Quality Certification Services Inc.

Laboratory Advisory Committee (LAC) Meeting

September 9, 2013
Doubletree by Hilton Hotel
Bakersfield, CA

1. Call to Order – Jere High, Chair, LAC
2. Agenda Review and Repair
3. Appointment of Recording Secretary
4. Minutes from 2012 LAC Meeting – attached
5. Old Business
    a. SCC Standards and Calibration Ranges – Steven Sievert & John Rhoads
        i. FDA standard of MD ±15% for <200,000 SCC and ±10% for >201,000 SCC (page 20, Auditing of SCC Instruments for Calibration checks of *Auditing Procedures for Laboratories)*
        ii. Calibration range – currently 100,000-1,200,000
    b. 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. Samples Unknown Program
        i. Late Submission of Data - Steven Sievert
        ii. Data Entry Errors – Steven Sievert
        iii. 2014 Unknowns Schedules – Steven Sievert
        iv. Data Entry Hints using newer browsers (IE10, Chrome, etc.)
    c. MUN Calibration Shift
    d. Laboratory Manager and Technician Training
    e. Questions/revisions on current *Auditing Procedures for Laboratories*
7. New Business
8. Adjourn

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.

Calibration Check Frequency

Instrument calibration must be checked weekly. It must also be checked when a problem is suspected or when major equipment maintenance is performed.

Calibration Check Procedure

At least four fresh, raw milk samples must be obtained from an approved source. The SCC's must have been determined by direct microscopic SCC and must be in the range of 100,000 to 1,200,000 cells/ml.

The samples must be warmed and analyzed at least four times and the instrument results compared to the reference values.

Acceptable Readings for Calibration Checks

The calibration check is acceptable if the mean percent difference is within 5% and the standard deviation of percent differences is within 10%.

Response to Calibration Check Failures

If the instrument fails the calibration check, it should be recalibrated according to approved procedures.

Alternative Procedures

If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed.

Before implementation however, the auditor must scrutinize a copy of the alternative procedure and the laboratory must receive written authorization.

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QCS Sample Unknown Schedule for 2014

Batch Number	Week Starting	
194	January 13	
195	February 10	
196	March 17	One week later due to National DHIA Annual Meeting March 10-14
197	April 14	
198	May 12	
199	June 9	
200	July 14	
201	August 11	
202	September 15	
203	October 13	
204	November 10	
205	December 8	

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ELISA Proficiency Program

2014 Samples Unknown Schedule

Trial Number	Date Samples Shipped to Labs	Due Date for Results
149	January 13	January 31
150	January 31 (from NVSL-tentative)	February 28
151	March 17	March 31
152	April 14	April 30
153	May 12	May 31
154	June 9	June 30
155	July 14	July 31
156	August 11	August 31
157	September 15	September 30
158	October 13	October 31
159	November 10	November 30
160	December 8	December 31

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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
..... Dairy One Cooperative Inc. – State College
..... United Federation of DHIAs

August ..... Asociación Holstein de México, Santiago de Querétaro, Querétaro, México
..... Alpura, Edo. de México, México, México
..... 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..... AgSource Cooperative Services/CRI – North West Labs
..... High Desert Dairy Lab
..... Rocky Mountain DHIA
..... Arizona DHIA

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

QCS Laboratory Program Update

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

Quality Certification Services Inc.

Lab Advisory Committee Meeting
September 9, 2013

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**
  - ❑ **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, website listings, and monitoring instrument performance.**

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Laboratory Auditing Schedule

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

- **Updates are published on QCS website when changes occur.**
- **Some labs may have to move to balance work load in certain geographic regions.**
  - **25 labs in even-numbered years**
  - **22 labs in odd-numbered years**
- **QCS and Lab Auditor work cooperatively on schedule.**

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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 until audit can be completed.

