The Illusion of Quality:

A Discussion of Roadblocks to Laboratory Quality and Case Studies of How to Make Things Better

Frederick G. Strathmann, PhD

2015 IFL Quarterly Webinar Series

ARUP Institute for Learning

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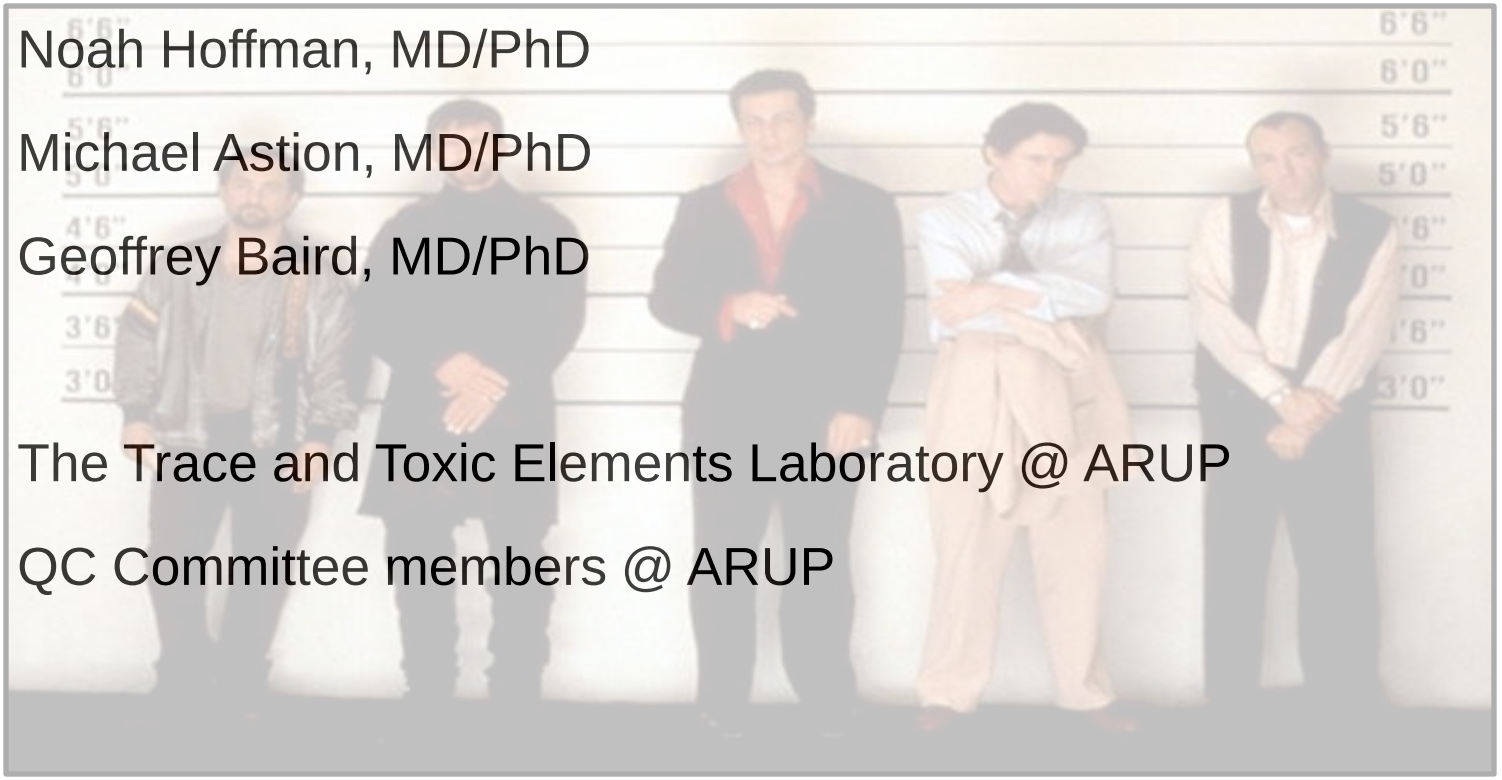

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Learning Objectives

- *List several areas of the specimen life cycle where risk assessment is needed*
- *Compare an equivalent QC plan with an IQCP*
- *Discuss available methods and techniques to acquire a current state assessment of laboratory quality*
- *Develop a plan to implement a change to current quality practices*
- *Demonstrate the positive outcomes of a successful quality redesign*

IQCP: At a glance

An IQCP requires:

– Risk Assessment (RA)

– Quality Control Plan (QCP)

– Quality Assessment (QA)

Outcomes of the IQCP Process

- After you complete this process, it is possible that you may determine that the amount of QC you have been doing all along is sufficient to achieve CLIA compliance.

- However, you could discover potential sources of error that you had not previously considered, and may need to implement additional QC activities.

- Anyone else think this is a trap?

Equivalent QC: The Good

- Minimal effort
- Majority of the responsibility on the producer (not the user)
- 2 or more levels of QC per day

  AND/OR

- No external QC if manufacturers' internal QC are adequate

Equivalent QC: The Bad

- Minimal quality set point
- Focus on assumption of performance
- Missed warnings provided from more extensive statistical QC

1. Perform the required number of external liquid controls per test per day
2. Continue to follow EQC procedures
3. Implement an IQCP

After January 1, 2016, EQC will no longer be a QC option.

IQCP: At a glance

An IQCP requires:

– Risk Assessment (RA)

– Quality Control Plan (QCP)

– Quality Assessment (QA)

Risk Assessment

What does it mean?

- Knowing and finding the weak points of your processes
  - Preanalytical
    - Mislabels
  - Analytical
    - Ineffective QC policy
  - Postanalytical
    - Transcription errors

Where do you look?

- Specimen
- Test System
- Reagents
- Environment
- Testing Personnel

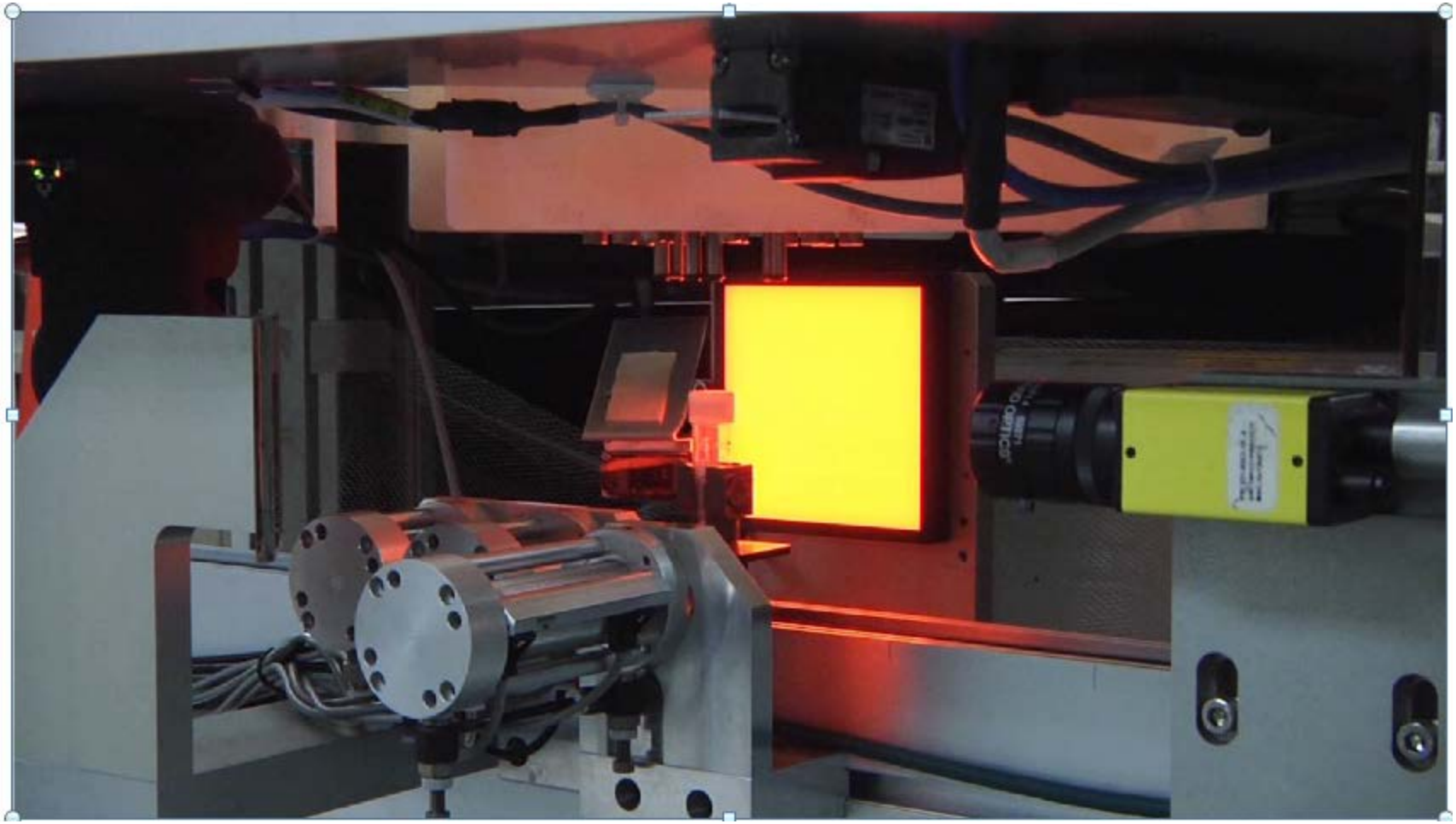
Examples of Findings/Symptoms

- Preanalytical
  - Mislabels: Mislabel rate high and found by physician inquiry. Incidental findings during the testing process.
- Analytical
  - Ineffective QC: Failed PT with QC that passed. 2sd QC policy with “repeat, repeat, repeat” as the troubleshooting guide. Problems that “come out of nowhere”.
- Postanalytical
  - Transcription errors: Results that fail to repeat (found by physician inquiry). Failed internal PT that are patient repeats. Troubleshooting unrelated find result discrepancies.

