Quality Certification Services Inc.

Laboratory Advisory Committee (LAC) Meeting

September 14, 2015
Embassy Suites
Syracuse, NY

1. Call to Order – John Rhoads, Chair, LAC
2. Agenda Review and Repair
3. Appointment of Recording Secretary
4. Approval of Minutes from 2014 LAC Meeting – attached
5. Old Business
    a. Milk Pregnancy ELISA Samples Unknown – Steven Sievert
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. 2016 Unknowns Schedule – Steven Sievert
        iv. Samples Unknown Program revision plans
    c. Potential MUN tolerances for Samples Unknown Program
    d. Laboratory Manager and Technician Training
    e. Questions/revisions on current *Auditing Procedures for Laboratories*
7. New Business
    a.
    b.
8. 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.

Quality Certification Services Inc.

Laboratory Advisory Committee (LAC) Meeting
September 14, 2015
Embassy Suites Hotel, Syracuse, NY

1. LAC meeting called to order by Chairman John Rhoads at 8:35 a.m.

2. The agenda was approved as distributed.

3. Hearing no opposition from attendees, John Rhoads appointed Steven Sievert to take minutes for the 2015 meeting.

4. It was moved, seconded and passed to approve the minutes from the 2014 LAC meeting as presented.

5. Steven Sievert, QCS Program Manager, provided a QC Program update (attached to minutes)
    a. Current auditing schedule distributed and discussed.
    b. 2016 Samples Unknown schedules for component and ELISA laboratories were distributed.
    c. Update on the Samples Unknown programming.
    d. Review of procedural steps following on-site laboratory audits.
    e. Report on the late data submission by laboratories.
    f. Discussions on data entry errors in the Samples Unknown program.
    g. Review of the approved protocol for new instruments and components.
    h. Update on MUN program.

6. During the 2014 meeting, Steven Sievert reported that here are no clearly defined tolerances for accuracy or repeatability for MUN 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.

    a. A subcommittee of John Rhoads, ELS, and Julee O'Reilly, DHI Cooperative Inc., volunteered to work with Steven Sievert on development of a MUN program proposal, however this work was not completed prior to the 2015 LAC meeting. Carol Decker, NorthStar Cooperative – Wisconsin, volunteered to join the MUN subcommittee. (Note – Muril Niebuhr, Minnesota DHIA – Zumbrota, also volunteered to join the MUN subcommittee after the meeting was adjourned). Additional expertise may be solicited in this work area and Steven Sievert will present a draft proposal at the 2016 LAC meeting.

    b. Discussion on the suitability of both the unknown and calibration sets for MUN was brought to the floor. Dave Barbano, Cornell University, also shared with the group the work by the MMA using an enzymatic colorimetric method as a replacement for CL-10 as a reference method for MUN. The MUN subcommittee was encouraged to consider these comments in their proposal.

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

8. The meeting was adjourned at 9:32 a.m.

Recorded by:

Steven Sievert
QC Program Manager
Quality Certification Services Inc.

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.

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 ..... MQT Lab Services
..... 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
..... NorthStar Cooperative DHI Services - Michigan

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

2016 Samples Unknown Schedule

Trial Number	Date Samples Shipped to Labs	Due Date for Results
173	January 11	January 29
174	February 8	February 29
175	March 14	March 31
176	April 11	April 29
177	May 9	May 31
178	June 13	June 30
179	July 11	July 29
180	August 8	August 31
181	September 19	September 30
182	October 10	October 31
183	November 14	November 30
184	December 12	December 30

Note: The 2016 NVSL Johne's trial dates have not been determined. A revised schedule will be distributed once the trial dates are finalized. Labs will receive their samples that month from NVSL and report results on both the NVSL and the QCS ELISA reporting sites.

Quality Certification Services
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DHI Component Laboratories -

2016 Samples Unknown Schedule

Batch Number	Week Starting	
218	January 11	
219	February 8	
220	March 14	One week later due to National DHIA 51st Annual Meeting March 8-10, 2016
221	April 11	
222	May 9	
223	June 13	
224	July 11	
225	August 8	
226	September 19	
227	October 10	
228	November 14	
229	December 12	

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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 14, 2015

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.**

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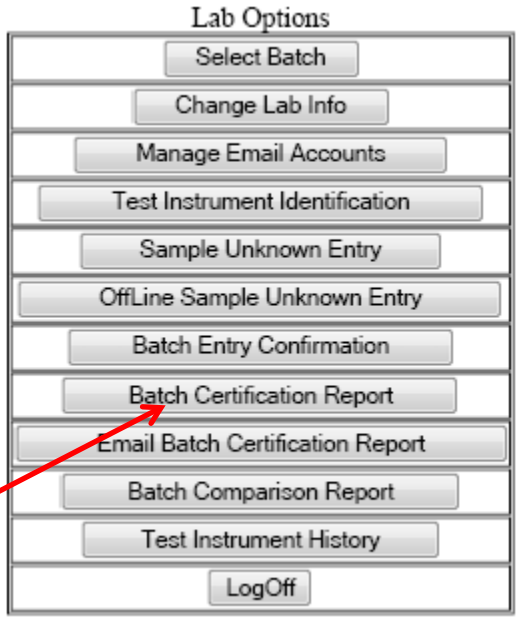
Renaming of Instruments/Line Identification

- **Notify QCS Program Manager (Steven) 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.**

Notification of Certification Reports

- **QCS moved Samples Unknown database to new server in late June.**
  - **All unknowns data and reports are secure.**
  - **Compatibility of new server software with old programming with emailing of certification reports is an issue. The email creates certification report with data through June 2015.**
  - **Please login into Samples Unknown site to retrieve your certification report.**
  - **Select the correct batch from the drop-down list of monthly trials**



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On-Site Audits

Laboratory Auditing Schedule

Auditing/centering month schedule is periodically updated to reflect the current DHI laboratories.

- **Updates are published on QCS website when changes occur.**
- **QCS works to have a balanced audit schedule for Paul Sauvé.**
  - **23 labs in even-numbered years**
  - **22 labs in odd-numbered years**
  - **Current centering month schedules in handout**
- **One lab closing and one new laboratory starting to analyze DHI samples since last LAC meeting.**

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Availability of Samples During Audit

- Laboratory MUST have samples to run the day of the on-site audit. If there are no samples available, the on-site audit will be terminated and will have to 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).
- Note that the certification expiration date cannot be extended and the auditor's schedule may push subsequent audit date past the existing expiration date. The net result is decertification of the laboratory until the on-site audit can be completed. Decertified laboratories may not send data to the CDCB.

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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.'**
- **May bypass the 'Conditional' status if additional serious noncompliant issues are identified during the course of the subsequent audit.**
- **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.' If a laboratory continues to fail to address the noted noncompliant issues, the laboratory may be decertified.**

After your lab audit…

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

Samples Unknown

Review of Monthly Samples Unknown Results

1. **Paul Sauvé provides QCS with 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. This response should be sent to both Paul Sauvé and QCS.**

3. **QCS and Paul Sauvé 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.**

Review of Monthly Samples Unknown Results

During the analysis of the [redacted] 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 [redacted] Please include both Paul and myself on this communication.

Best regards,
Steven

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

NATIONAL DHIA

Quality Certification Services Inc.

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 are responsible for the data they submit**
  - **If QCS does not correct mistakes, the all instrument averages are affected.**
- **Batch entry confirmation report is available – each lab should print and double check the data entered. It is your proof of submission.**
- **Corrected data is late data as agreed upon during 2013 LAC Meeting**

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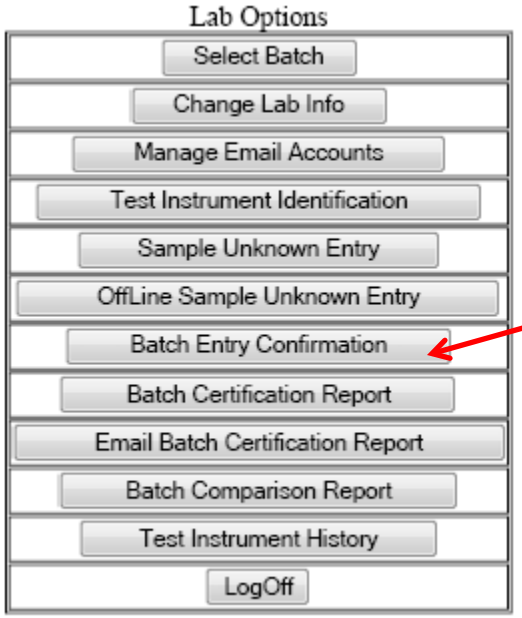
Batch Entry Confirmation Report



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

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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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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 since implementation**
  - **17 labs have 'one strike' today**

August 2015

- **1 late lab - definite improvement during the last 12 months**
- **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

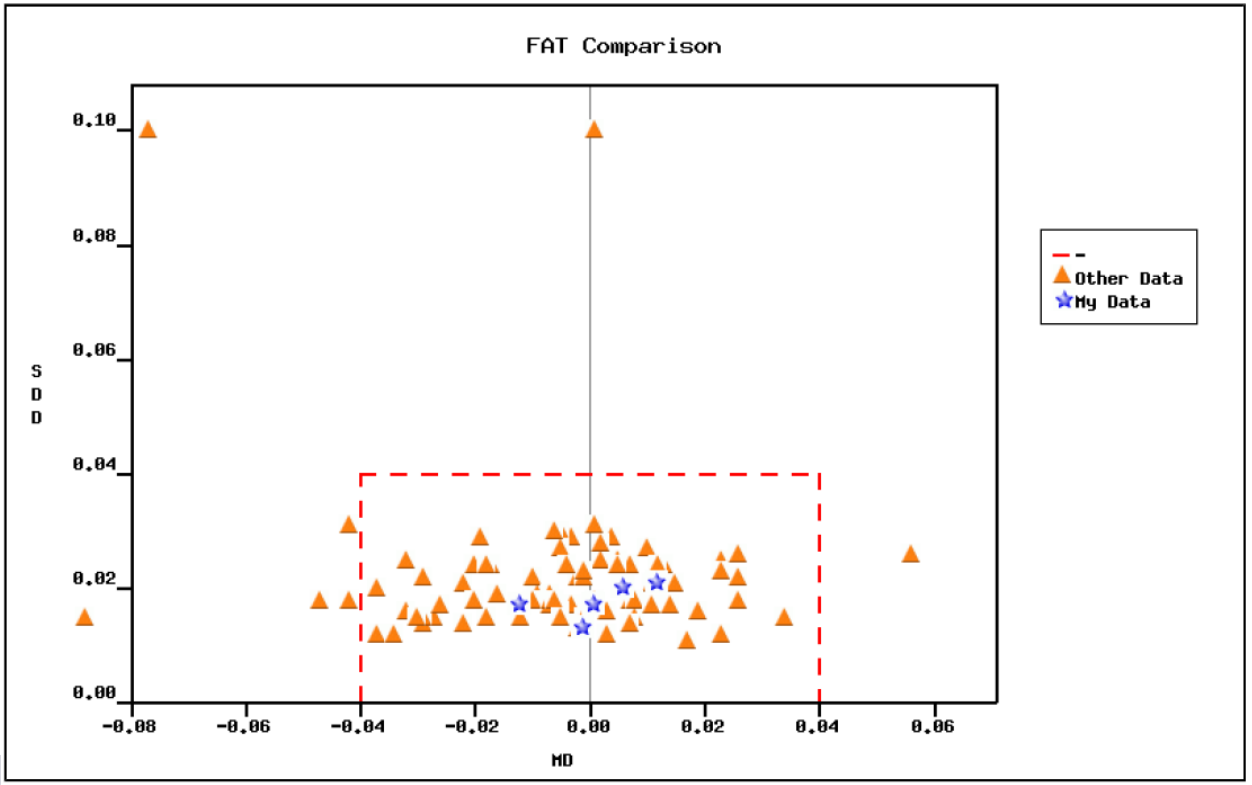
Samples Unknown Programming Plans

- **QCS is working on a rewrite 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**
  - **Add additional ELISA testing programs – PAG, BLV, BVD**
  - **Internal data handling and editing needs**
  - **Exploring options for interface for result submission**
    - **Challenges - different instruments with different output and labs handle unknowns differently**

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

- **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 adds instrument on Samples Unknown website. The Samples Unknown website will create a new history file for the instrument.**
- **Documentation Required**
  - **Manufacturer training is required and subsequent documentation sent to the QCS Program Manager**
  - **Analyze one set of 'special' unknowns with results sent to QC Program Manager and Paul Sauvé.**
  - **Perform appropriate and routine QC checks with calibration checks, hourlies and dailies for the first three weeks of operation with results sent to QC Program Manager and Paul Sauvé.**

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

- Same notification to QC Program Manager and documentation requirements
- 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

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MUN Update

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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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!