After your lab audit…

1. Paul provides a summary list to lab with non-compliance 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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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)**
- **Laboratory then adds instrument on Samples Unknown website. The Samples Unknown website will create a new history file for the instrument.**
- **Enter data as normal during the next Samples Unknown trial.**
- **Component results for herds with data going to the GEP should not be submitted to DRPC until satisfactory instrument history is established:**
  - ❑ **4 samples unknown trials, or**
  - ❑ **1 trial plus 3 special weekly sets of unknowns**

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Renaming of Instruments/Line Identification

- **Notify QCS Program Manager of desire to rename instrument:**
  - **Has to be done by QCS 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.**
- **QCS will link the history files and email confirmation to lab.**
- **Enter data as normal during the next Samples Unknown trial.**

Late Entry of Samples Unknown Results

- **Laboratory Guidelines changed in 2009 – any lab submitting data late (unexcused) twice in a 12 month period will have certification status changed to provisional.**
  - **5 Labs have been made provisional, 16 labs have 'one strike' today.**
- **What are valid excuses?**
  - **Acceptable Reasons**
    - Instrument problems
    - Samples out of condition
    - Samples arrived late
  - **Unacceptable Reasons**
    - Vacation
    - Did not get around to running the samples
    - Forgot to enter the results
    - Ran out of time on Friday

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 the labs' mistakes, more labs may potentially be 'out of compliance.'
- Batch entry confirmation report is available – each lab should print and double check the data entered.
- Bottom Line – Labs need to be accountable and corrections take time.

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

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 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 will negatively affect your certification status.**

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.

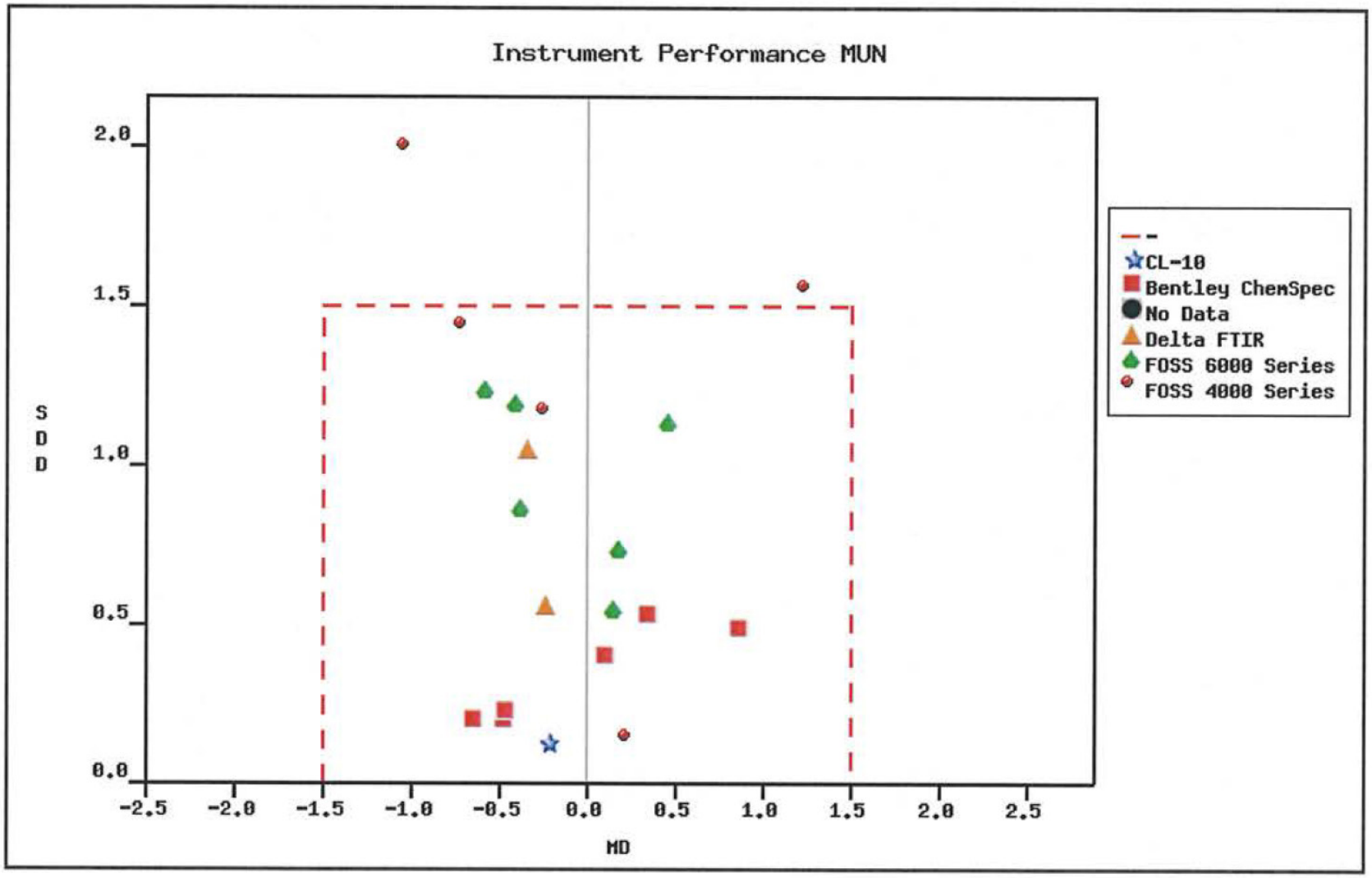
   - Increased SDD for all Chemspecs
   - All Chemspecs had a negative MD except for one instrument