Formulating an IQCP

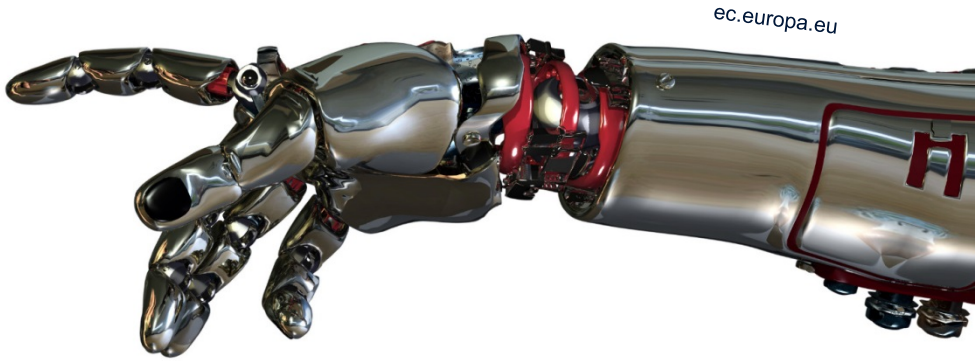
- Incorporating the RA findings: Mislabels
  - Track mislabels by month and report to staff
- Solutions:
  - Double checking
  - Triple checking
  - OCR multidimensional label reader

Courtesy of ARUP Laboratories (Dr. Charlie Hawker)



Roadblock #1

- No access to futuristic robots, Dr. Charlie Hawker, or the ARUP Automation & Bioengineering groups



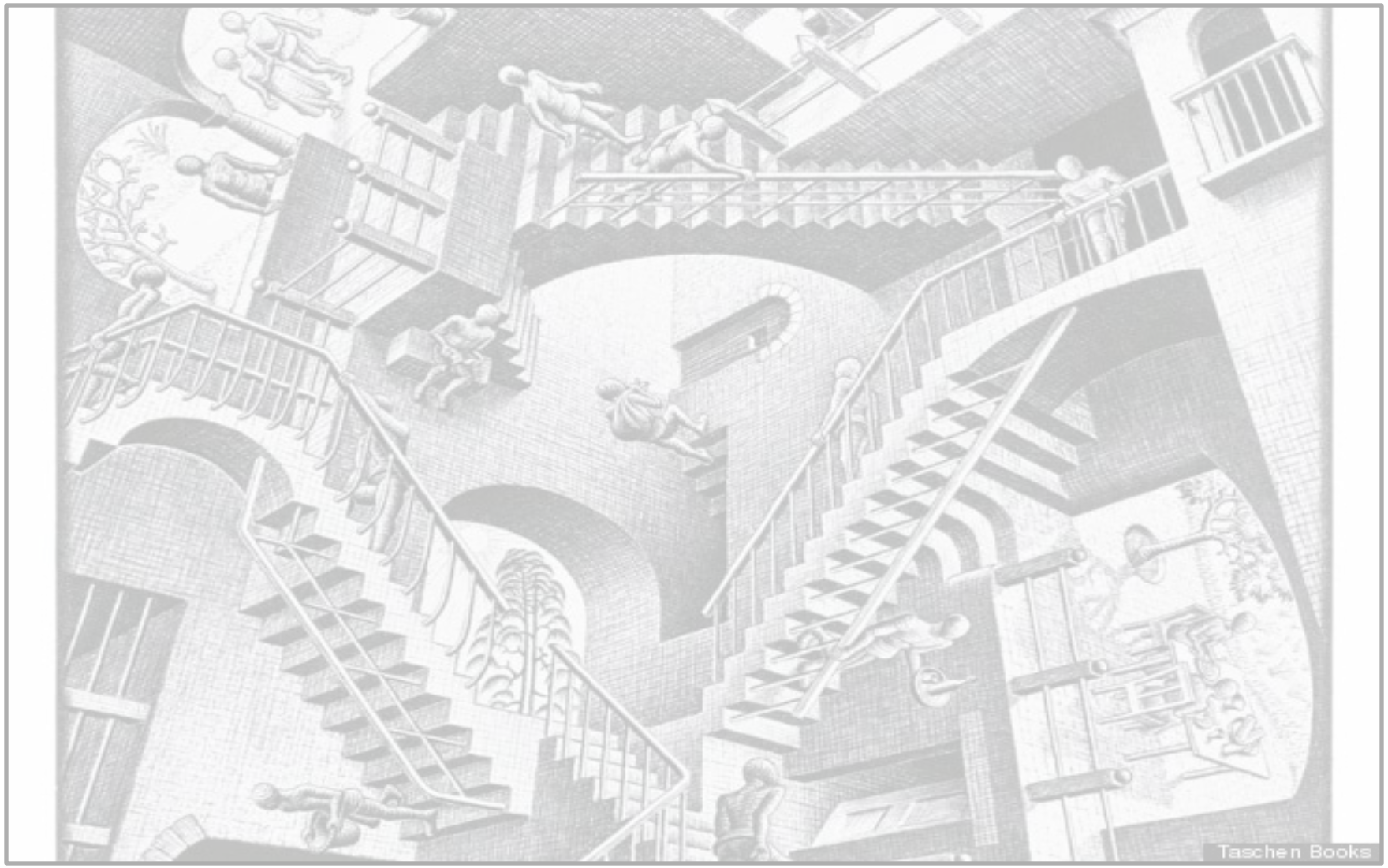
Formulating an IQCP

- Incorporating the RA findings: Transcription errors
  - Track corrected reports (performance appraisal metric)
- Solutions include:
  - Interfaces (electronic shuttling of data from instrument to LIS)
    - Autoverification
    - More quality checks
    - IT support is substantial
  - Double verification
    - Perform technologist different than verify technologist
  - DAR (daily activity review)
    - Person that reviews all results verified from the day before (retrospective)

Formulating an IQCP

- Incorporating the RA findings: Inadequate QC
  - Track PT failures
  - Track QC failures
  - Track troubleshooting success/failure
- Solutions:
  - Do nothing (if you're hitting the minimum requirement)
  - Take the opportunity to vet your QC
  - Enhance and optimize your QC
  - KNOW that your lab is generating high quality results

Finding the Path to Better Quality



Eye Opening Experiences for Me – TTE Lab

- Trace and Toxic Element Laboratory
- Inductively-coupled plasma mass spectrometry
- 20 staff members
  - 1 x Supervisor, 1 x Lead Technologist, 1 x Technical Specialist, 17 x Bench technologists
- 20 different assays
- *No QC failures for almost 6 months*

Eye Opening Experiences for Me – cont.

- PT Failures with no explanations
  - QC all passed on the day of PT
- Staff complaints of difficult workload
- Obsession with NY guidelines, PT acceptance criteria
- Apparent disconnect between several bench technologists and patients
- *A high quality lab that could be better – but didn't know it!*

Round 1

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Roadblocks to Quality

- Roadblocks to Quality
  1. Lab culture & bench disconnect
  2. One-size-fits-all QC rules
  3. Unclear troubleshooting processes
  4. Lack of QC life-cycle and metrics to track improvements

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Quality Control: Getting back to basics

January 2013

TTE Staff Meeting

Topics to cover

- What is QC?
- What can statistics tell us about our QC process?
- How are we currently doing QC?
- How is QC reviewed currently?
- How could we change QC to enhance lab quality?

Why talk about QC?

- As the lab evolves, our quality measures must evolve.
- It is easy to disconnect from the *true goal of QC*.
- Change is good, but only if it is the right change.
- Reduce rework, increase efficiency, spend time on more appropriate aspects.
- Ensure we never forget our responsibility to the “patient in the tube”.

What is QC?

QC Strategy

- Intended to monitor the analytical performance of a measurement procedure and alert analysts to problems that might limit the usefulness of a test result.