Quality Certification Services Inc.

Paperless Lab Technologies

NALMA, September 14, 2015

Syracuse, New York

Paul Sauvé, CLS

CAPITAL Laboratory Services

DHI Laboratory Audits:

Strengths

- Sample processing and analysis
- Equipment maintenance
- Real-time quality control
- Instrument calibration

Weaknesses:

- Document management
- Records management
- Troubleshooting (Why?)

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Common question:

Can we keep electronic records or do we need to keep hard copies?

From the CDCB Auditing Guidelines:

Record Keeping Systems
Calibration checks and maintenance records may be documented in the form of a computerized spreadsheet, manual listing, or other organized system. If manual listings are used, results should be recorded in ink.

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A better question:

Should we keep electronic records?

YES!

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Common Lab Documents:

- *Quality Management System (QMS)*
- *Procedures*
  - *Sample receipt*
  - *Sample processing*
  - *Equipment maintenance*
  - *Staff training*
  - *Quality control*
- *Lists (procedures, forms, equipment, suppliers, inventory, staff, customers)*
- *Schedules (sample receipt, staffing, maintenance)*
- *Forms*
  - *Paper (worksheets)*
  - *Electronic (templates)*
- *Completed forms become Records (test results, QC, HR, etc.)*
- *Reports*

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Quality Management System:

A Quality Management System (QMS) is the full set of processes put in place by an organization to ensure that quality objectives are met and that customer requirements are satisfied.

It consists of detailed, up-to-date policies and procedures and defines a formal system for maintaining associated documents, records and reports.

It is fully auditable both internally by management and staff and externally by recognized accreditation or certification agencies.

CAPITAL Laboratory Services

Procedures:

Procedures ensure that all staff are performing key functions correctly.

They are critical to appropriate training of laboratory staff.

They can also be used to demonstrate competence to clients and to auditors.

CAPITAL Laboratory Services

SOP #132	Hourly Zero Checks and Zero Adjustments (IR)
REVISION #002	February 15, 2015

Scope:

Hourly zero checks and/or adjustments are performed in order to monitor the stability of infrared analyzers on an hourly basis during routine testing of all DHI client samples.

Responsibility:

All Instrument Operators are responsible for performing the hourly zero checks in accordance with the following procedure.

SOP #132	Hourly Zero Checks and Zero Adjustments (IR)
REVISION #002	February 15, 2015

Procedure:

1. Sealed vials of zero solution (0.1% TX-100 ref. SOP #119) are held in the 42C waterbaths until needed.
2. Immediately following the hourly pilot sample check (ref. SOP #131), one vial of zero solution is tested manually three times in succession.
3. The second two fat and protein results are averaged and the values are recorded in the appropriate fields on Form #17C.
4. If drift for either component exceeds +/- 0.03%, the zero is reset and the adjustment is noted by checking the appropriate box on Form #17C.
5. If drift for either component exceeds +/- 0.06%, testing is discontinued and the Lab Manager or Shift Supervisor is consulted.

L #003	Master List of Standard Operating Procedures
Page 1 of 3	August 25, 2015

SOP	TITLE	REVISION
L001	Start-up, Foss FT+	March 10, 2015
L002	Repeatability Check, Foss FT+	July 13, 2014
L003	Zero Check, Foss FT+	April 2, 2014
L004	Pilot Sample Check, Foss FT+	February 27, 2013
L005	Calibration Check, Foss FT+	December 11, 2013
L006	Calibration Adjustment, Foss FT+	December 11, 2013
L007	Shut-down, Foss FT+	June 4, 2014
L008	Start-up, Foss FC	November 24,2014
L009	Repeatability Check, Foss FC	March 30, 2013
L010	Zero Check, Foss FC	August 21, 2015

CAPITAL Laboratory Services

Schedules:

Typical DHI laboratories maintain schedules of numerous activities:

- *Staffing*
- *Sample Receipt*
- *Special Testing (Johnes, Leukosis, Pregnancy, etc)*
- *Equipment Maintenance*
- *Quality Control*
- *Reagent Preparation*
- *Inventory Receipt*
- *Receipt and Testing of Unknown Samples*

CAPITAL Laboratory Services

Forms:

Forms provide a standardized means of recording critical information. They ensure that all necessary data generated in the procedure is appropriately recorded.

Forms can either be hard copy documents (worksheets) or electronic documents (templates).

The laboratory should maintain a standard list of all current forms (worksheets or electronic templates) in use.

Completed forms become records.

CAPITAL Laboratory Services

XYZ DHIA	Daily IR Worksheet	Form #17C

Date: _____ Operator: _____

Line: _____ Supervisor: _____

Target Values: Fat: _____ (+/- .04%) Protein: _____ (+/- .04%)

Time	Pilots (+/- .04%)			Zeros (+/- .03%)			Comments
	Fat	Pro.	Status	Fat	Pro.	Reset	
			[] IN [] OUT			[] YES [] NO	
			[] IN [] OUT			[] YES [] NO	
			[] IN [] OUT			[] YES [] NO	
			[] IN [] OUT			[] YES [] NO	
			[] IN [] OUT			[] YES [] NO	

XYZ DHIA	Daily IR Worksheet	Form #17C

Date: March 15, 05 Operator: Paul Sauvé

Line: Bentley #1 Supervisor: Brian Corrigan

Target Values: Fat: 3.50 (+/- .04%) Protein: 3.15 (+/- .04%)

Time	Pilots (+/- .04%)			Zeros (+/- .03%)			Comments
	Fat	Pro.	Status	Fat	Pro.	Reset	
8:30	3.50	3.16	[X] IN [] OUT	0.02	0.00	[] YES [X] NO	OK
9:28	3.52	3.10	[] IN [X] OUT	-0.01	-0.07	[X] YES [] NO	Supervisor contacted. Repair documented in log.
10:32	3.48	3.15	[X] IN [] OUT	0.00	0.01	[] YES [X] NO	OK
11:25	3.49	3.14	[X] IN [] OUT	0.02	-0.01	[] YES [X] NO	OK
11:45	3.50	3.16	[X] IN [] OUT	0.00	0.01	[] YES [X] NO	End of shift.

Reports:

DHI laboratories develop and maintain various types of reports:

- *Internal*
  - *Workplace incidents / accidents*
  - *Staff performance reviews*
  - *Etc.*
- *External*
  - *Test Results*
  - *Sample condition*
  - *Annual business*
  - *Etc.*

CAPITAL Laboratory Services

Technician Training – Associated Lab Documents:

- *Quality Management System (QMS)*
  - *Job descriptions, requirements*
  - *Policies (training, confidentiality, continuing education)*
  - *Hiring policies and procedures (salaries, benefits)*
- *Procedures*
  - *New Technician training*
  - *On-going training*
- *Lists*
  - *Staff*
  - *Training activities and authorizations*
- *Schedules*
  - *Training*
  - *Staff meetings*
  - *Off-site conference and workshops*

CAPITAL Laboratory Services

Technician Training – Associated Lab Documents:

- *Forms*
  - *Training checklist*
- *Records*
  - *Completed training checklists*
- *Reports*
  - *Incident reports*
  - *Performance reviews*

CAPITAL Laboratory Services

F #019	New Technician Training Record Page 1 of 3
Technician: B. Smith	Date Hired: June 12, 2015

Activity	Related SOP's	By:	Date(s):	Notes
Sample receipt / log-in	002, 003, 004	JPS	Jun 13, 15	-authorized
Inst. start-up / shut-down	006, 008	JPS	Jun 14, 15	-authorized
Sample analysis	009	JPS	Jun 16, 15	-authorized
Routine QC checks	010 to 019	DMB	Jun 17-21, 15	-authorized
Routine maintenance	021 to 025			-scheduled for Nov, 2015
Calibration checks	027, 029	JPS	Aug 4-7, 15	-authorized
Calibration adjustments	028, 030		Aug 4-7, 15	-more training needed, not authorized
Johnes testing	045	JPS	Sep 9, 15	-authorized
Pregnancy testing	049			
Preparation of reagents	051, 052, 053	DMB	Jul 21, 15	-authorized
Computer backups	074	IMK	Sep 11, 15	-authorized

Retention Time (Lab Records)

According to CDCB Guidelines:

"Documentation of all calibration checks and maintenance records should be maintained for a minimum of two years."

Is this sufficient?

Doesn't it make more sense to keep this information for the full life of the analyzer?

Why isn't the specified retention period longer?

CAPITAL Laboratory Services

Storage Capacity:

A typical new pc (<$500) is equipped with 1 terabyte of on-board storage.

- *average 2000 characters on a page*
- *Average 2 bytes / character*
- *Approximate storage capacity: 250 million pages of data*

Size of a storage facility to keep the same amount of information in hard-copy:

- *150,000 square feet*
- *or…about 100 typical DHI facilities*

Quantity of documents / lab records from a typical DHI laboratory that can be stored on a 1 terabyte hard drive:

~ 3000 years

(A very rough estimate but you get the point!)

CAPITAL Laboratory Services

Common Lab Documents:

- *Quality Management System (QMS)*
- *Procedures*
- *Lists*
- *Schedules*
- *Forms*
- *Records*
- *Reports*

All of these items can be developed, revised, and stored electronically.

CAPITAL Laboratory Services

Advantages of Going Paperless:

- *Reduction of office supplies (paper, ink cartridges, file folders, boxes, filing cabinets, etc.)*
- *Elimination of storage space*
- *Elimination of retention times for critical lab records*
- *Preservation of data (Paper records can be lost, damaged or destroyed. Electronic records can be backed up in multiple locations.)*
- *More organized records.*

CAPITAL Laboratory Services

Advantages of Going Paperless:

- *More complete records*
- *More uniform records (Encourage staff to conduct procedures in a systematic fashion.)*
- *Searchable records*
- *Better security (password protection, limited access)*
- *Increased traceability (samples, staff, test line, reagent batches, etc.)*

CAPITAL Laboratory Services

Advantages of Going Paperless:

- *Real-time QC (Checks requiring calculations are completed immediately. Problems are identified before test results are compromised.)*
- *Increased accuracy (elimination of transcription or calculation errors)*
- *Increased legibility (Not everyone has excellent penmanship.)*
- *Greater flexibility (i.e. adding a test parameter, BHB)*