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

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

5. QCS and Lab Auditor have reviewed and continue to monitor results monthly.

MUN – July 2012



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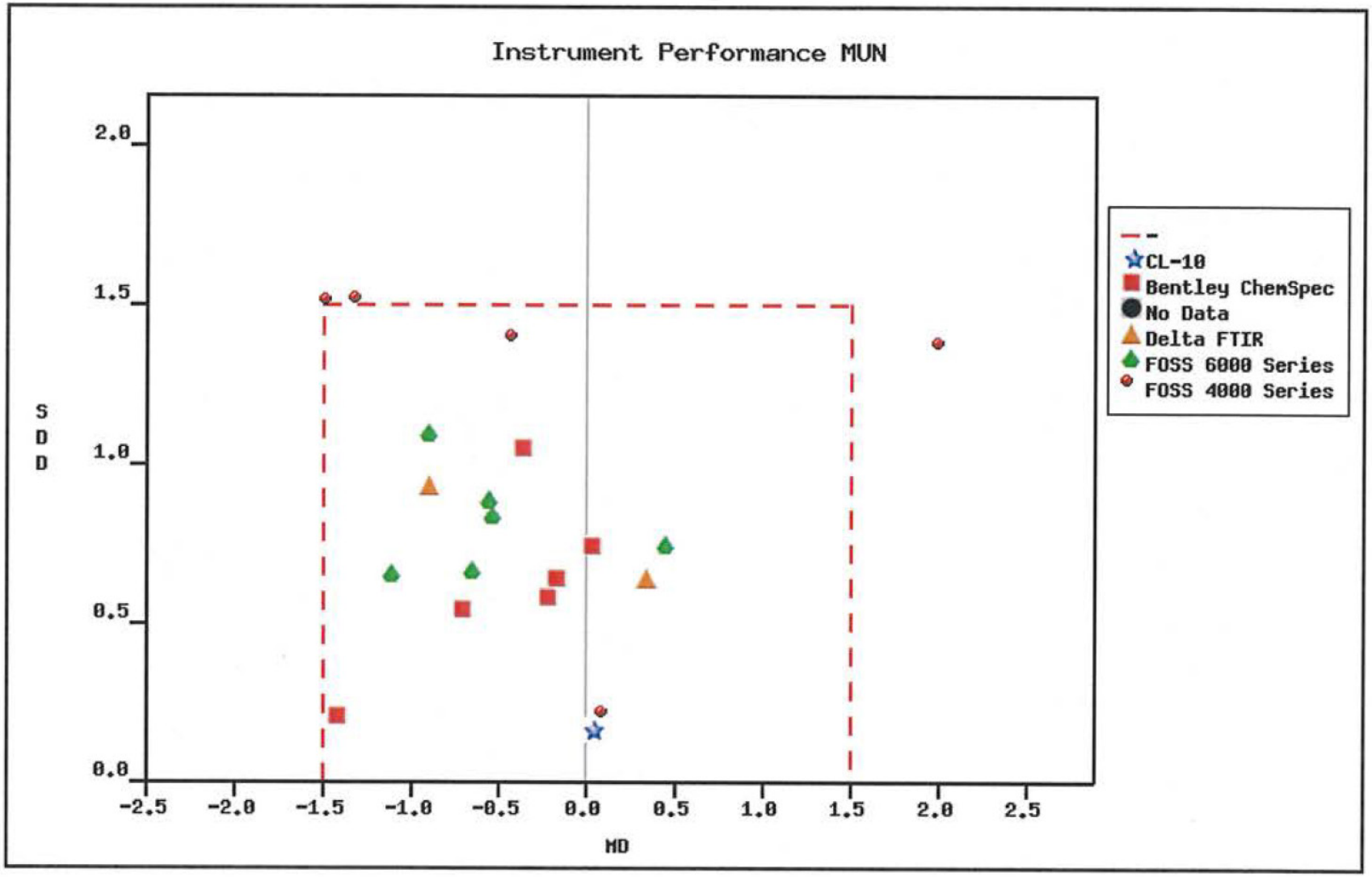
MUN – August 2012