- Tells the analyst if the unknown (patient) results are valid

1. Test and method specific (materials, rules, number, frequency)
2. Define an “analytical run” or batch
3. Run QC and have an appropriate response plan

Key Features of Good QC

- Prepped at the same time as patient samples and standards
  - *Any mistakes made with QC were likely made with patients too!*

- Represent the only known values and provide a reality anchor
  - *Like looking up the answers in the back of the book – VALIDITY!*

- Must be done consistently with ALL data collected, good or bad

  - *Allows a timeline of assay performance – PREDICTIVE and PREVENTATIVE*

- Rules identify real failures and are investigated to find a root cause
  - *Just enough QC with the right rules*

Features of Bad QC

- QC prepped independently of patients
  - *QC only validates calibration, can't find non-cognitive errors*
- QC repeated over and over until "it's in"
  - *5% of the time, good QC is out. 5% of the time, bad QC is in.*
- Reporting in the range of "good QC" and ignoring "bad QC"
  - *Might be fine once, but trends, shifts, and future problems are looming.*
- Running QC before the instrument is ready
  - *Introduces unwanted variability (long term monitoring skewed)*

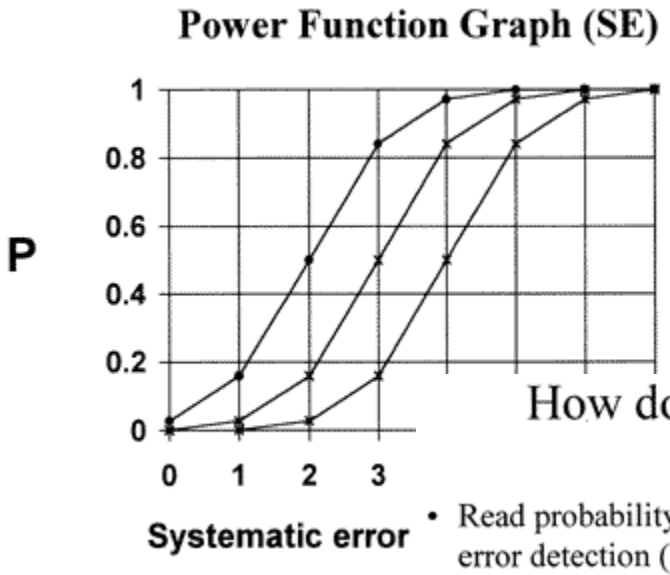
A Closer Look: Our Current State

Test	N	Set Mean	Obv. Mean	Set SD	Obv. SD *	Z Score	Prev Mont Z	Set CV	Curr Month CV	Prev Month CV	Expected Range
Lead WB Venous	375	1.7	1.72	0.3	0.125643	0.08	0.044199	17.647059	7.287862	5.89	1.100-2.300
Lead WB Venous	320	5.2	5.27	0.5	0.553706	0.144375	0.032298	9.615385	10.502404	4.83	4.200-6.200
Lead WB Venous	292	22.8	22.76	2.2	1.525024	-0.016656	-0.076027	9.649123	6.699468	6.65	18.400-27.200
Lead WB Venous	253	83.1	85.40	8.3	4.290246	0.276585	0.1562	9.987966	5.023963	4.42	66.500-99.700
Mang, Serum	20	1	1.01	0.5	0.298946	0.02	0.484211	50	29.598566	30.04	0.000-2.000
Mang, Serum	16	4.6	5.41	1	0.472537	0.80625	0.953333	21.73913	8.740578	9.84	2.600-6.600
Mang, Serum	13	14.7	18.14	2.2	1.08285	1.562937	1.710744	14.965986	5.969911	6.27	10.300-19.100
Mang, Serum	15	27.2	32.26	4.1	2.074608	1.234146	1.314634	15.073529	6.4309	4.56	19.000-35.400

How do we do this?

- Find and identify assay or workflow problems inhibiting best practices for QC
- Establish “appropriate targets” for all QC
- Standardize comments and troubleshooting steps
- Modify rules to ensure appropriate balance of control
  - *Not too much, not too little*
- Adhere to good QC practice at all times
  - *QC prepped with patient samples*
  - *No repeating of “out” QC*
  - *Root cause of failed QC*

Rule performance



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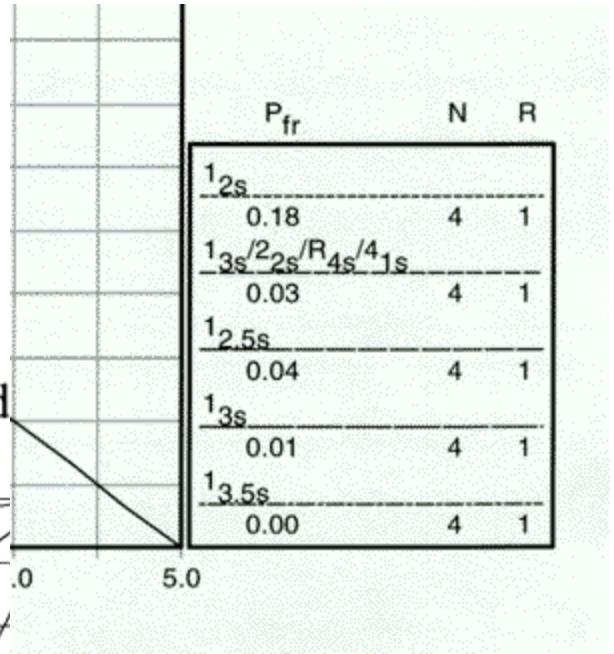
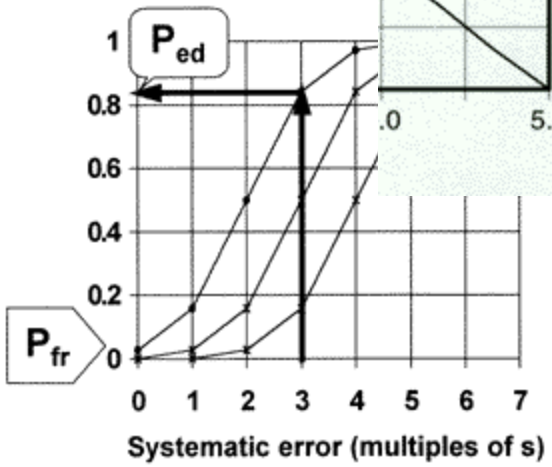
1_{3s} N=1

1_{4s} N=1



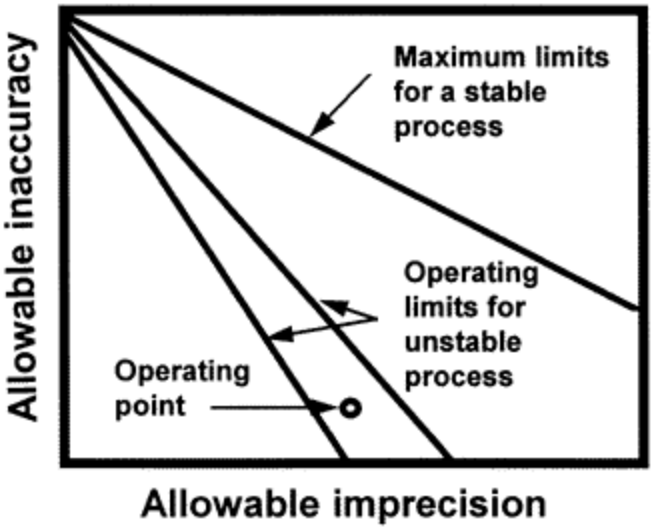
How do you determine P_{ed} and

- Read probability for error detection (P_{ed}) at point on power curve corresponding to critical-sized error
- Read probabilty for false rejection (P_{fr}) from y-intercept



QC Goals

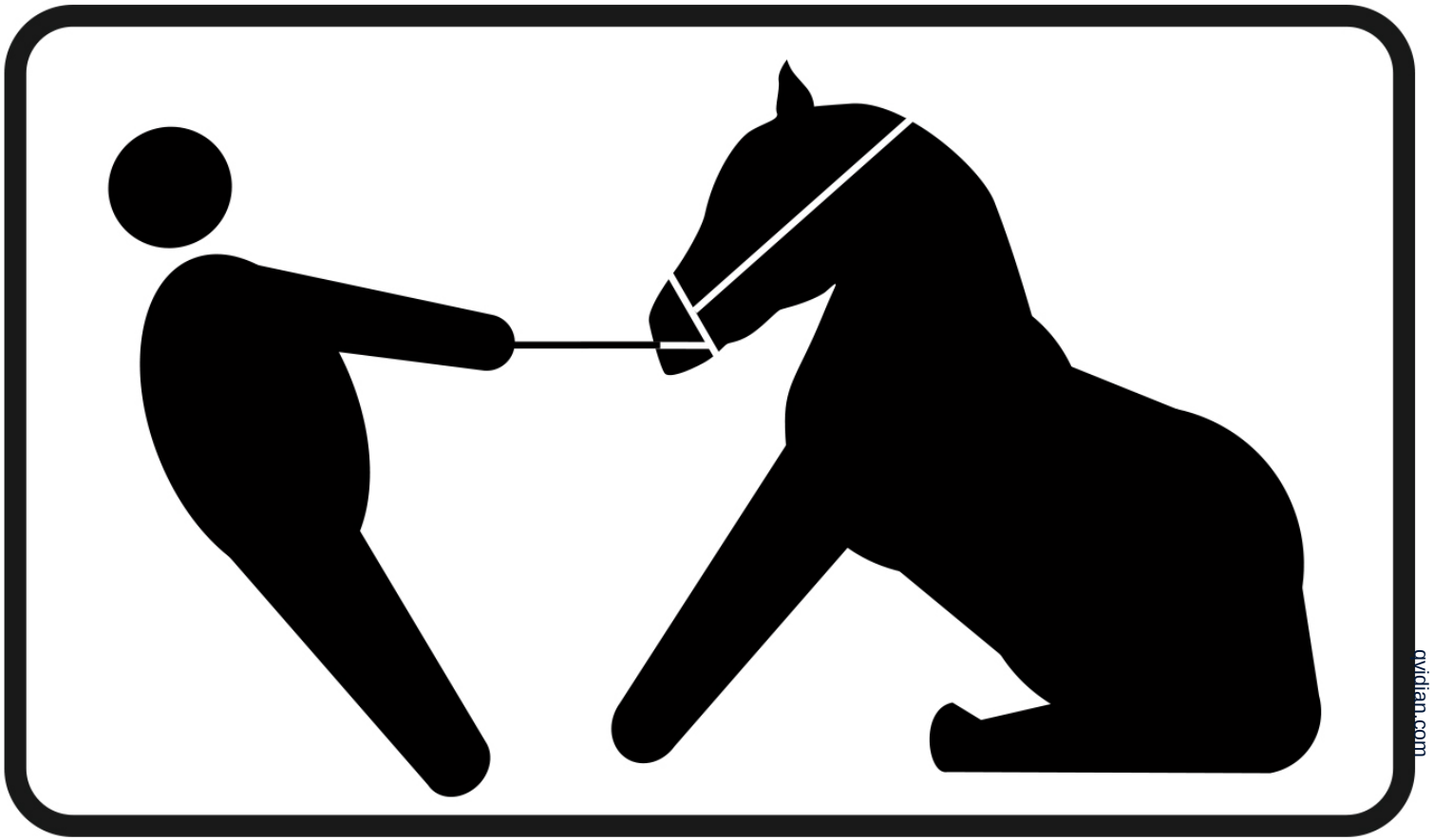
- Total allowable error
- Medical decision limits
- Assay bias
- Assay precision



What's next?