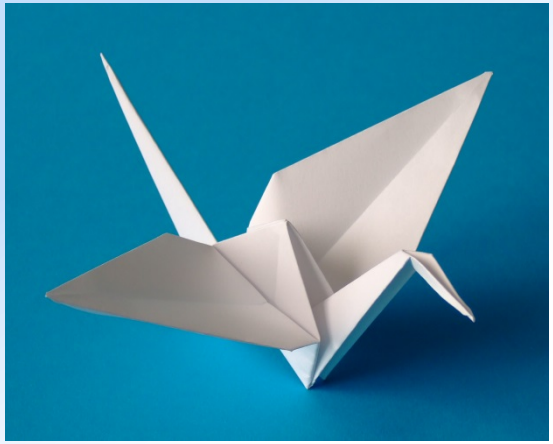
CAPITAL Laboratory Services

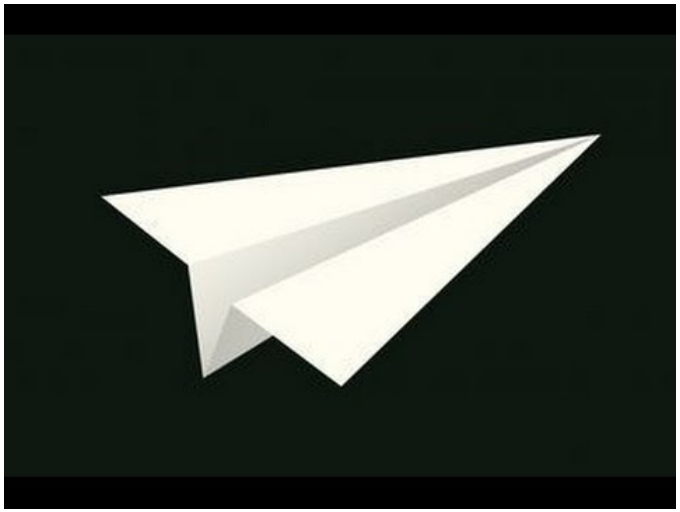
Advantages of Going Paperless:

- *Ensure currency (A printed version of a procedure may be out of date. The official electronic copy is always current.)*
- *Remote access (Digital records can be accessed securely from anywhere.)*
- *Increased functionality (Digital records can be used to identify trends, generate control charts, etc.)*
- ***GREENER***

CAPITAL Laboratory Services

Advantages of Maintaining Paper Records:





CAPITAL Laboratory Services

Hardware Solutions:

- *Direct use of line pc (concurrent windows)*
- *Secondary pc(s) at the test lines*
- *Technician tablets*
- *Auto-capture via programmed QC routines*
  - *Bar-coded or RF ID'd samples (routine and/or QC)*
  - *Manual selection of QC routines by Technicians*

CAPITAL Laboratory Services

Software Solutions:

Commercial DMS, LIMS, and Custom Systems

Document Management System:

A document management system (DMS) is used to track, manage and store electronic documents.

Most are capable of keeping a record of the various versions created and modified by different users (history tracking).

CAPITAL Laboratory Services

There are numerous Document Management Systems on the market.

CAPITAL
Laboratory Services

Software Solutions:

Laboratory Information Management System:

A Laboratory Information Management System (LIMS) is software that allows you to manage samples, quality control and associated data.

CAPITAL Laboratory Services

There are numerous Laboratory Information Management Systems on the market.

LABVANTAGE®
Laboratory Knowledge. Delivered.

STARLIMS

Labtronics

lablite

LABSOFT

CAPITAL
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Custom Systems:

In most cases, Managers of typical DHI laboratories will chose to develop custom systems for document control and for maintenance of lab records.

Documents:

- *Document files – i.e. Microsoft Word ™*
- *Ideally these are linked to master lists and to the overall QMS*

Lab Forms:

- *Spreadsheet templates – i.e. Microsoft Excel ™*
- *Ideally these are linked to the master lists and to the overall QCS*

CAPITAL Laboratory Services

Custom Systems:

Records:

- *Lab records will be made up of completed lab forms.*
- *Separate digital files will be used for specific data sets:*
  - *Date*
  - *Technician*
  - *Line*
  - *Etc.*
- *Digital files will be stored indefinitely in an organized, searchable and retrievable manner.*
- *Digital data will be backed up regularly in multiple formats and locations. Real-time backups are best.*

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Interface:

How does information get from the user to the digital record?

For example – QC results from daily start-up checks or hourly control sample checks:

- *Data entry (keying)*
  - *Time consuming (but no more than writing the information on paper)*
  - *Possibility of transcription errors (as with paper)*
  - *Real-time review and assessment of instrument status*
  - *Requires Technician to pay attention to instrument status*

- *Direct upload from machine software*
  - *Requires compatible input from manufacturer's software*
  - *Failures can go unnoticed (without appropriate flags)*
  - *Rapid, less down-time*
  - *Can be integrated with bar-code or RF ID samples*

CAPITAL Laboratory Services

Data Storage and Protection:

- *Network backups*
- *Mirrored hard drives*
- *External hard drives (useful for off-site backups)*
- *Other media (cd's, USB sticks)*
- ***Web-based (cloud) services (remote access!!!)***

Considerations:

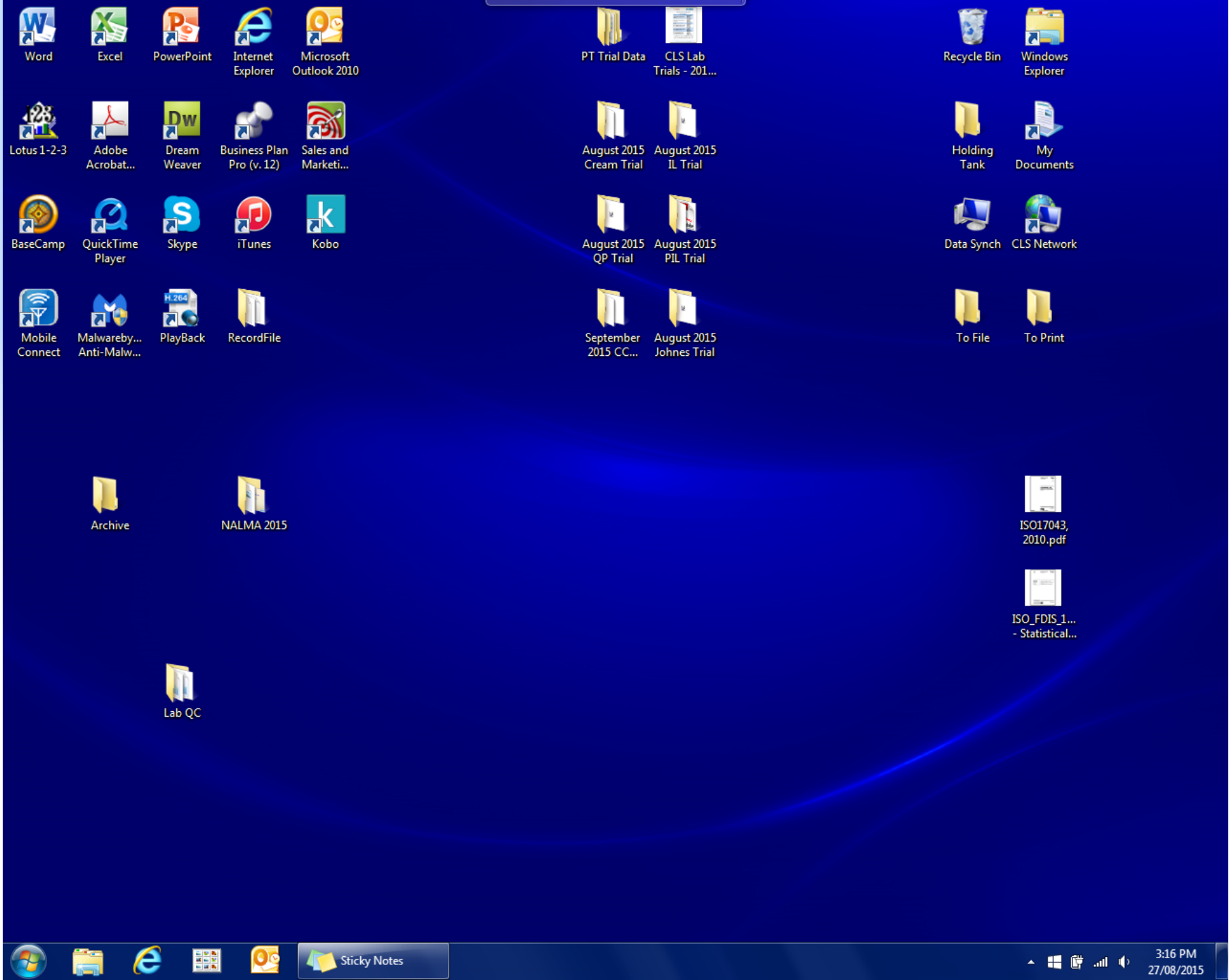
- *Real-time (live) backups are preferred over scheduled backups*
- *Multiple sources are required, Every storage device (media) will eventually fail*
- *Off-site backups are required (cloud, removable media)*

CAPITAL Laboratory Services

Organization of Digital Records:

Digital records can also be organized or disorganized.

CAPITAL Laboratory Services


Word
Excel
PowerPoint
Internet Explorer
Microsoft Outlook 2010
PT Trial Data
CLS Lab Trials - 201...
Recycle Bin
Windows Explorer
Lotus 1-2-3
Adobe Acrobat...
Dream Weaver
Business Plan Pro (v. 12)
Sales and Marketi...
August 2015 Cream Trial
August 2015 IL Trial
Holding Tank
My Documents
BaseCamp
QuickTime Player
Skype
iTunes
Kobo
August 2015 QP Trial
August 2015 PIL Trial
Data Synch
CLS Network
Mobile Connect
Malwareby... Anti-Malw...
PlayBack
RecordFile
September 2015 CC...
August 2015 Johnes Trial
To File
To Print
Archive
NALMA 2015
ISO17043, 2010.pdf
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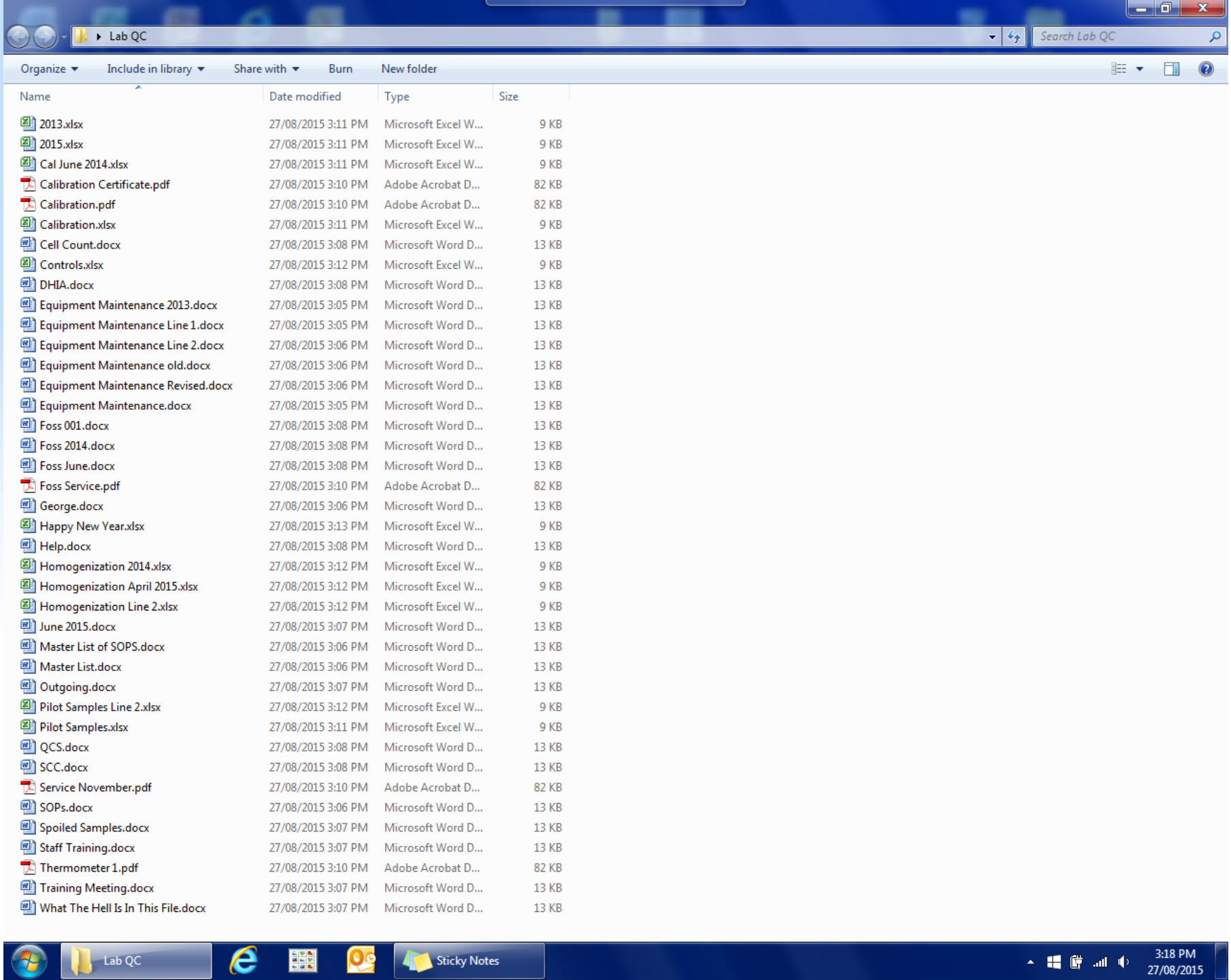
Lab QC
Sticky Notes
3:16 PM
27/08/2015