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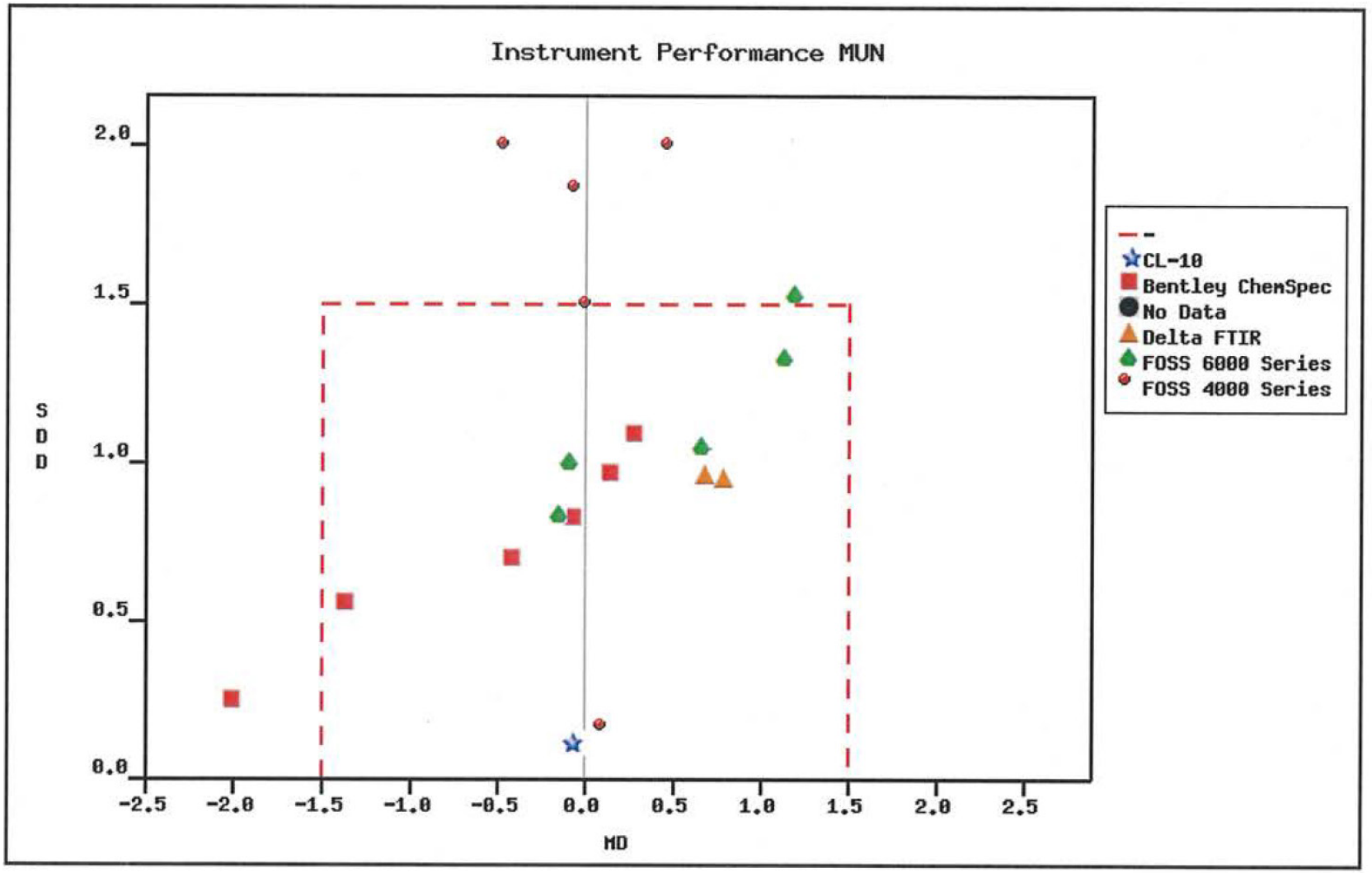
MUN – December 2012



