty of the method. Someone other than the analyst should review the data and control charts to assert that the method has been validated with a stated uncertainty range.

Research laboratories often are faced with a situation where it is the only one running the test as well as the added challenge of a method without a history of use. Validation begins with clearly communicating the procedures used to develop the method, typically through publication in a scientific journal. Publication enables others: 1) to assess the method for systemic errors; and 2) to reproduce the work to obtain the same results as the initial work. If the sample tested by both the initial researcher and those reproducing the work is an SRM, the new method has taken a significant step toward validation.

4. USE TRACEABLE STANDARD REFERENCE MATERIALS

Reference material uses include validating methods that help ensure accurate data from individual test runs, calibrating instruments and assessing analyst proficiency. In the United States, a NIST standard reference material is considered the "gold standard" for that material. NIST has more than a thousand different SRMs covering diverse technologies.[2] The results of analyses backed by NIST-traceable SRMs are widely accepted as valid.

An SRM must be fit for its intended use, for example:

- In an analytical chemical laboratory for a quantitative analysis, a series of reference materials with known elemental contents encompassing the analysis range of interest; or
- In a medical laboratory, a known virus or bacteria for qualitative analysis, or a serum with a known glucose content for quantitative diabetes testing.

While substantial in number, NIST SRMs do not cover all laboratory analysis needs. Standards from other organizations are often valuable. Surplus test items may be retained and used as reference materials, particularly by laboratories that perform repetitive testing of an item and have unusual analytical requirements, for example, elemental content. A typical benefit of retained items for repetitive testing is that they almost always have the same matrix. If the test is nondestructive, for example, X-ray fluorescence, a retained item has an almost unlimited life span.

In all cases, maintain high quality reference materials to maximize their usable life, and when you find a good one, don't let it out of your sight.

Closely related is the purity of other chemicals used in testing. Solid chemicals used to create calibration curves for determining elemental content and acids used to dissolve the solids, etc., with rare exception, all must be reagent grade or better.[3] Test methods should identify the lowest grade of the chemicals required for the method. Results are only as good as the weakest component in the system.

5. RUN IN DUPLICATE

The purpose of duplicate (sometimes triplicate) testing is to add to the confidence that the test run has produced good data for the test object. Replicate data that is in agreement is a good measure of method reproducibility but does not prove data accuracy (validity). If the

same test run includes a reference material, then the confidence in the validity of the data for the test object is significantly raised. If the object's replicate test data is not in agreement, one or more of the data points may be invalid; the object should be retested and/or the procedure should be reviewed.

Take care not to run out of sample. There are extenuating circumstances when replicate testing is not possible, such as an insufficient amount of the test object from a surface wipe or fragmental samples in some forensic environments; the high cost of the object when the test is destructive, for example, precious metals; or an overwhelming number of different but related objects when time is of the essence, for example, samples from different places to assess "how clean is clean" when cleaning a contaminated building. The use of reference materials as controls (see below) becomes paramount when only a single test object sample is included in a test run. When testing occurs in sequence with little human intervention, such as with automated laboratory analyzers, controls should be placed at or very near the beginning and end of a test run, at a minimum. When there are numerous test run samples, additional controls should be spaced appropriately throughout the sample set to give confidence that the data from each test object is valid.

6. KEEP ORIGINAL DATA

Whether data is first recorded in electronic/digital form, in a notebook or on the closest piece of scrap paper, keep it. In modern laboratories, handwritten original data is no longer the norm, but if data is first recorded by hand, that document becomes critical to maintain. No matter how often the data is transposed to electronic spreadsheets, databases or any other media, the initial point at which the data is recorded must become part of the documentation.

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Interlaboratory Study Program

The ASTM Interlaboratory Study Program assists technical committees with aspects of creating the precision and bias sections required in ASTM test methods. The ASTM ILS staff can help a committee design an interlaboratory study, identify potential samples, solicit volunteer laboratories, collect and analyze data, compile information for the research report, produce a draft precision statement and more. Once a work item has been registered, new ILS programs can be initiated.

Standards for Quality and Statistics

An ASTM technical committee whose work applies to diverse industry sectors in developing standards is Committee E11 on Quality and Statistics. The committee promotes the appropriate use of statistical and quality control principles and methods in ASTM International standards, and it develops standards to assist ASTM committees in this work. E11's standards include practices for conducting interlaboratory studies (E691) and ruggedness tests (E1169) as well as reporting uncertainty (E2554) and identifying statistical procedures (E1488), among others.

Numerous standards from ASTM International technical committees cover many aspects of laboratory practice and operation. From practices about preparing and using reference materials to guides for minimum requirements for laboratories that test construction materials, ASTM standards guide numerous industry sectors in their laboratory work and interactions.

Electronic data acquisition is the norm in a laboratory today, particularly with automated analyzers used in laboratories for all scientific disciplines. The advantage of digital data is that great quantities of it can be stored on relatively small devices, for example, CDs or USB flashdrives. However, consideration must be given to recover data from outdated electronic media. Laboratory procedures should address how long test results will be maintained, which depends on the organization's business, customer needs and the potential for legal actions. For this time period, laboratories should be able to read original data, either by maintaining equipment or by transferring data to new media. (Addendum to the golden rule: if you can't access a document, you didn't document it sufficiently.)