- Deeper analysis for all analytes in the lab
- Standardization of comments and troubleshooting steps
- Identify high yield, low false positive rules for each analyte
- Establish more accurate goals for QC ranges (based on performance)
- More fun, less work!

Progress Summary:
January 2013 to September 2013



Why was there no progress?

- Staff didn’t believe there was a problem.
- Management didn’t have the tools in place to change.
- Lots of *MY* ideas, lots of *MY* enthusiasm, no *STAFF* buy-in.

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Round 2

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The Beginning of Buy-in

- A few more failed PTs
- A supervisor and a lead “encouraged” to find the causes with a medical director that wouldn’t let up.
- Weekly Quality Assurance & Quality Control meetings
- Monthly QC review as a group
  - ***Viewing the lab from my point of view***
- “Is it possible our QC is not as good as we think?”

The Illusion of Quality

A Discussion of Outdated QC Approaches and Case Studies of Progress

Frederick G. Strathmann

ARUP Nuts and Bolts Series

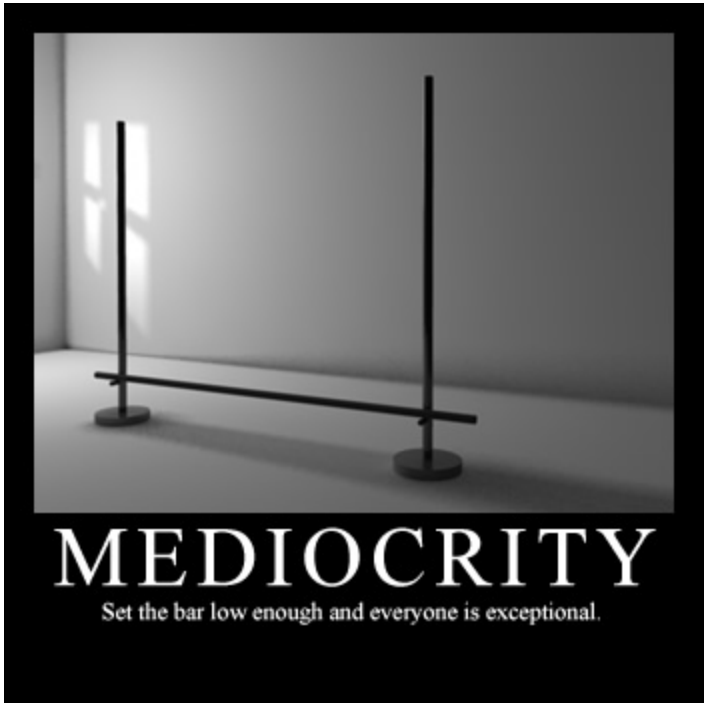
October 15, 2013

Outline

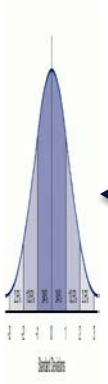
- Common Mistakes
- Necessary components of a QC plan
- Areas for continuous improvement
- Strategies for addressing quality weak points

Necessary Component #1

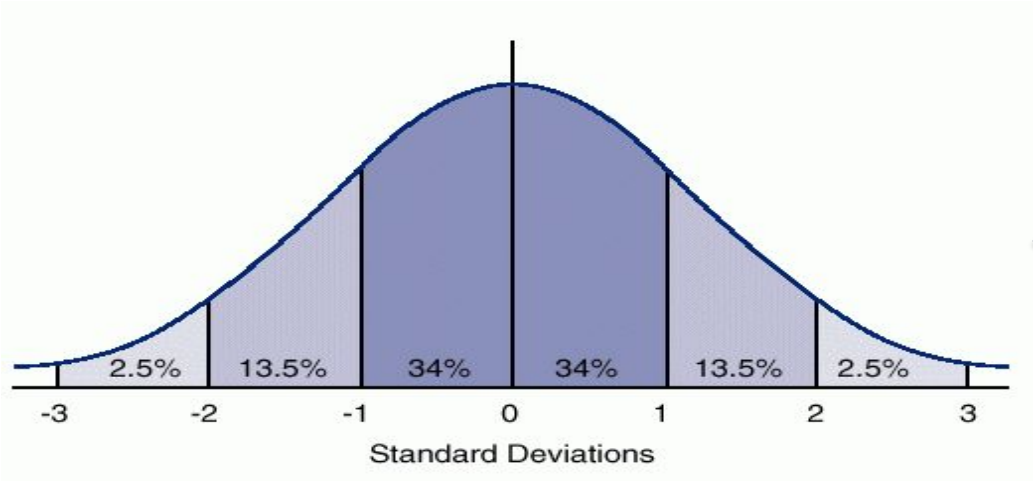
- Appropriate targets and ranges



#3 Unrealistic QC Targets



Instrument performance



Lab expectations

Identifying Weak Points

Test	N	Set Mean	Obv. Mean	Set SD	Obv. SD *	Z Score	Prev Mont Z	Set CV	Curr Month CV	Prev Month CV	Expected Range
Lead WB Venous	375	1.7	1.72	0.3	0.125643	0.08	0.044199	17.647059	7.287862	5.89	1.100-2.300
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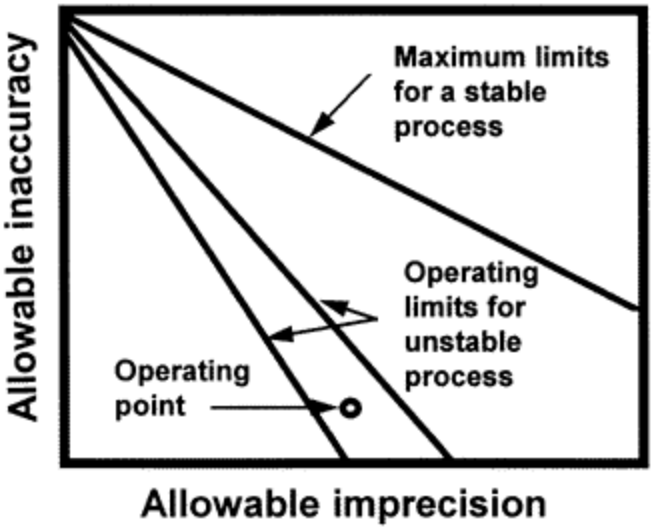
Lead WB Venous	253	83.1	85.40	8.3	4.290246	0.276585	0.1562	9.987966	5.023963	4.42	66.500-99.700

Necessary Component #2

- Rules that fit the assay

QC Goals

- Total allowable error
- Medical decision limits
- Assay bias
- Assay precision



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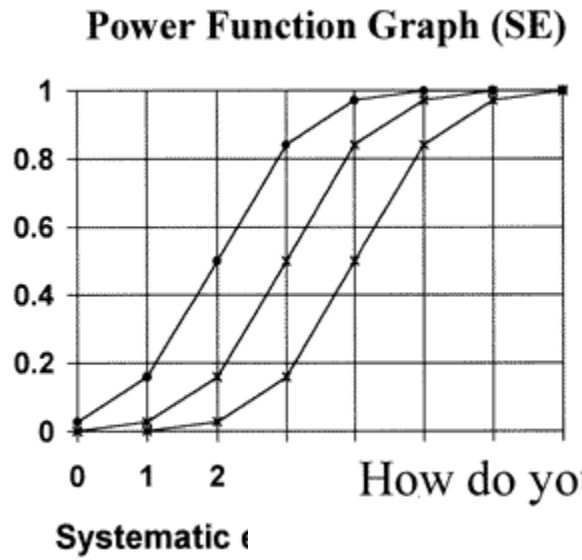