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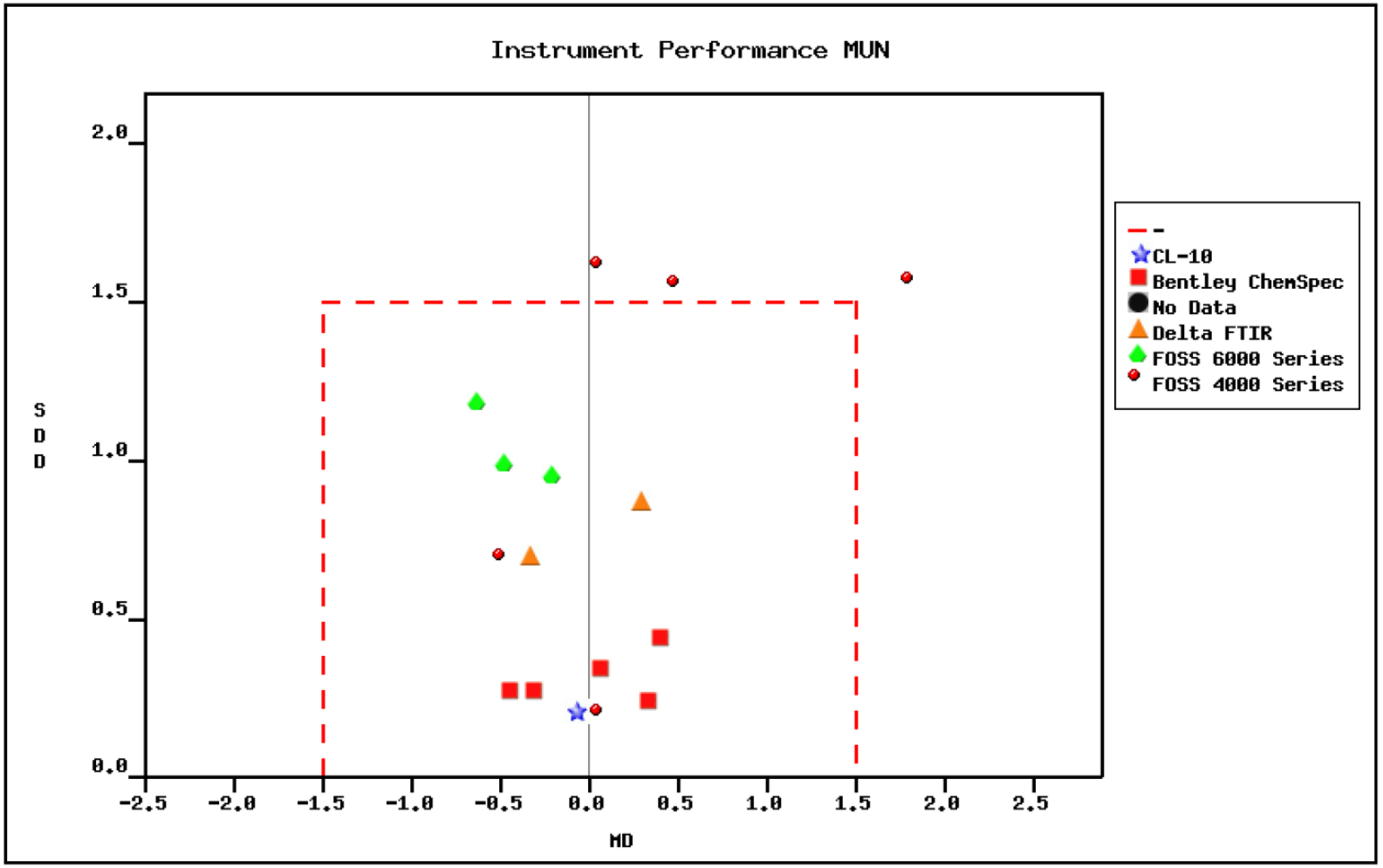
Shift in Milk Urea Nitrogen (MUN) Results

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.**
3. **QCS and Lab Auditor have reviewed and continue to monitor results monthly as well as work with manufacturers and standards suppliers.**
4. **Need to define tolerances for MD and SDD for MUN for the Samples Unknown program.**

MUN – August 2013



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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 QCS 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**

- **Would meet the training requirements in *Auditing Procedures for Laboratories*.**

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