Lab QC
Search Lab QC
Organize
Include in library
Share with
Burn
New folder
Name
Date modified
Type
Size
2013.xlsx 27/08/2015 3:11 PM Microsoft Excel W... 9 KB
2015.xlsx 27/08/2015 3:11 PM Microsoft Excel W... 9 KB
Cal June 2014.xlsx 27/08/2015 3:11 PM Microsoft Excel W... 9 KB
Calibration Certificate.pdf 27/08/2015 3:10 PM Adobe Acrobat D... 82 KB
Calibration.pdf 27/08/2015 3:10 PM Adobe Acrobat D... 82 KB
Calibration.xlsx 27/08/2015 3:11 PM Microsoft Excel W... 9 KB
Cell Count.docx 27/08/2015 3:08 PM Microsoft Word D... 13 KB
Controls.xlsx 27/08/2015 3:12 PM Microsoft Excel W... 9 KB
DHIA.docx 27/08/2015 3:08 PM Microsoft Word D... 13 KB
Equipment Maintenance 2013.docx 27/08/2015 3:05 PM Microsoft Word D... 13 KB
Equipment Maintenance Line 1.docx 27/08/2015 3:05 PM Microsoft Word D... 13 KB
Equipment Maintenance Line 2.docx 27/08/2015 3:06 PM Microsoft Word D... 13 KB
Equipment Maintenance old.docx 27/08/2015 3:06 PM Microsoft Word D... 13 KB
Equipment Maintenance Revised.docx 27/08/2015 3:06 PM Microsoft Word D... 13 KB
Equipment Maintenance.docx 27/08/2015 3:05 PM Microsoft Word D... 13 KB
Foss 001.docx 27/08/2015 3:08 PM Microsoft Word D... 13 KB
Foss 2014.docx 27/08/2015 3:08 PM Microsoft Word D... 13 KB
Foss June.docx 27/08/2015 3:08 PM Microsoft Word D... 13 KB
Foss Service.pdf 27/08/2015 3:10 PM Adobe Acrobat D... 82 KB
George.docx 27/08/2015 3:06 PM Microsoft Word D... 13 KB
Happy New Year.xlsx 27/08/2015 3:13 PM Microsoft Excel W... 9 KB
Help.docx 27/08/2015 3:08 PM Microsoft Word D... 13 KB
Homogenization 2014.xlsx 27/08/2015 3:12 PM Microsoft Excel W... 9 KB
Homogenization April 2015.xlsx 27/08/2015 3:12 PM Microsoft Excel W... 9 KB
Homogenization Line 2.xlsx 27/08/2015 3:12 PM Microsoft Excel W... 9 KB
June 2015.docx 27/08/2015 3:07 PM Microsoft Word D... 13 KB
Master List of SOPS.docx 27/08/2015 3:06 PM Microsoft Word D... 13 KB
Master List.docx 27/08/2015 3:06 PM Microsoft Word D... 13 KB
Outgoing.docx 27/08/2015 3:07 PM Microsoft Word D... 13 KB
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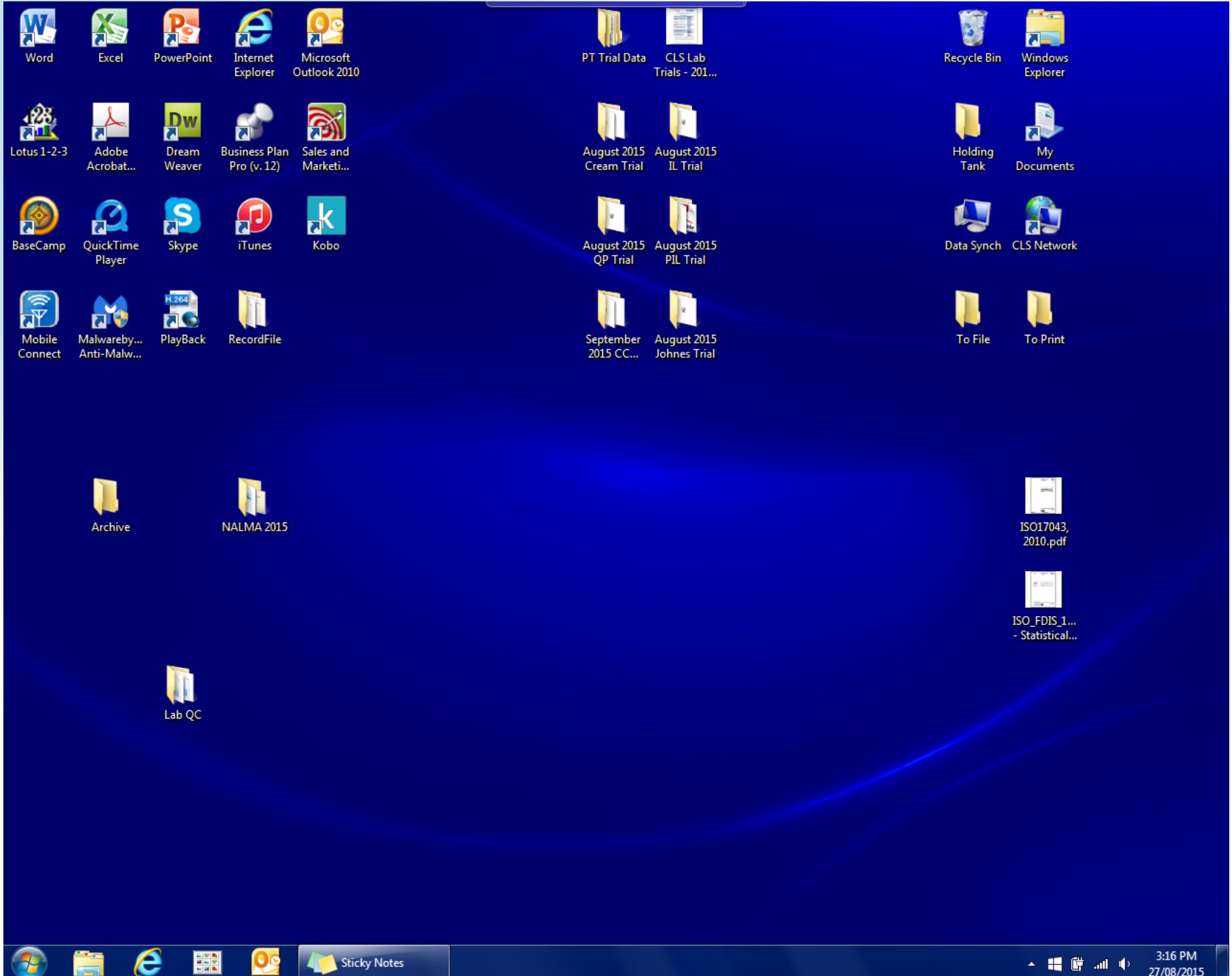
Pilot Samples.xlsx 27/08/2015 3:11 PM Microsoft Excel W... 9 KB
QCS.docx 27/08/2015 3:08 PM Microsoft Word D... 13 KB
SCC.docx 27/08/2015 3:08 PM Microsoft Word D... 13 KB
Service November.pdf 27/08/2015 3:10 PM Adobe Acrobat D... 82 KB
SOPs.docx 27/08/2015 3:06 PM Microsoft Word D... 13 KB
Spoiled Samples.docx 27/08/2015 3:07 PM Microsoft Word D... 13 KB
Staff Training.docx 27/08/2015 3:07 PM Microsoft Word D... 13 KB
Thermometer 1.pdf 27/08/2015 3:10 PM Adobe Acrobat D... 82 KB
Training Meeting.docx 27/08/2015 3:07 PM Microsoft Word D... 13 KB
What The Hell Is In This File.docx 27/08/2015 3:07 PM Microsoft Word D... 13 KB
Lab QC
Sticky Notes
3:18 PM
27/08/2015


Word
Excel
PowerPoint
Internet Explorer
Microsoft Outlook 2010
PT Trial Data
CLS Lab Trials - 201...
Recycle Bin
Windows Explorer
Lotus 1-2-3
Adobe Acrobat...
Dream Weaver
Business Plan Pro (v. 12)
Sales and Marketi...
August 2015 Cream Trial
August 2015 IL Trial
Holding Tank
My Documents
BaseCamp
QuickTime Player
Skype
iTunes
Kobo
August 2015 QP Trial
August 2015 PIL Trial
Data Synch
CLS Network
Mobile Connect
Malwareby... Anti-Malw...
PlayBack
RecordFile
September 2015 CC...
August 2015 Johnes Trial
To File
To Print
Archive
NALMA 2015
ISO17043, 2010.pdf
ISO_FDIS_1... - Statistical...
Lab QC
Sticky Notes
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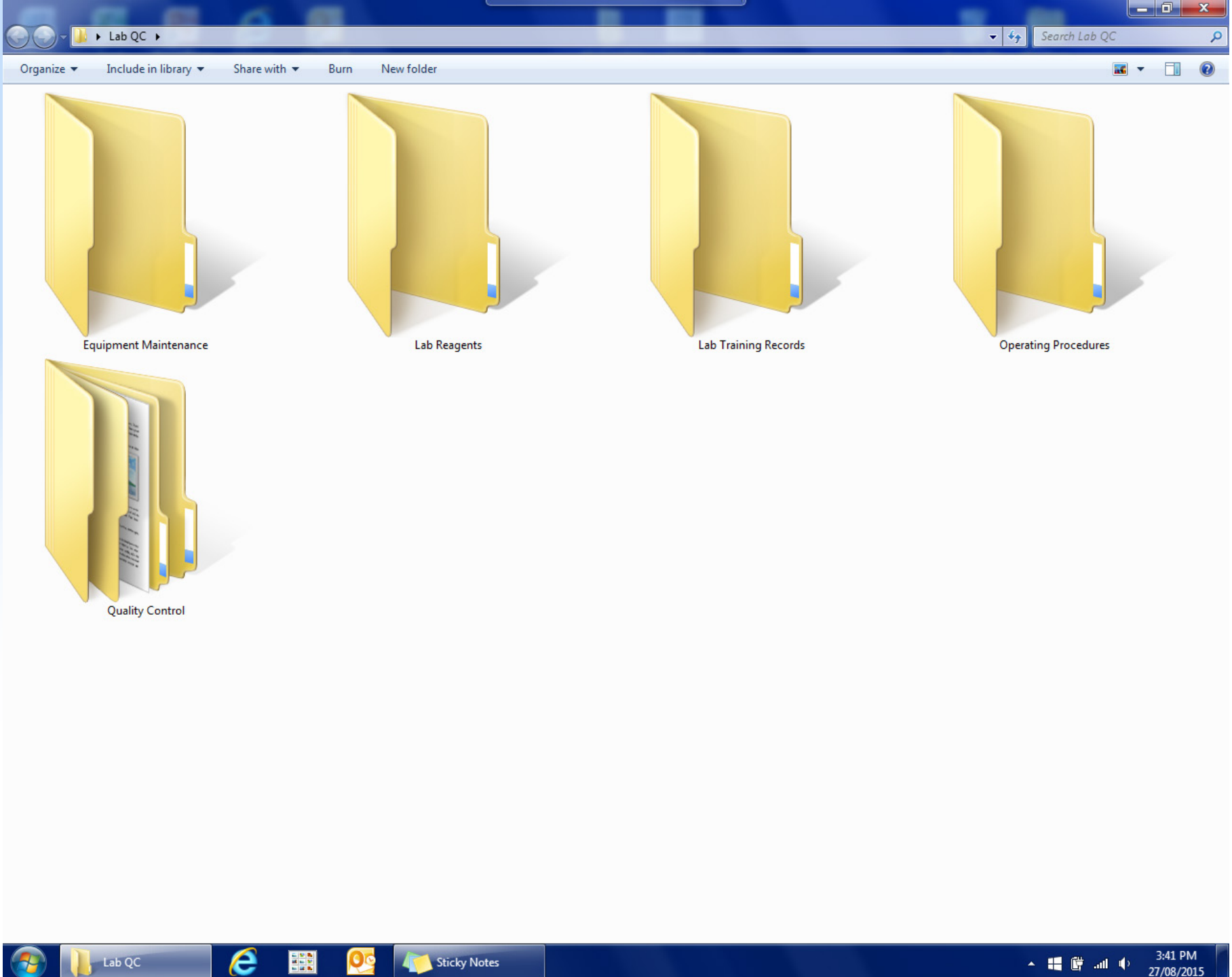
27/08/2015