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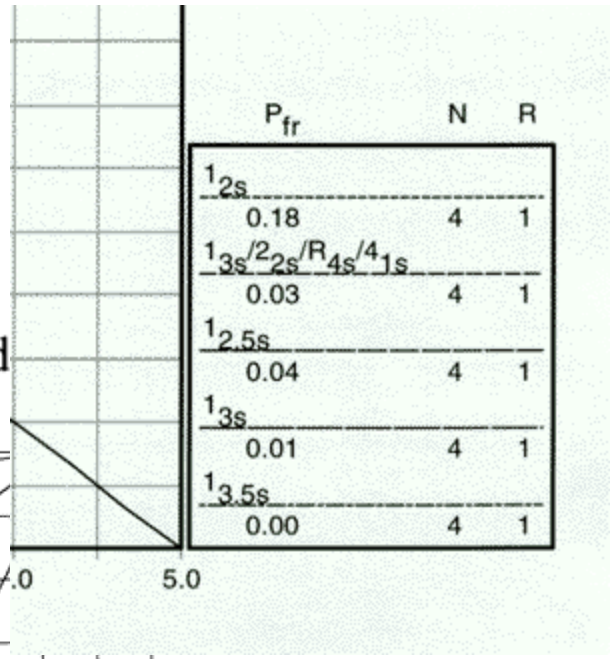

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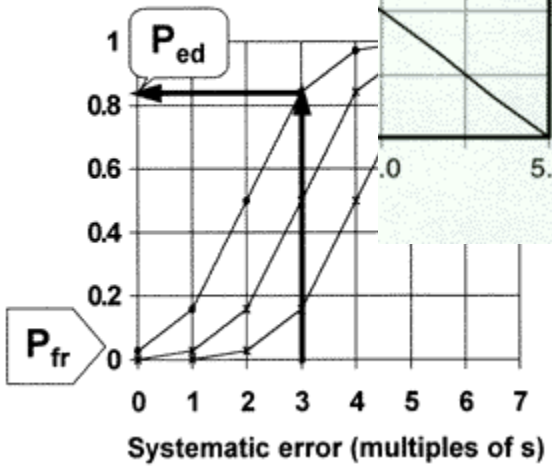

Almost…Not Quite

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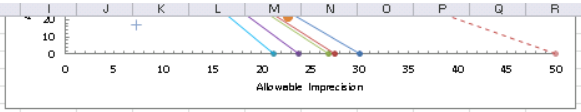
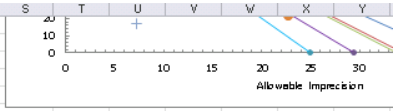
Current state assessment

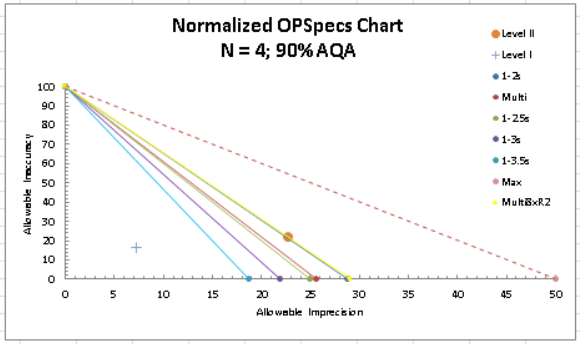
Test	Test Site	Control Name	Control Lot	N	Set Mean	Obv. Mean	Set SD	Obv. SD	Z Score	Prev Mont Z	Set CV	Curr Month CV	Prev Month CV	Expected Range
AS DMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	13.33	1.5	0.691375	-1.113333	-0.802381	10	5.186812	6.60	12.000-18.000
AS DMA	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	102	94.49	10.2	4.422419	-0.736275	-0.392157	10	4.680304	6.40	81.600-122.400
AS III	TEC Fractionation	861 AS UF LEVEL I	72778.1	14	21	22.69	2.1	2.472575	0.802721	1.638655	10	10.899259	8.37	16.800-25.200
AS MMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	14.03	1.5	0.980803	-0.65	-0.385714	10	6.993245	6.87	12.000-18.000
AS MMA	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	103	94.43	10.3	3.89576	-0.832039	-0.440376	10	4.125554	5.24	82.400-123.600
AS Organic	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	52	44.19	5.2	1.71584	-1.501923	-1.120679	10	3.882868	6.19	41.600-62.400
AS Organic	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	394	341.51	39.4	19.552484	-1.332234	-1.065708	10	5.725298	5.64	315.200-472.800
AS V	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	13	12.68	1.3	1.079413	-0.25	0.615385	10	8.516078	7.25	10.400-15.600
AS V	TEC Fractionation	861 AS UF LEVEL II	72778.2	18	98	95.40	9.8	4.631732	-0.265306	0.184767	10	4.855065	6.00	78.400-117.600
Antimony Blood	TEC ICP MS Dig	861 BLD DIG LEVEL I	68819.1	10	1.3	1.10	0.5	0.316228	-0.4	-0.6	38.461538	28.747979	0.00	0.300-2.300
Antimony Blood	TEC ICP MS Dig	861 BLD DIG LEVEL II	68819.2	10	6.4	5.50	1	0.527046	-0.9	-0.9	15.625	9.58256	9.96	4.400-8.400
Bismuth WB	TEC ICP MS Dig	861 BLD DIG LEVEL I	68819.1	8	1.9	1.88	0.5	0.353553	-0.05	-0.05	26.315789	18.856181	18.86	0.900-2.900
Bismuth WB	TEC ICP MS Dig	861 BLD DIG LEVEL II	68819.2	8	5.4	5.38	1	0.517549	-0.025	-0.4	18.518519	9.628822	0.00	3.400-7.400
Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL I	37635	8	0.56	0.53	0.1	0.138873	-0.35	0.928412	17.857143	26.452003	18.85	0.360-0.760
Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL I	83459	25	15	14.68	1.4	1.091253	-0.228571	0.069333	9.333333	7.433804	9.85	12.200-17.800
Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL II	69152	22	3.3	3.37	0.53	0.211979	0.137221	0.410172	16.060606	6.285089	9.53	2.240-4.360
Copper, Free	TEC ICP MS Dig	861 CU FREE NIST	1643E	19	2.28	2.25	0.3	0.100026	-0.108772	-0.22983	13.157895	4.53981	4.88	1.680-2.880
CU Weight	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	28	2	2.52	2	0.557706	0.259808	0.383409	100	22.134564	23.27	-2.000-6.000
CU Weight	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	28	3	2.78	1	0.753833	-0.216077	0.210455	33.333333	27.097549	18.77	1.000-5.000
FE Weight	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	28	2	2.62	2	0.636045	0.308077	0.396571	100	24.312198	28.78	-2.000-6.000
FE Weight	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	28	3	2.77	1.2	0.74372	-0.191026	0.285227	40	26.841642	24.21	0.600-5.400
Hep Copper Cont	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	28	81.5	81.38	28.2	18.042157	-0.004364	0.37837	34.601227	22.171098	22.63	25.100-137.900
Hep Copper Cont	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	28	5.6	5.77	1.7	1.550497	0.099548	1.040107	30.357143	26.990772	21.38	2.200-9.000

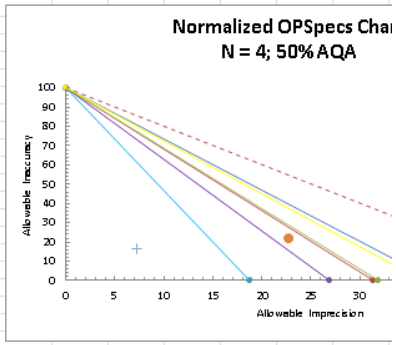
Current state assessment

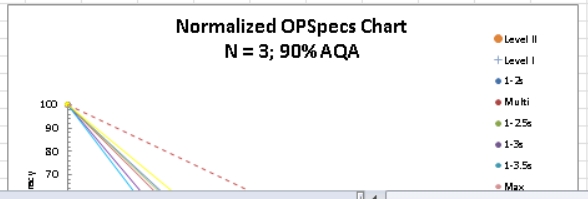
	A	B	C	D	E	F	G
16	0	38.75	1-3s/2of3-2s/R-4s/3-1s/8x	6	1	0.5	0.07
17	100	0	1-3s/2of3-2s/R-4s/3-1s	6	1	0.5	0.05
18	0	34.375	1-3s/2of3-2s/R-4s/3-1s	6	1	0.5	0.05
19	100	0	1-2.5s	6	1	0.5	0.06
20	0	33.75	1-2.5s	6	1	0.5	0.06
21	100	0	1-3s	6	1	0.5	0.01
22	0	29.375	1-3s	6	1	0.5	0.01
23	100	0	1-3.5s	6	1	0.5	0
24	0	25	1-3.5s	6	1	0.5	0
25	100	0	Max				
26	0	50	Max				
27							
28	100	0	1-2s	4	1	0.9	0.18
29	0	28.75	1-2s	4	1	0.9	0.18
30	100	0	1-3s/2-2s/R-4s/4-1s	4	1	0.9	0.03
31	0	25.625	1-3s/2-2s/R-4s/4-1s	4	1	0.9	0.03
32	100	0	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.9	0.03
33	0	29.07	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.9	0.03
34	100	0	1-2.5s	4	1	0.9	0.04
35	0	25	1-2.5s	4	1	0.9	0.04
36	100	0	1-3s	4	1	0.9	0.01
37	0	21.875	1-3s	4	1	0.9	0.01
38	100	0	1-3.5s	4	1	0.9	0
39	0	18.75	1-3.5s	4	1	0.9	0
40	100	0	Max				
41	0	50	Max				
42							
43	100	0	1-2s	4	1	0.5	0.18
44	0	37.5	1-2s	4	1	0.5	0.18
45	100	0	1-3s/2-2s/R-4s/4-1s	4	1	0.5	0.03
46	0	31.25	1-3s/2-2s/R-4s/4-1s	4	1	0.5	0.03
47	100	0	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.5	0.03
48	0	36.23	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.5	0.03
49	100	0	1-2.5s	4	1	0.5	0.04
50	0	31.875	1-2.5s	4	1	0.5	0.04
51	100	0	1-3s	4	1	0.5	0.01
52	0	26.875	1-3s	4	1	0.5	0.01
53	100	0	1-3.5s	4	1	0.5	0
54	0	23.75	1-3.5s	4	1	0.5	0
55	100	0	Max				
56	0	50	Max				
57							
58	100	0	1-2s	3	1	0.9	0.14
59	0	25.625	1-2s	3	1	0.9	0.14
60	100	0	1-3s/2of3-2s/R-4s-/4-1s	3	1	0.9	0.02
61	0	23.75	1-3s/2of3-2s/R-4s-/4-1s	3	1	0.9	0.02
62	100	0	1-3s/2of3-2s/R-4s/3-1s/8x	3	2	0.9	0.03
63	0	28.65	1-3s/2of3-2s/R-4s/3-1s/8x	3	2	0.9	0.03
64	100	0	1-2.5s	3	1	0.9	0.03
65	0	25	1-2.5s	3	1	0.9	0.03
66	100	0	1-3s	3	1	0.9	0.01
67	0	20	1-3s	3	1	0.9	0.01
68	100	0	1-3.5s	3	1	0.9	0
69	0	18.125	1-3.5s	3	1	0.9	0
70	100	0	Max				