7. ASSIGN INSTRUMENTS AND EQUIPMENT TO ANALYSTS

Scientific instruments are temperamental tools; they need individual attention. The more sophisticated the instruments are, the more temperamental they can become, particularly if labeled research grade. When an instrument is used mainly by one staff member, usage time, calibration, maintenance and other issues are minimized. However, a good practice is to formally assign that analyst the responsibility for keeping the instrument operational and for alerting management to malfunctions. When an instrument is used by multiple staff members, assign these responsibilities to a primary user, who should schedule usage time for other staff members, provide training and mentoring to new users, ensure that any instrument control charts are current and ensure that calibration and maintenance occur on schedule.

The primary user should also have on hand a reasonable store of basic repair parts (lamps, ferrules, tubing, etc.) and basic consumables, such as carrier gases. This preparation will reduce instrument downtime. If an instrument is out of order, the primary user should determine with laboratory management if there are sufficient funds to call for a repair, and when funds are available, see that the repair is completed. The primary user should also alert other users about the problem, perhaps with a simple, conspicuous "out of service" tag on the apparatus.

8. CALIBRATE INSTRUMENTS

Instrument calibration, for this discussion, is confirming that an instrument is working correctly before performing a test method, whether a simple balance or a sophisticated analyzer. (For accredited laboratories, periodic instrument calibration by certified outside organizations is often required.)

An incorrect result with an SRM may indicate a problem with instrument performance. An experienced analyst will often know where the problem lies by "listening" to the instrument. Often a simple recalibration, such as running a procedure to reset the instrument's electronic system, can cure the situation. If the erratic behavior cannot be cured by simple recalibration, the assigned analyst should resolve the problem either with a call for a professional calibration service or an instrument technician.

9. USE CONTROL CHARTS

Control charts are excellent tools for several uses, including those already noted. A control chart enables a laboratory to track the results of a reference material and/or control sample at the end of each test run. It gives the laboratory a snapshot of test run quality and a picture of the quality of the laboratory's results for that particular test over time.

A Shewhart control chart plots individual test results for a reference material or control sample over time.[4] While Shewhart set a 3-sigma deviation from the mean as acceptable control limits, control limits can be set on a case-by-case basis. Customers of the test method should have input into setting control limits.

Control charts typically are used to track test performance for the organization as a whole, but they may be set up for each instrument, analyst, variable or combination thereof. Control charts give an immediate, visual and measurable indication of whether each test run has been performed correctly. When a control sample yields a result outside the control limits, the test run accuracy is in question. Typically, laboratories will rerun the test. If the retest yields a result for the control sample that is within the control limits, the laboratory will continue with normal operations and report the results from the correct run. Both the original and rerun control results should be recorded on the control chart for future monitoring. Should control samples continue to yield results outside control limits, demonstrate a drift[5] or other erratic behavior, the laboratory should not conduct this test until the problem is found and fixed. Control charts are valuable in that they can prevent questionable results from being reported to customers. However, should previously reported results come into question, customers receiving those reports should be notified. (For accredited laboratories, notification is a requirement.)

10. DOCUMENT EVERYTHING AND MAINTAIN GOOD RECORDS

To return to the golden rule of, "If you didn't document it, you didn't do it," organized records benefit a test organization. An ordered records system can be a prima facie indication to customers, auditors, government and legal authorities, and others that the organization follows its procedures. Records provide a fount of information for training new staff members to perform the stable of methods of the laboratory. When customers request copies of their test results, they are readily available, which makes for satisfied and repeat customers. More important, when test results have to be defended, these documents are critical.

Laboratories that pursue accreditation will need documents on method validation, proficiency testing, instrument calibration and most of the practices covered here. If the laboratory performs testing for regulated domains, records will be required to prove competency for that domain. In legal actions, for example, when the test object causes harm, records can prove that the test organization followed the applicable test procedures and thus reduce or eliminate liability. When documents are not available, questions can be brought to bear regarding test result validity, and potentially, organizational competence or negligence. The test organization is vulnerable to loss of customers, fines, penalties or other consequences to individual analysts, managers and owners.

The need for documentation occurs at different points while conducting a test, so good laboratory practice places continuing responsibility on the individual analyst to initiate and maintain documents. The person who performs a function is responsible for documenting it and storing the record in its proper place. It is a reminder that quality is the responsibility of each analyst and must be incorporated into every aspect of an analysis, including the paperwork. As the adage goes, "Quality is built in, not inspected in."

REFERENCES

1. The author would like to acknowledge that some of this work is an outgrowth of a study on conformity assessment for the U.S. Department of Homeland Security performed under funding by the DHS Office of Standards, Division of Test and Evaluation, and the Standards, Science and Technology Directorate. Additionally, the author is indebted to Eric Sylwester, Ph.D., of the Homeland Security Studies and Analysis Institute, and Robert Tuohy III for their thoughts and suggestions that were invaluable in enhancing these best practices.
2. For more information on NIST SRMs, see www.nist.gov/srm.
3. The term reagent grade is a term of art for chemicals of acceptable purity to be used in the most accurate level of chemical analysis. Acceptable purities are often set in published standards of a standards development organization, e.g., ASTM International, AOAC International.
4. For more information about the control charts developed by Walter A. Shewhart, see "Shewhart Control Chart," at www.itl.nist.gov/div898/handbook/mpc/section2/mpc221.htm and "Statistical Quality Control Using Control Charts," at www.gigawiz.com/qc.html#VarQC.
5. A drift is a steady fall or rise in a control sample test result that, if continued, will eventually cause the result to fall outside the control limits.

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