Lab QC
Search Lab QC
Organize
Include in library
Share with
Burn
New folder
Equipment Maintenance
Lab Reagents
Lab Training Records
Operating Procedures
Quality Control
Lab QC
Sticky Notes
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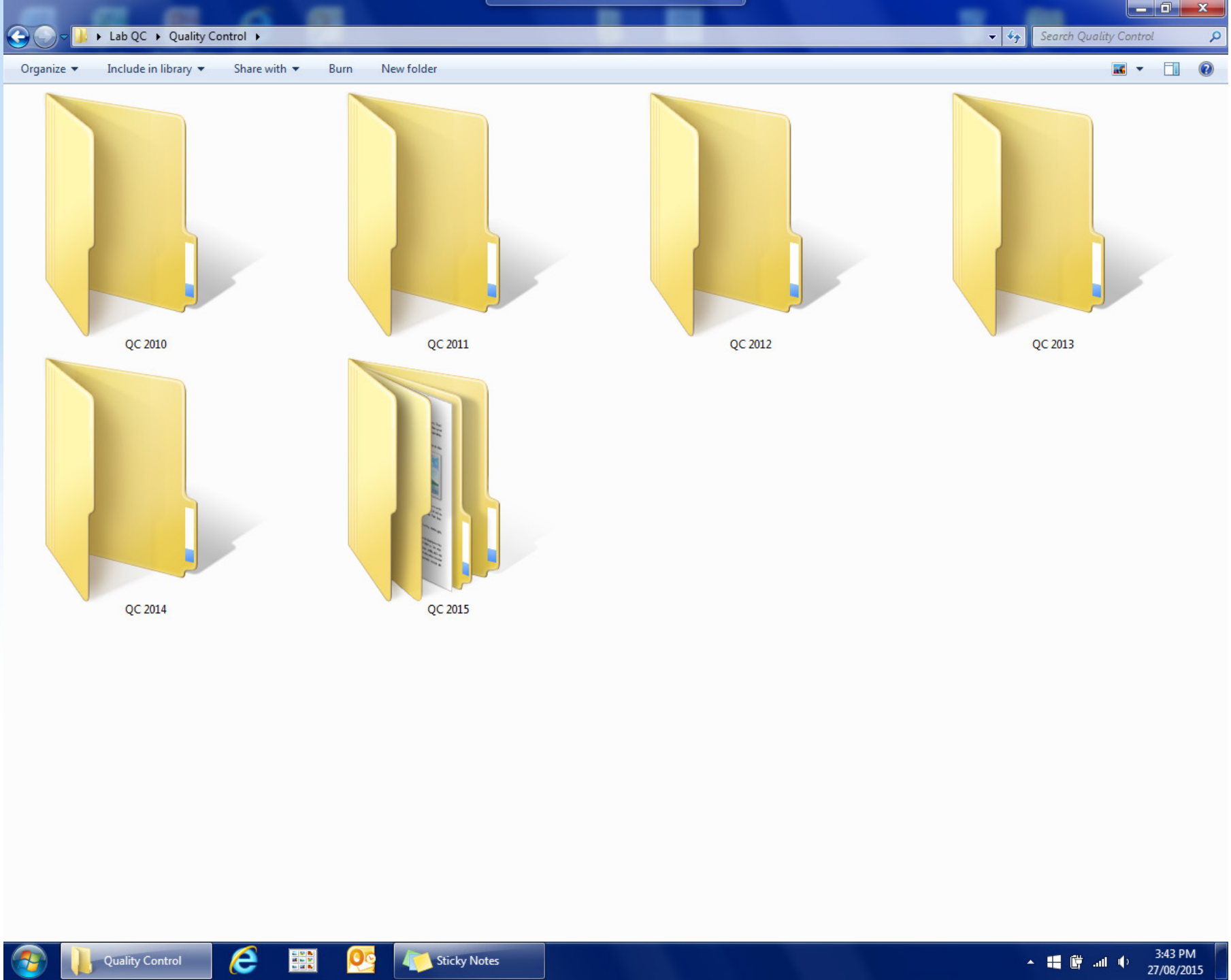
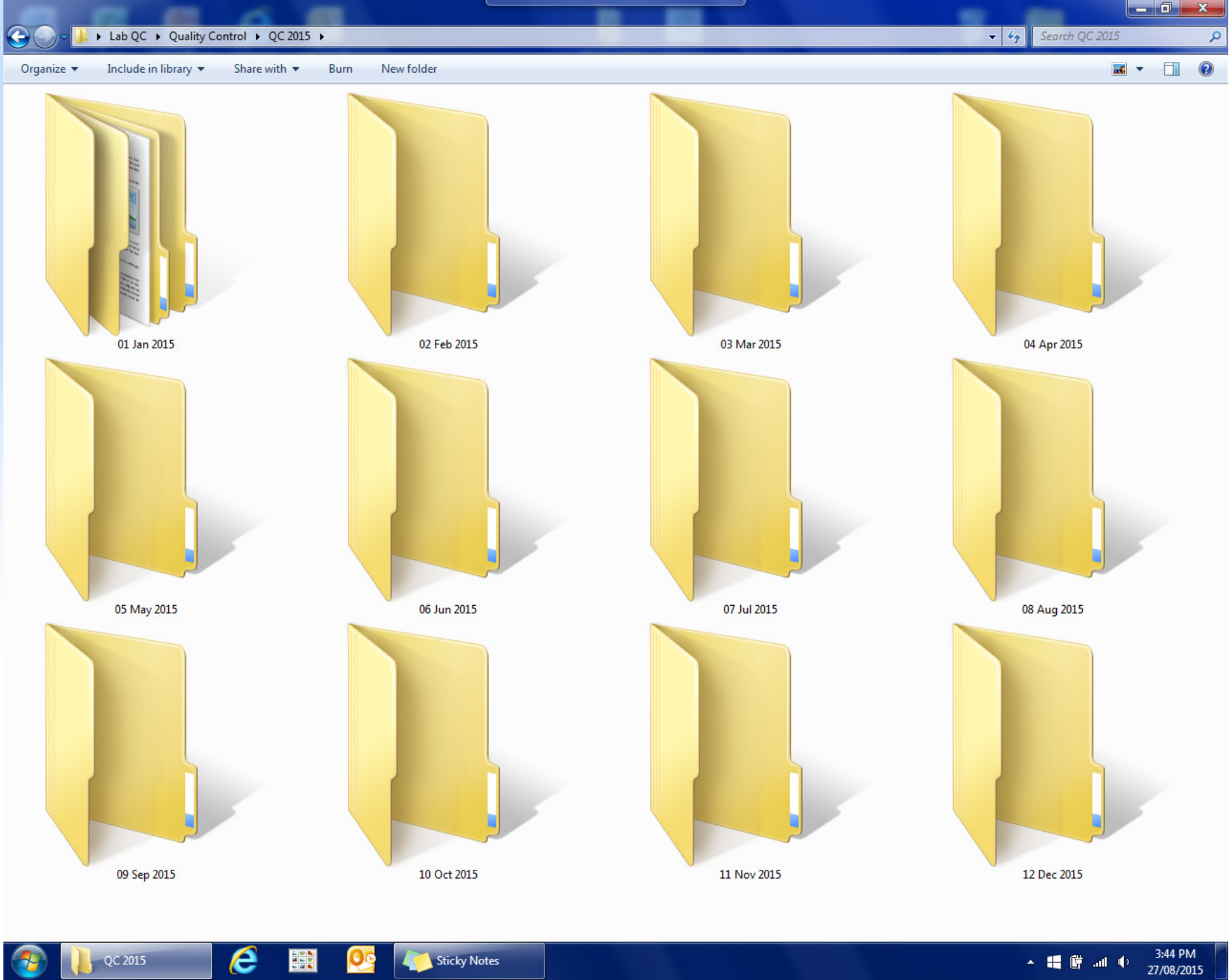
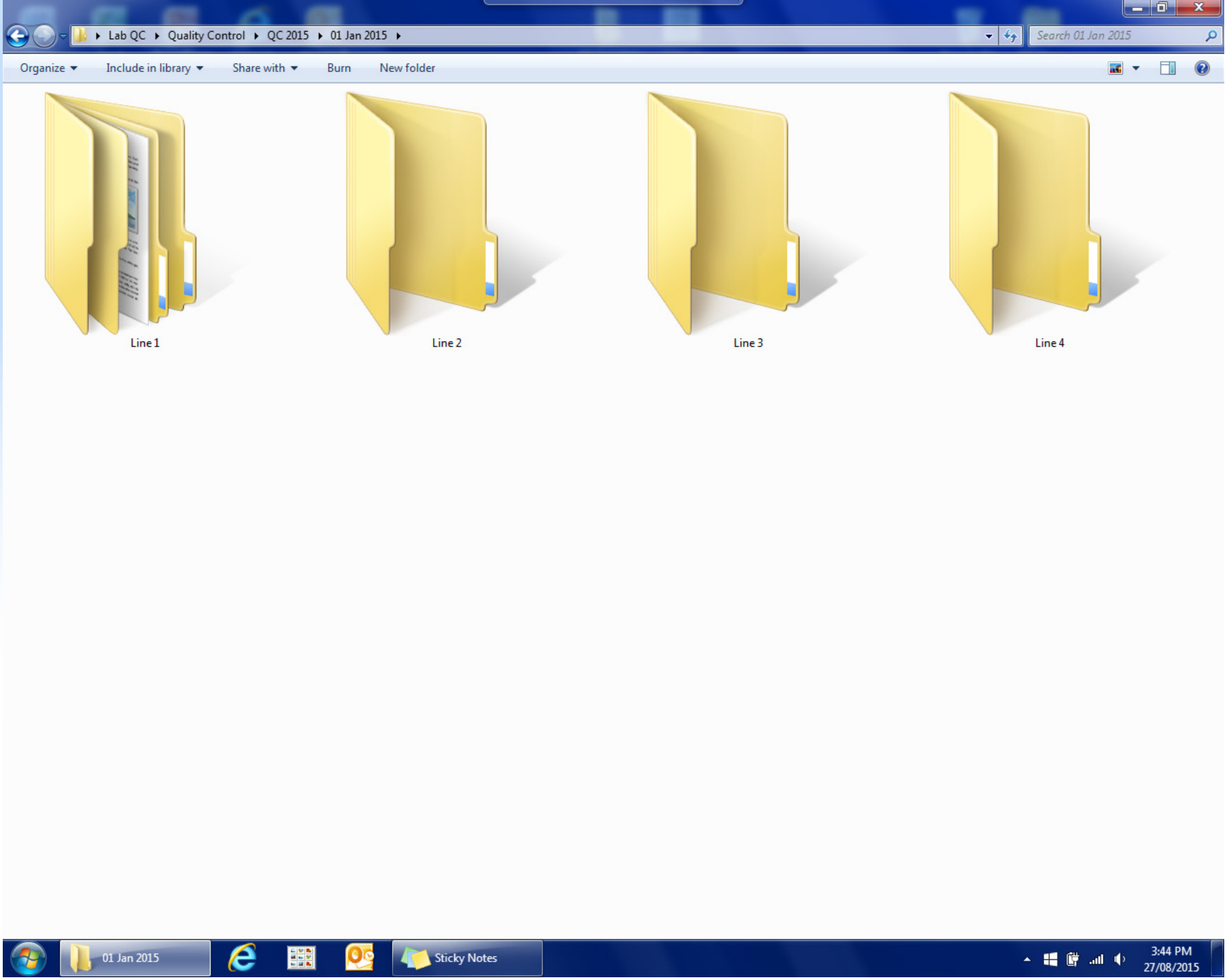
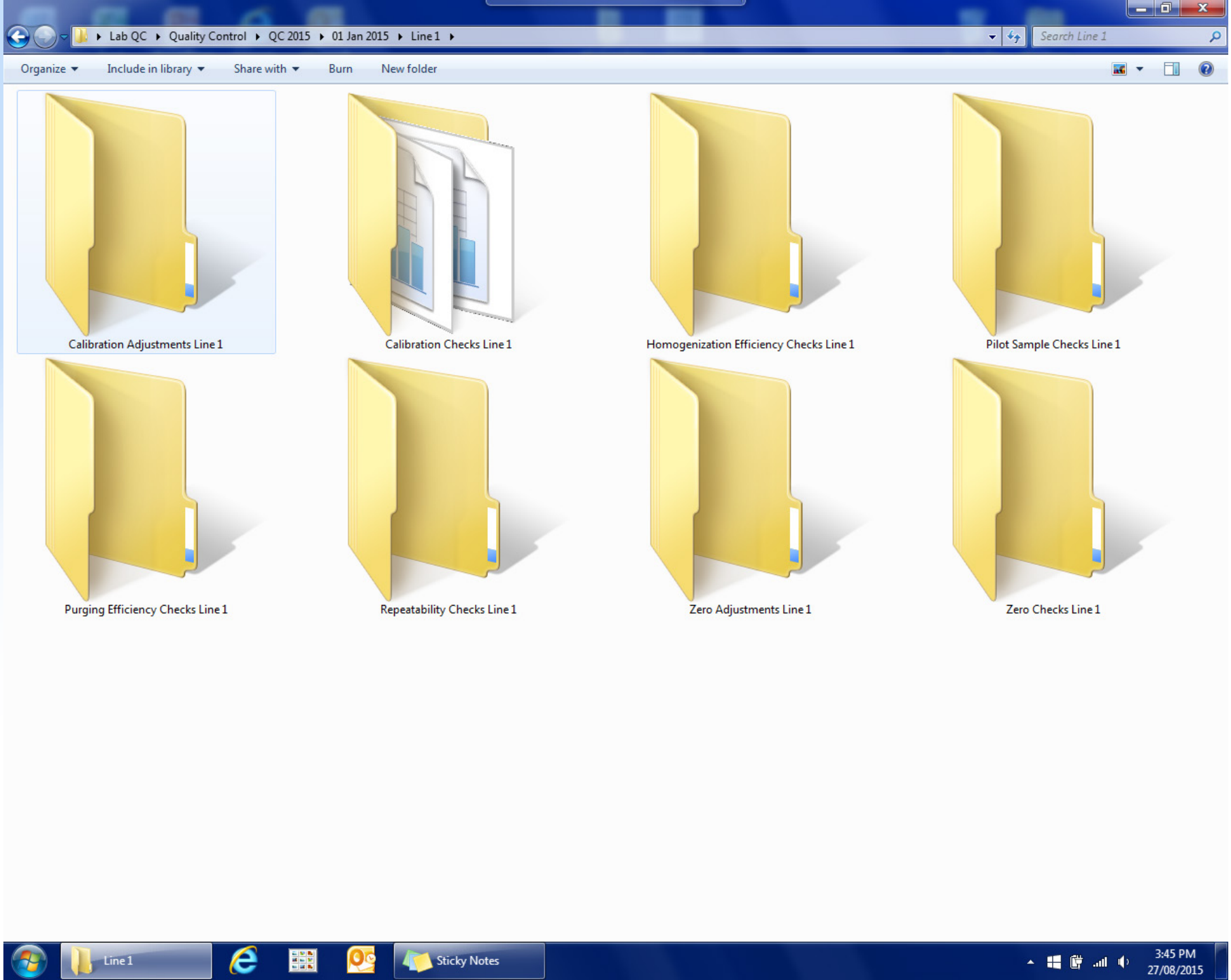
27/08/2015