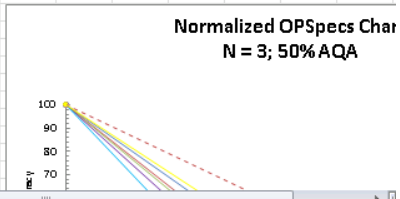






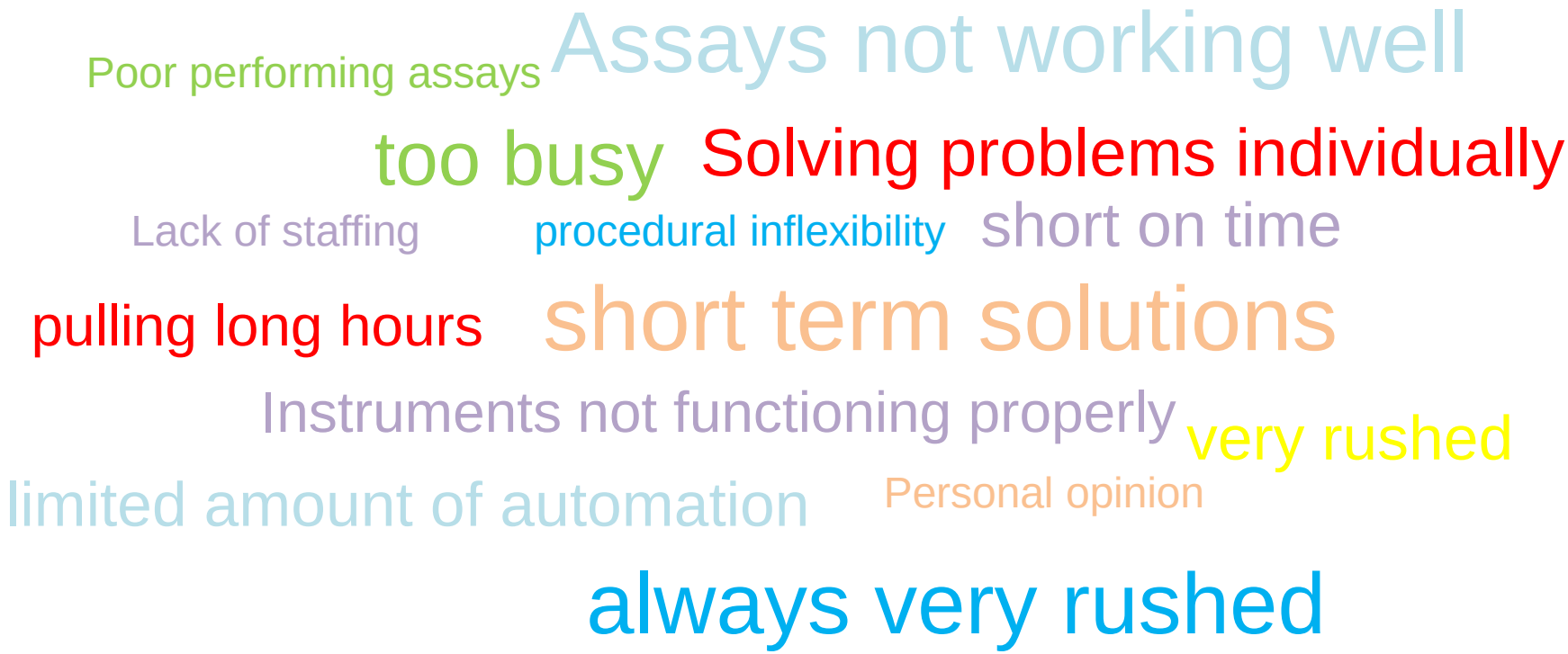






Custom Rules | Lead WB | Assay Next

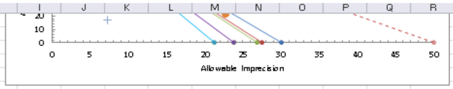
Ask the staff

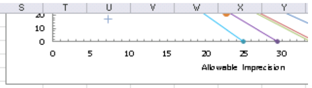


QC rules evaluated on a continuous basis

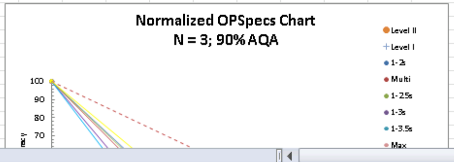
	A	B	C	D	E	F	G
16	0	38.75	1-3s/2of3-2s/R-4s/3-1s/6x	6	1	0.5	0.07
17	100	0	1-3s/2of3-2s/R-4s/3-1s	6	1	0.5	0.05
18	0	34.375	1-3s/2of3-2s/R-4s/3-1s	6	1	0.5	0.05
19	100	0	1-2.5s	6	1	0.5	0.06
20	0	33.75	1-2.5s	6	1	0.5	0.06
21	100	0	1-3s	6	1	0.5	0.01
22	0	29.375	1-3s	6	1	0.5	0.01
23	100	0	1-3.5s	6	1	0.5	0
24	0	25	1-3.5s	6	1	0.5	0
25	100	0	Max				
26	0	50	Max				
27							
28	100	0	1-2s	4	1	0.9	0.18
29	0	28.75	1-2s	4	1	0.9	0.18
30	100	0	1-3s/2-2s/R-4s/4-1s	4	1	0.9	0.03
31	0	25.625	1-3s/2-2s/R-4s/4-1s	4	1	0.9	0.03
32	100	0	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.9	0.03
33	0	29.07	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.9	0.03
34	100	0	1-2.5s	4	1	0.9	0.04
35	0	25	1-2.5s	4	1	0.9	0.04
36	100	0	1-3s	4	1	0.9	0.01
37	0	21.875	1-3s	4	1	0.9	0.01
38	100	0	1-3.5s	4	1	0.9	0
39	0	18.75	1-3.5s	4	1	0.9	0
40	100	0	Max				
41	0	50	Max				
42							
43	100	0	1-2s	4	1	0.5	0.18
44	0	37.5	1-2s	4	1	0.5	0.18
45	100	0	1-3s/2-2s/R-4s/4-1s	4	1	0.5	0.03
46	0	31.25	1-3s/2-2s/R-4s/4-1s	4	1	0.5	0.03
47	100	0	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.5	0.03
48	0	36.23	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.5	0.03
49	100	0	1-2.5s	4	1	0.5	0.04
50	0	31.875	1-2.5s	4	1	0.5	0.04
51	100	0	1-3s	4	1	0.5	0.01
52	0	26.875	1-3s	4	1	0.5	0.01
53	100	0	1-3.5s	4	1	0.5	0
54	0	23.75	1-3.5s	4	1	0.5	0
55	100	0	Max				
56	0	50	Max				
57							
58	100	0	1-2s	3	1	0.9	0.14
59	0	25.625	1-2s	3	1	0.9	0.14
60	100	0	1-3s/2of3-2s/R-4s-/4-1s	3	1	0.9	0.02
61	0	23.75	1-3s/2of3-2s/R-4s-/4-1s	3	1	0.9	0.02
62	100	0	1-3s/2of3-2s/R-4s/3-1s/6x	3	2	0.9	0.03
63	0	28.65	1-3s/2of3-2s/R-4s/3-1s/6x	3	2	0.9	0.03
64	100	0	1-2.5s	3	1	0.9	0.03
65	0	25	1-2.5s	3	1	0.9	0.03
66	100	0	1-3s	3	1	0.9	0.01
67	0	20	1-3s	3	1	0.9	0.01
68	100	0	1-3.5s	3	1	0.9	0
69	0	18.125	1-3.5s	3	1	0.9	0
70	100	0	Max				