Lab QC
Quality Control
Search Quality Control
Organize
Include in library
Share with
Burn
New folder
QC 2010
QC 2011
QC 2012
QC 2013
QC 2014
QC 2015
Quality Control
Sticky Notes
3:43 PM
27/08/2015


Lab QC ▸ Quality Control ▸ QC 2015 ▸
Search QC 2015
Organize
Include in library
Share with
Burn
New folder
01 Jan 2015
02 Feb 2015
03 Mar 2015
04 Apr 2015
05 May 2015
06 Jun 2015
07 Jul 2015
08 Aug 2015
09 Sep 2015
10 Oct 2015
11 Nov 2015
12 Dec 2015
QC 2015
Sticky Notes
3:44 PM
27/08/2015


Lab QC ▸ Quality Control ▸ QC 2015 ▸ 01 Jan 2015 ▸
Search 01 Jan 2015
Organize
Include in library
Share with
Burn
New folder
Line 1
Line 2
Line 3
Line 4
01 Jan 2015
Sticky Notes
3:44 PM
27/08/2015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Search Line 1
Organize
Include in library
Share with
Burn
New folder
Calibration Adjustments Line 1
Calibration Checks Line 1
Homogenization Efficiency Checks Line 1
Pilot Sample Checks Line 1
Purging Efficiency Checks Line 1
Repeatability Checks Line 1
Zero Adjustments Line 1
Zero Checks Line 1
Line 1
Sticky Notes
3:45 PM
27/08/2015

Lab QC ▸ Quality Control ▸ QC 2015 ▸ 01 Jan 2015 ▸ Line 1 ▸ Calibration Checks Line 1

Search Calibration Checks Line 1

Organize | Include in library | Share with | Burn | New folder

Jan 2, 2015.xlsx

Jan 9, 2015.xlsx

Jan 16, 2015.xlsx

Jan 23, 2015.xlsx

Jan 30, 2015.xlsx

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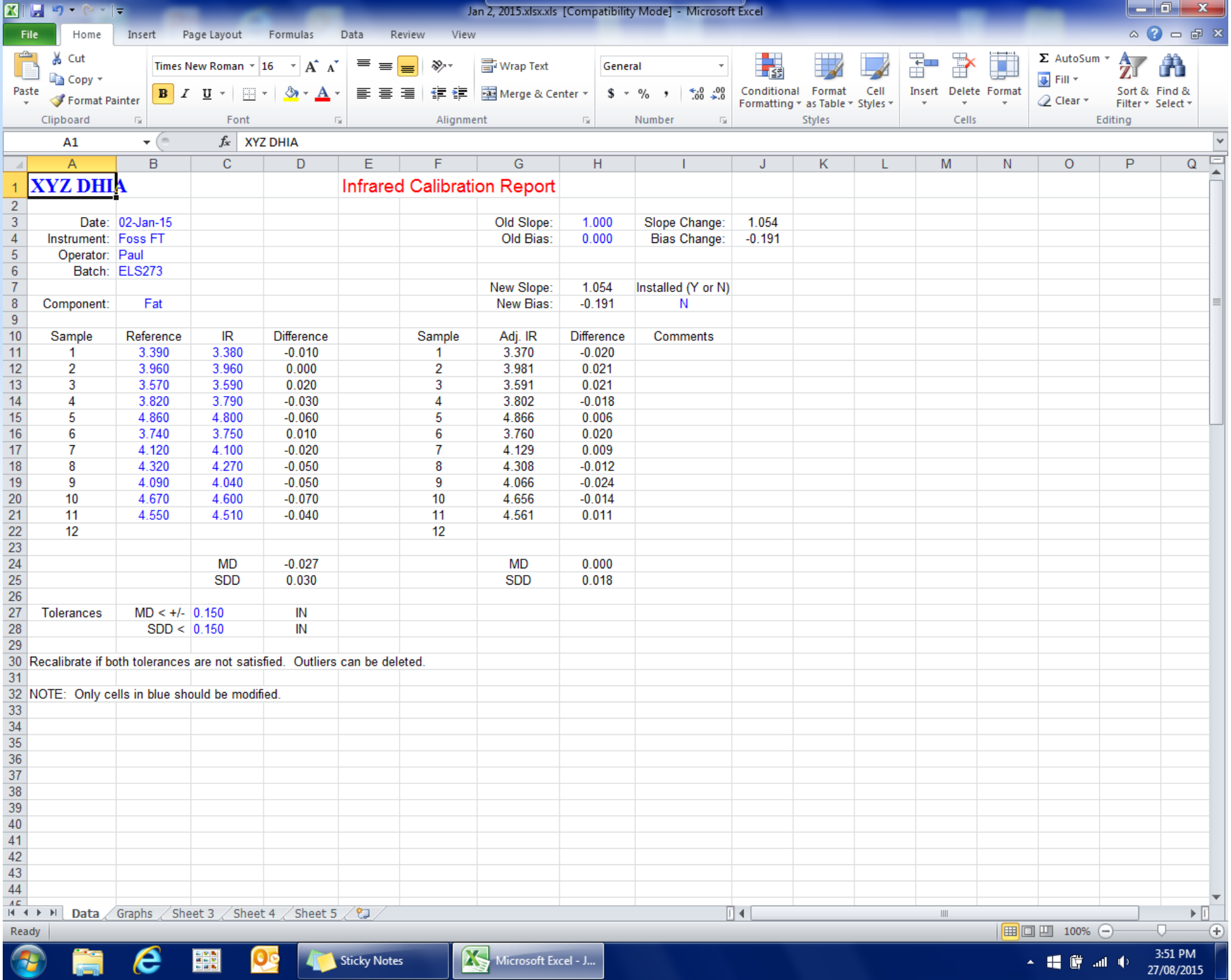

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Cut | Copy | Format Painter | Paste | Clipboard

Times New Roman | 16 | Font

Wrap Text | Merge & Center | Alignment

General | Number

Conditional Formatting | Format as Table | Cell Styles | Styles

Insert | Delete | Format | Cells

AutoSum | Fill | Clear | Sort & Filter | Find & Select | Editing

A1 | XYZ DHIA

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	XYZ DHIA				Infrared Calibration Report												
2																	
3	Date:	02-Jan-15					Old Slope:	1.000	Slope Change:	1.054							
4	Instrument:	Foss FT					Old Bias:	0.000	Bias Change:	-0.191							
5	Operator:	Paul															
6	Batch:	ELS273															
7							New Slope:	1.054	Installed (Y or N)								
8	Component:	Fat					New Bias:	-0.191	N								
9																	
10	Sample	Reference	IR	Difference		Sample	Adj. IR	Difference	Comments								
11	1	3.390	3.380	-0.010		1	3.370	-0.020									
12	2	3.960	3.960	0.000		2	3.981	0.021									
13	3	3.570	3.590	0.020		3	3.591	0.021									
14	4	3.820	3.790	-0.030		4	3.802	-0.018									
15	5	4.860	4.800	-0.060		5	4.866	0.006									
16	6	3.740	3.750	0.010		6	3.760	0.020									
17	7	4.120	4.100	-0.020		7	4.129	0.009									
18	8	4.320	4.270	-0.050		8	4.308	-0.012									
19	9	4.090	4.040	-0.050		9	4.066	-0.024									
20	10	4.670	4.600	-0.070		10	4.656	-0.014									
21	11	4.550	4.510	-0.040		11	4.561	0.011									
22	12					12											
23																	
24			MD	-0.027			MD	0.000									
25			SDD	0.030			SDD	0.018									
26																	
27	Tolerances	MD < +/-	0.150	IN													
28		SDD <	0.150	IN													
29																	
30	Recalibrate if both tolerances are not satisfied. Outliers can be deleted.																
31																	
32	NOTE: Only cells in blue should be modified.																
33																	
34																	
35																	
36																	
37																	
38																	
39																	
40																	
41																	
42																	
43																	
44																	

Data | Graphs | Sheet 3 | Sheet 4 | Sheet 5

Ready | 100%

Sticky Notes | Microsoft Excel - J...

3:51 PM
27/08/2015

2015 Calendar

January 2015

M	Tu	W	Th	Fr	Sa	Su
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

February 2015

M	Tu	W	Th	Fr	Sa	Su
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	

March 2015

M	Tu	W	Th	Fr	Sa	Su
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

April 2015

M	Tu	W	Th	Fr	Sa	Su
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

August 2015

M	Tu	W	Th	Fr	Sa	Su
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

December 2015

M	Tu	W	Th	Fr	Sa	Su
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

May 2015

M	Tu	W	Th	Fr	Sa	Su
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

June 2015

M	Tu	W	Th	Fr	Sa	Su
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

July 2015

M	Tu	W	Th	Fr	Sa	Su
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

September 2015

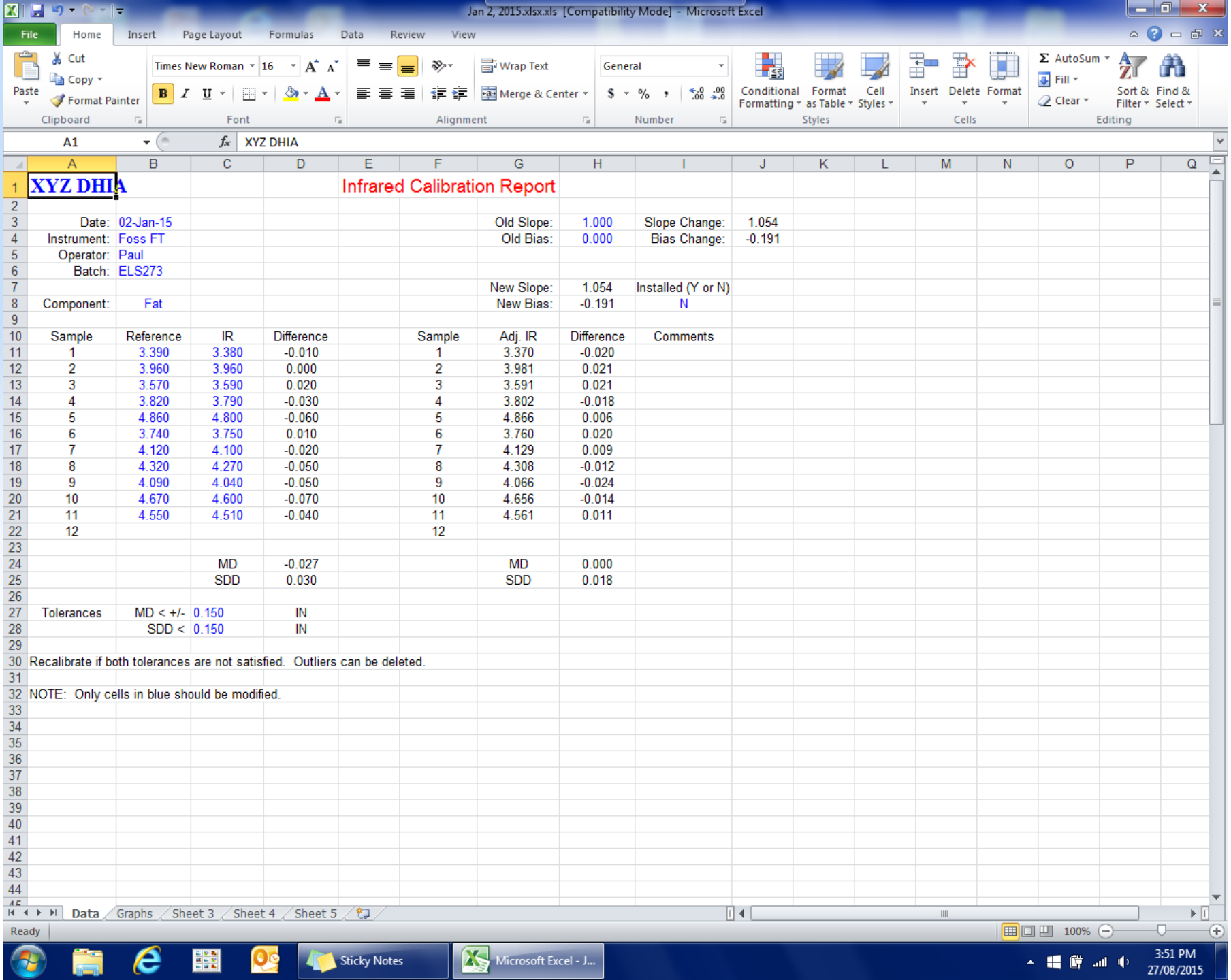
M	Tu	W	Th	Fr	Sa	Su
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

October 2015

M	Tu	W	Th	Fr	Sa	Su
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

November 2015

M	Tu	W	Th	Fr	Sa	Su
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						



Jan 2, 2015.xlsx.xls [Compatibility Mode] - Microsoft Excel

File | Home | Insert | Page Layout | Formulas | Data | Review | View

Cut | Copy | Format Painter | Paste | Clipboard

Times New Roman | 16 | Font

Wrap Text | Merge & Center | Alignment

General | Number

Conditional Formatting | Format as Table | Cell Styles | Styles

Insert | Delete | Format | Cells

AutoSum | Fill | Clear | Sort & Filter | Find & Select | Editing

A1 | XYZ DHIA

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	XYZ DHIA				Infrared Calibration Report												
2																	
3	Date:	02-Jan-15					Old Slope:	1.000	Slope Change:	1.054							
4	Instrument:	Foss FT					Old Bias:	0.000	Bias Change:	-0.191							
5	Operator:	Paul															
6	Batch:	ELS273															
7							New Slope:	1.054	Installed (Y or N)								
8	Component:	Fat					New Bias:	-0.191	N								
9																	
10	Sample	Reference	IR	Difference		Sample	Adj. IR	Difference	Comments								
11	1	3.390	3.380	-0.010		1	3.370	-0.020									
12	2	3.960	3.960	0.000		2	3.981	0.021									
13	3	3.570	3.590	0.020		3	3.591	0.021									
14	4	3.820	3.790	-0.030		4	3.802	-0.018									
15	5	4.860	4.800	-0.060		5	4.866	0.006									
16	6	3.740	3.750	0.010		6	3.760	0.020									
17	7	4.120	4.100	-0.020		7	4.129	0.009									
18	8	4.320	4.270	-0.050		8	4.308	-0.012									
19	9	4.090	4.040	-0.050		9	4.066	-0.024									
20	10	4.670	4.600	-0.070		10	4.656	-0.014									
21	11	4.550	4.510	-0.040		11	4.561	0.011									
22	12					12											
23																	
24			MD	-0.027			MD	0.000									
25			SDD	0.030			SDD	0.018									
26																	
27	Tolerances	MD < +/-	0.150	IN													
28		SDD <	0.150	IN													
29																	
30	Recalibrate if both tolerances are not satisfied. Outliers can be deleted.																
31																	
32	NOTE: Only cells in blue should be modified.																
33																	
34																	
35																	
36																	
37																	
38																	
39																	
40																	
41																	
42																	
43																	
44																	

Data | Graphs | Sheet 3 | Sheet 4 | Sheet 5

Ready | 100%

Sticky Notes | Microsoft Excel - J...

3:51 PM
27/08/2015

Auditability

Lab Managers / staff should be conducting internal audits of their policies, procedures, records etc.

This should include confirmation that all records for each required procedure are available, accurate and complete.

This task is much easier with an organized digital system.

Portions of the job can be automated (automatic flags when data is missing or incomplete).

External Auditors can work more effectively and efficiently with organized electronic records.

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Added Value:

With electronic records, routine QC data can deliver added value to the Lab Manager:

- *Monitoring equipment wear and tear*
- *Monitoring lab efficiency*
- *Monitoring lab performance, control charting*
- *Comparing results from different analyzers*
- *Comparing results from different Technicians*

CAPITAL Laboratory Services

XYZ DHIA *Record of H-INDEX Values* Line 1 2015

Date	Technician	H-INDEX	Pass / Fail
Aug 3, 2015		6.1	[Y] Pass [ ] Fail
Aug 4, 2015		6.0	[Y] Pass [ ] Fail
Aug 5, 2015		6.0	[Y] Pass [ ] Fail
Aug 6, 2016		6.1	[Y] Pass [ ] Fail
Aug 7, 2015		5.9	[Y] Pass [ ] Fail
Aug 10, 2015		5.9	[Y] Pass [ ] Fail
Aug 11, 2015		6.0	[Y] Pass [ ] Fail
Aug 12, 2015		5.9	[Y] Pass [ ] Fail
Aug 13, 2015		5.8	[Y] Pass [ ] Fail
Aug 14, 2015		5.8	[Y] Pass [ ] Fail
Aug 17, 2015		5.9	[Y] Pass [ ] Fail
Aug 18, 2015		5.7	[Y] Pass [ ] Fail
Aug 19, 2015		5.7	[Y] Pass [ ] Fail
Aug 20, 2015		5.8	[Y] Pass [ ] Fail
Aug 21, 2015		5.6	[Y] Pass [ ] Fail
Aug 24, 2015		5.5	[Y] Pass [ ] Fail
Aug 25, 2015		5.6	[Y] Pass [ ] Fail
Aug 26, 2015		5.7	[Y] Pass [ ] Fail
Aug 27, 2015		5.6	[Y] Pass [ ] Fail
Aug 28, 2015		5.6	[Y] Pass [ ] Fail
Aug 31, 2015		5.4	[Y] Pass [ ] Fail
Sept 1, 2015		5.4	[Y] Pass [ ] Fail
Sept 2, 2015		5.3	[Y] Pass [ ] Fail
Sept 3, 2015		5.4	[Y] Pass [ ] Fail
Sept 4, 2015		5.3	[Y] Pass [ ] Fail
Sept 7, 2015		5.3	[Y] Pass [ ] Fail
Sept 9, 2015		5.3	[Y] Pass [ ] Fail