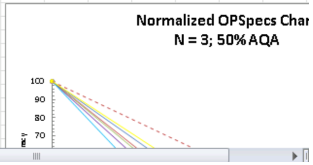
Custom Rules | Lead WB | Assay Next





Test	Test Site	Control Name	Control Lot	N	Set Mean	Obv. Mean	Set SD	Obv. SD	Z Score	Prev Mont Z	Set CV	Curr Month CV	Prev Month CV	Expected Range
AS DMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	13.33	1.5	0.691375	-1.113333	-0.802381	10	5.186612	6.60	12.000-18.000
AS DMA	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	102	94.49	10.2	4.422419	-0.736275	-0.392157	10	4.680304	6.40	81.600-122.400
AS III	TEC Fractionation	861 AS UF LEVEL I	72778.1	14	21	22.69	2.1	2.472575	0.802721	1.638655	10	10.899259	8.37	16.800-25.200
AS MMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	14.03	1.5	0.980803	-0.65	-0.385714	10	6.993245	6.87	12.000-18.000
AS MMA	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	103	94.43	10.3	3.89576	-0.832039	-0.449376	10	4.125554	5.24	82.400-123.600
AS Organic	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	52	44.19	5.2	1.71584	-1.501923	-1.120879	10	3.882868	6.19	41.600-62.400
AS Organic	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	394	341.51	39.4	19.552464	-1.332234	-1.065708	10	5.725298	5.64	315.200-472.800
AS V	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	13	12.68	1.3	1.079413	-0.25	0.615385	10	8.516076	7.25	10.400-15.600
AS V	TEC Fractionation	861 AS UF LEVEL II	72778.2	18	98	95.40	9.8	4.631732	-0.265306	0.184767	10	4.855065	6.00	78.400-117.600
Antimony Blood	TEC ICP MS Dig	861 BLD DIG LEVEL I	68819.1	10	1.3	1.10	0.5	0.316228	-0.4	-0.6	38.461538	28.747979	0.00	0.300-2.300
Antimony Blood	TEC ICP MS Dig	861 BLD DIG LEVEL II	68819.2	10	6.4	5.50	1	0.527046	-0.9	-0.9	15.625	9.58266	9.96	4.400-8.400
Bismuth WB	TEC ICP MS Dig	861 BLD DIG LEVEL I	68819.1	8	1.9	1.88	0.5	0.353553	-0.05	-0.05	26.315789	18.856181	18.86	0.900-2.900
Bismuth WB	TEC ICP MS Dig	861 BLD DIG LEVEL II	68819.2	8	5.4	5.38	1	0.517549	-0.025	-0.4	18.518519	9.628822	0.00	3.400-7.400
Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL I	37635	8	0.56	0.53	0.1	0.138873	-0.35	0.929412	17.857143	26.452003	18.85	0.360-0.760
Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL I	83459	25	15	14.68	1.4	1.091253	-0.228571	0.069333	9.333333	7.433804	9.85	12.200-17.800
Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL II	69152	22	3.3	3.37	0.53	0.211979	0.137221	0.410172	16.060606	6.285089	9.53	2.240-4.360
Copper, Free	TEC ICP MS Dig	861 CU FREE NIST	1643E	19	2.28	2.25	0.3	0.102026	-0.108772	-0.22963	13.157895	4.53981	4.88	1.680-2.880
CU Weight	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	26	2	2.52	2	0.557706	0.259808	0.363409	100	22.134564	23.27	-2.000-6.000
CU Weight	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	26	3	2.78	1	0.753833	-0.218077	0.210455	33.333333	27.097549	18.77	1.000-5.000
FE Weight	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	26	2	2.62	2	0.636045	0.308077	0.398571	100	24.312198	28.78	-2.000-6.000
FE Weight	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	26	3	2.77	1.2	0.74372	-0.191026	0.285227	40	26.841642	24.21	0.600-5.400
Hep Copper Cont	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	26	81.5	81.38	28.2	18.042157	-0.004364	0.37637	34.601227	22.171098	22.63	25.100-137.900
Hep Copper Cont	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	26	5.6	5.77	1.7	1.552487	0.099548	1.040107	30.357143	26.909772	21.38	2.200-9.000