H-INDEX Values must be > 5.2 to 6.0

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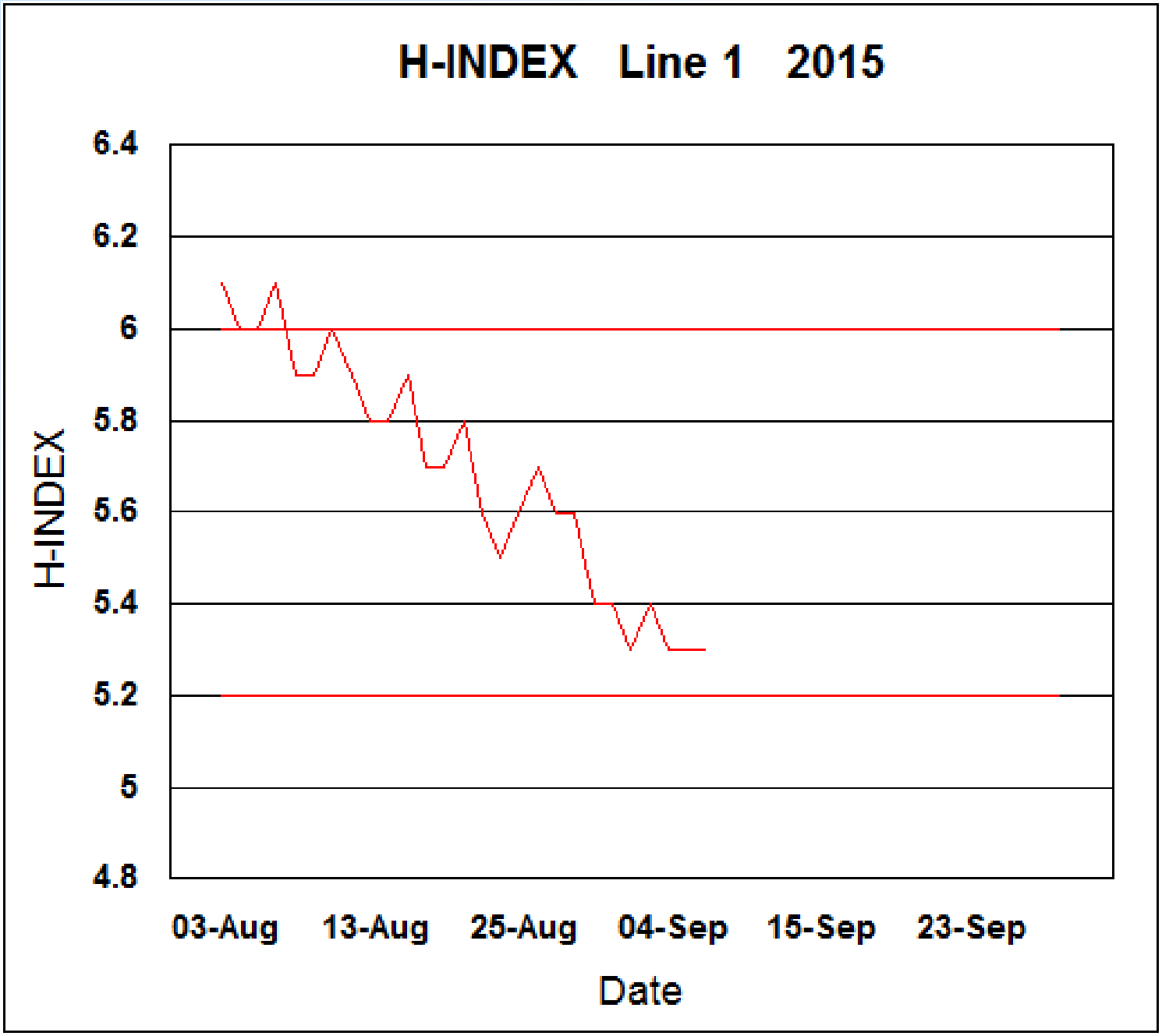
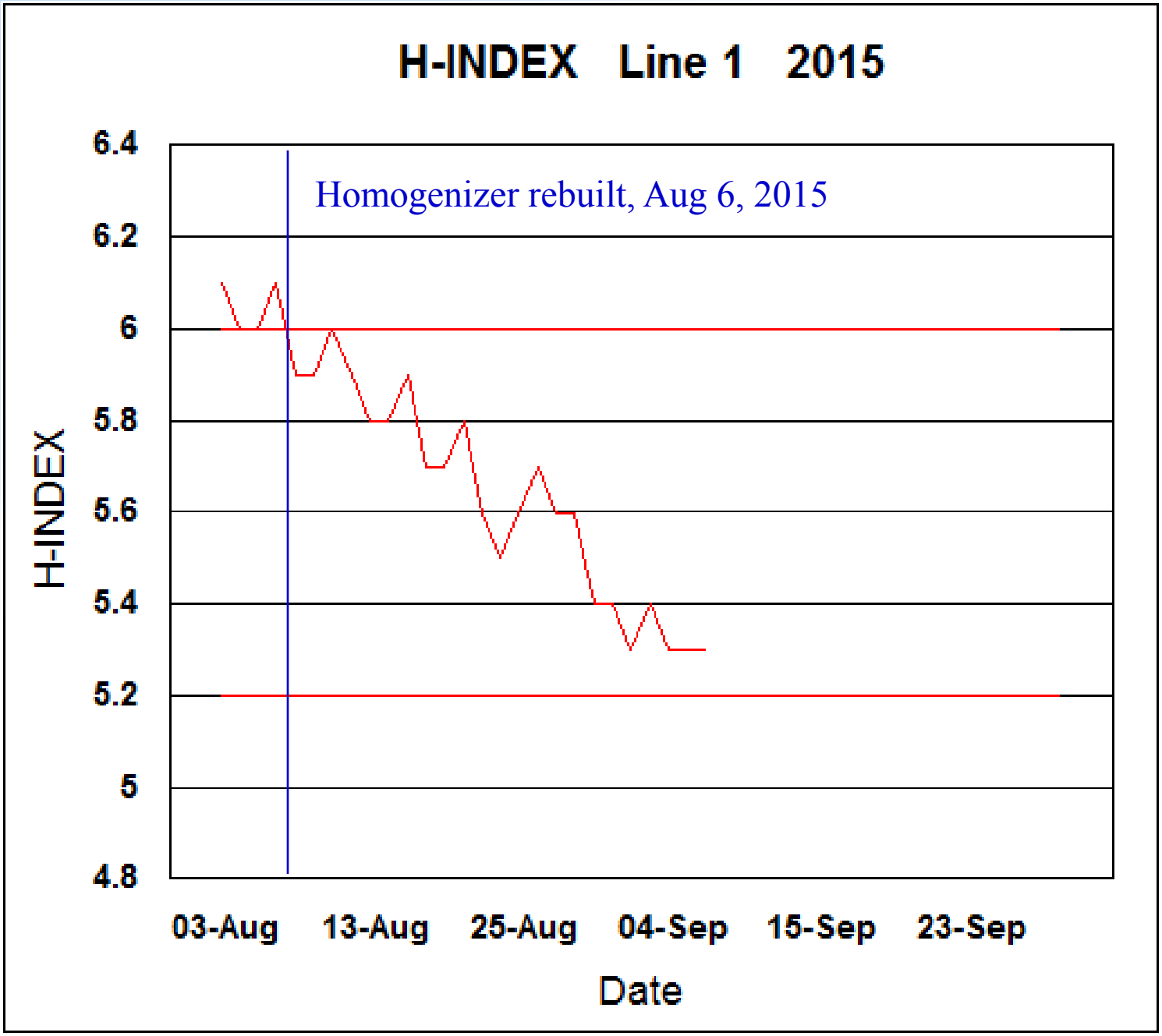
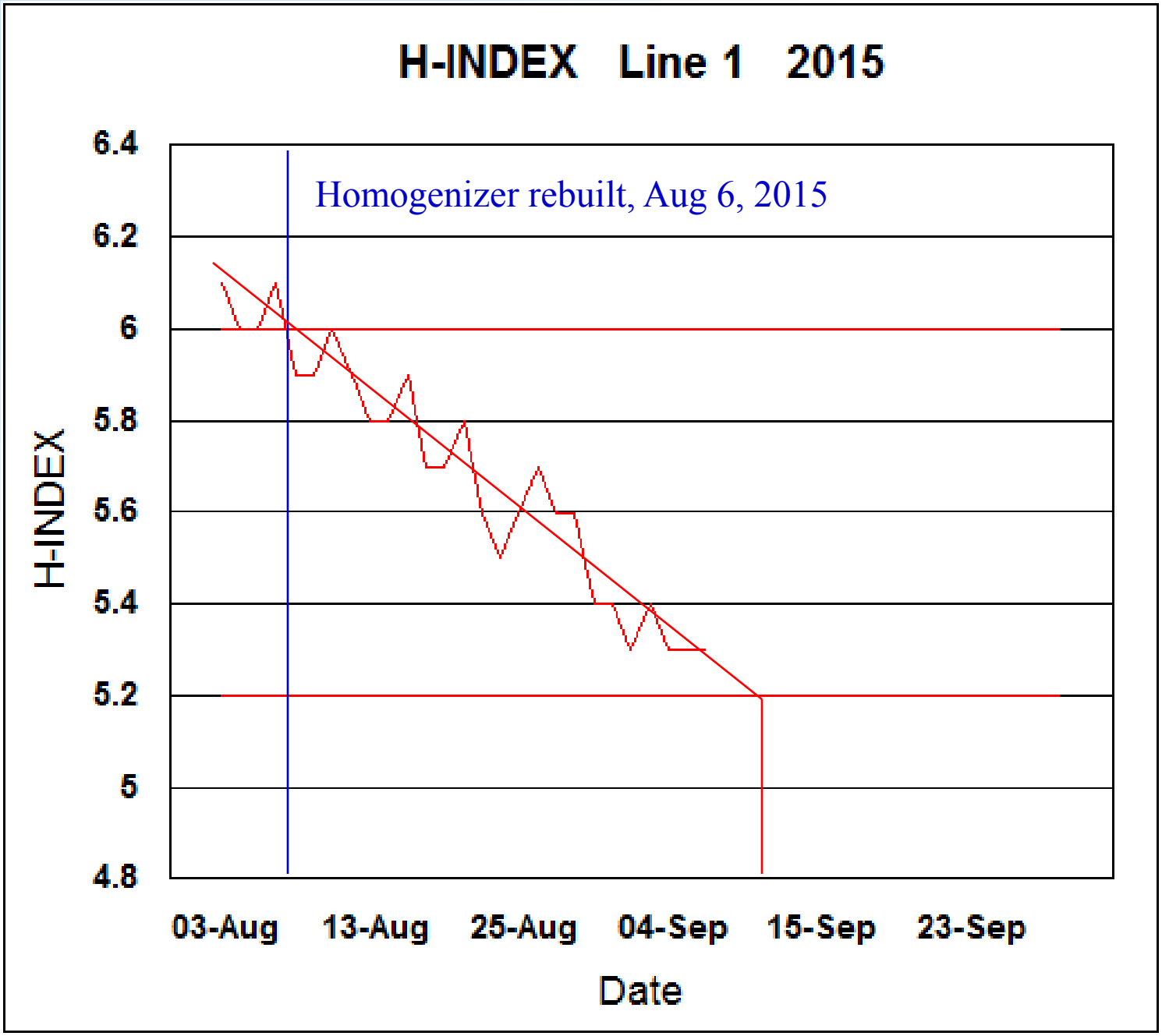


CAPITAL Laboratory Services



CAPITAL Laboratory Services



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Added Value:

Similar trend analyses can be done with many of the routine QC checks:

- *Pilot sample checks*
- *Zero checks*
- *Repeatability checks*
- *Calibration checks*
- *Purging efficiency checks*
- *Purge volume checks*
- *Performance checks (samples unknown)*

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100% Paperless – Is it possible?

- *PM reports from equipment suppliers (hard copies)*
- *Calibration certificates (thermometers, balances, pipettes)*
- *Letters from customers*
- *Test kit instructions (ELISA)*

There will likely always be the need to keep some hard copy records.

Some of these could be scanned and maintained electronically.

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Conclusions:

A paperless lab, if set-up and operated properly is:

- *More reliable*
- *More cost effective*
- *More thorough*
- *More complete*
- *More accurate*
- *Easier to audit*
- ***Greener***

It's not that difficult!

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Thank-you

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