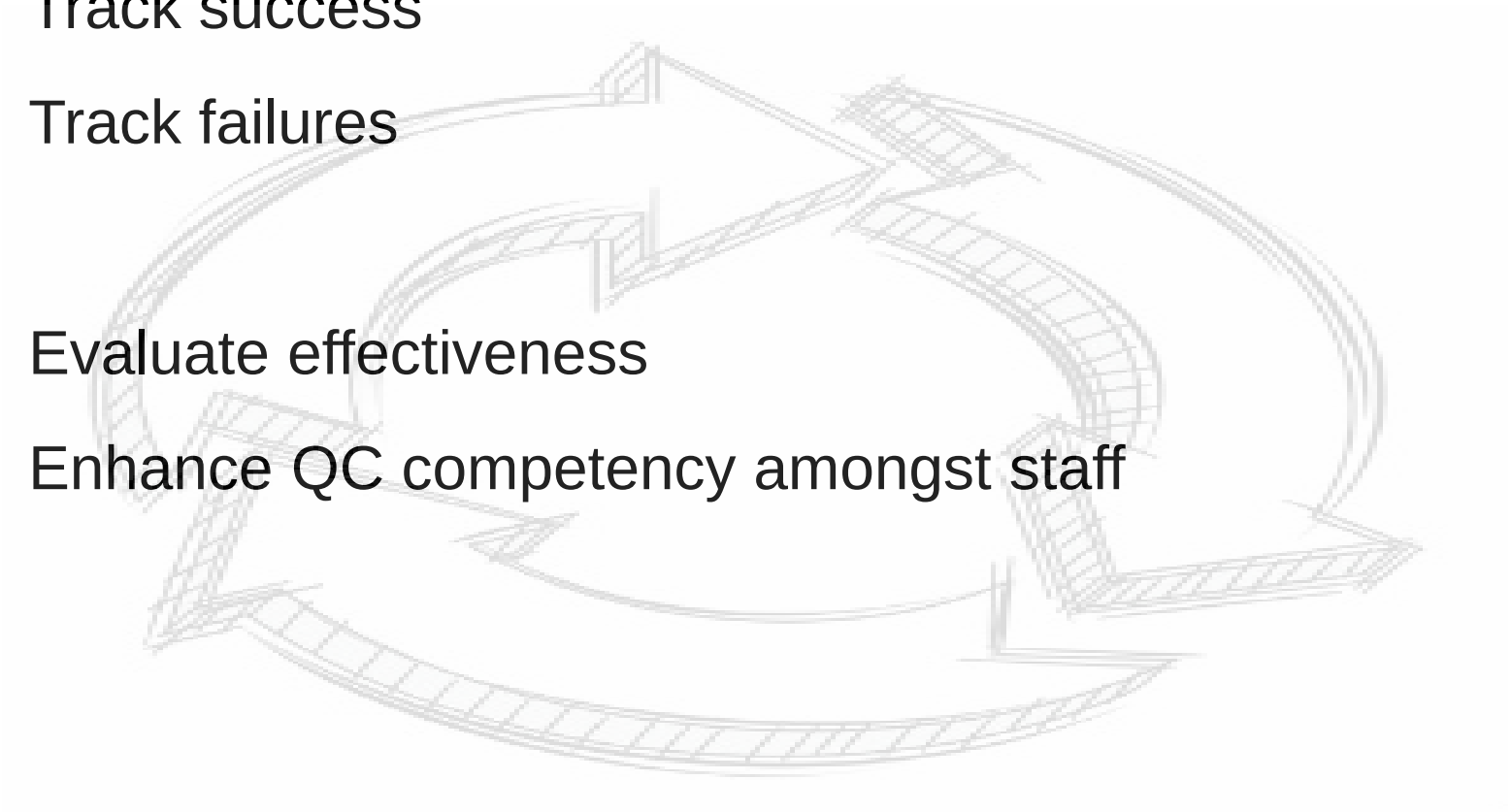




QC troubleshooting plan optimization

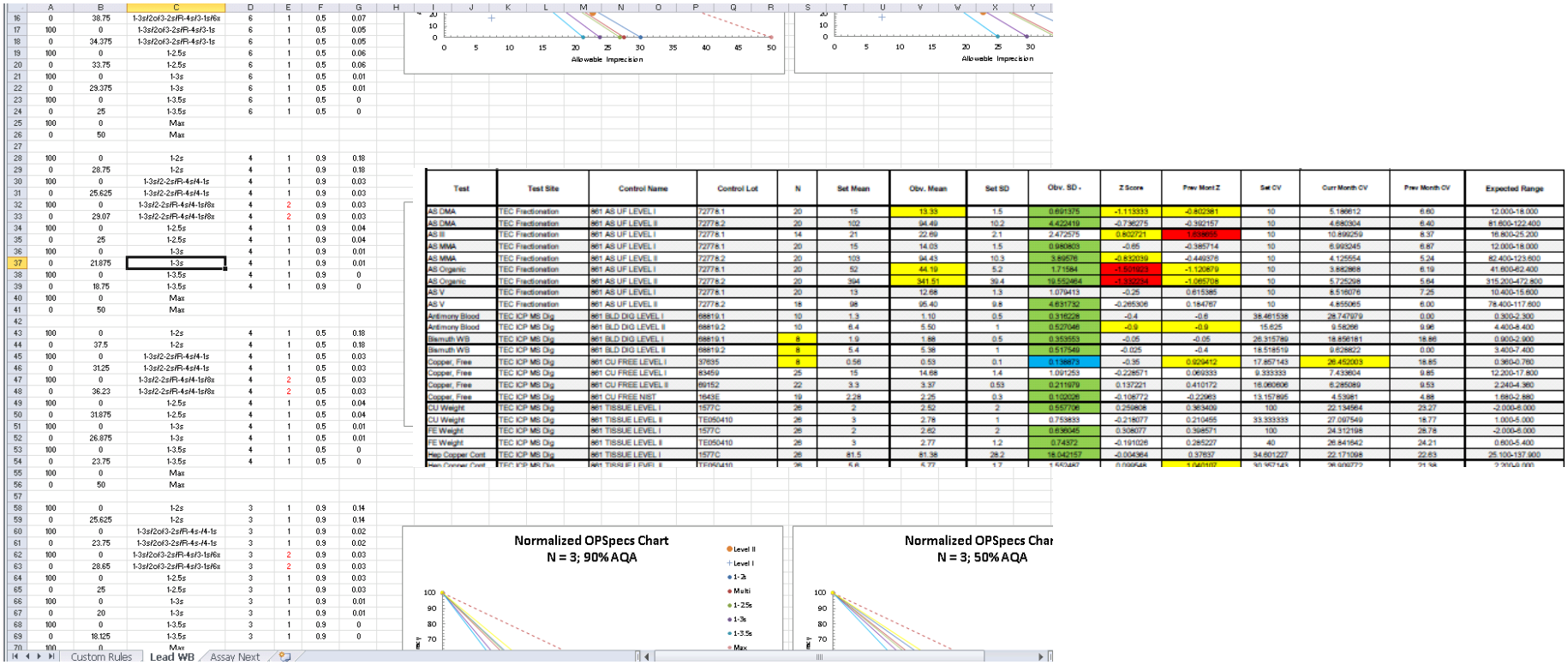
- Track success
- Track failures

- Evaluate effectiveness
- Enhance QC competency amongst staff



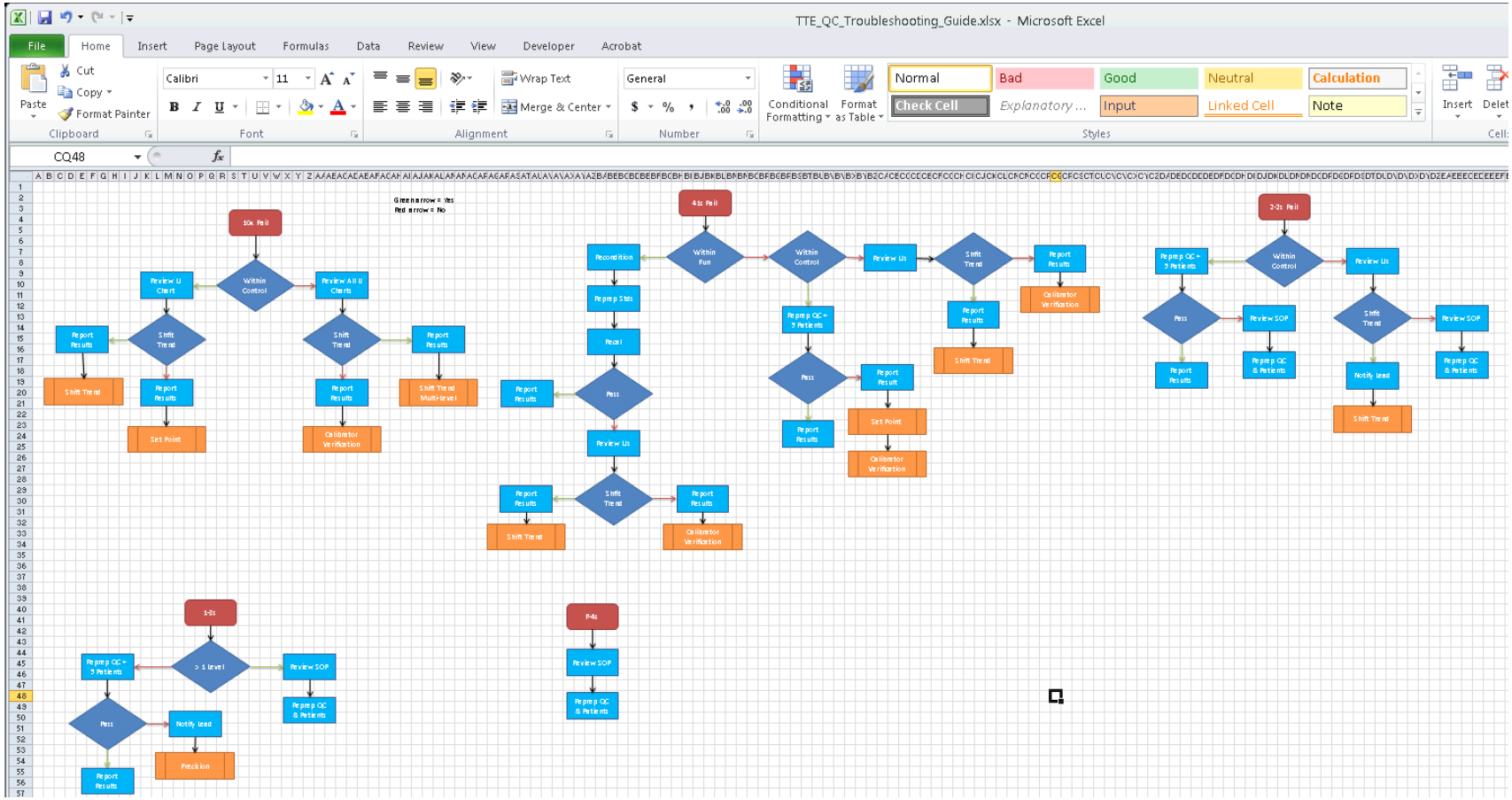
And Then it Happened

Current State Assessment Completed

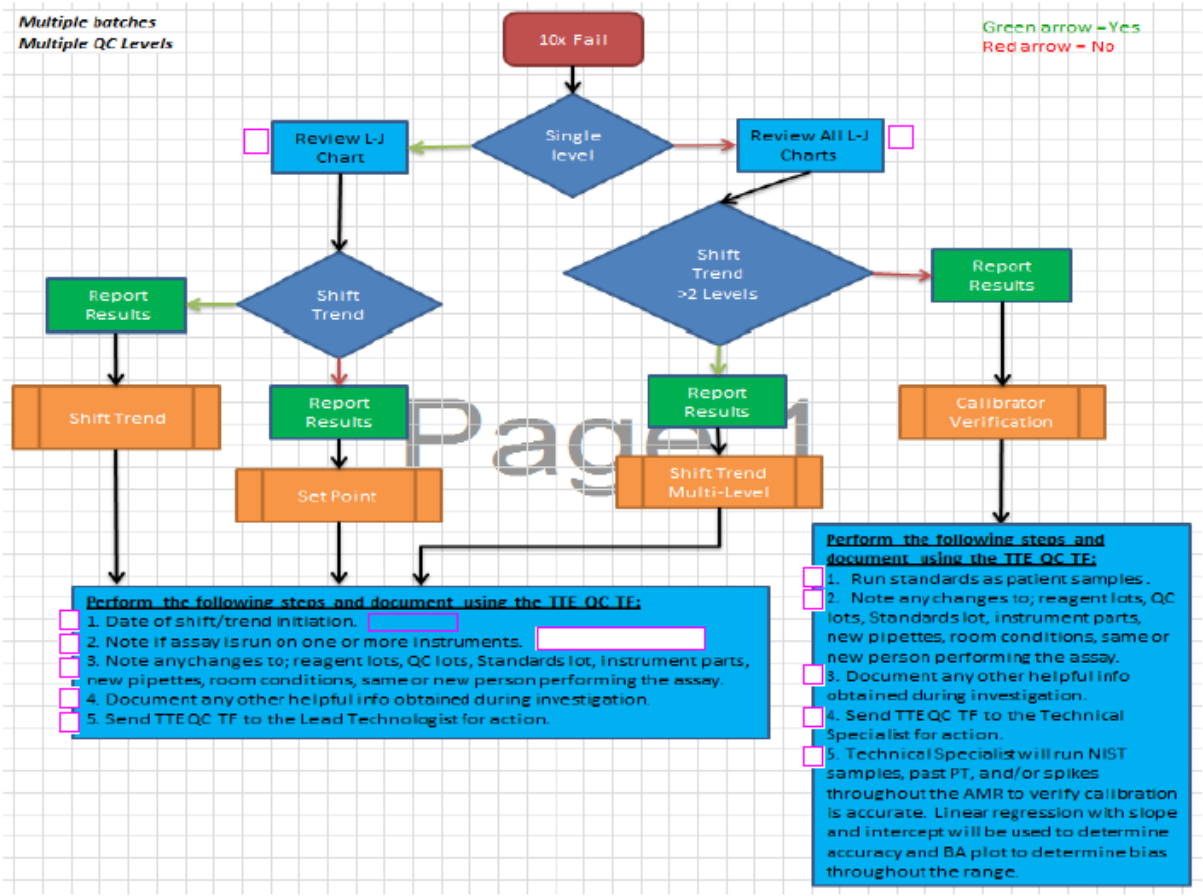


Test	Test Site	Control Name	Control Lot	N	Set Mean	Obv. Mean	Set SD	Obv. SD	Z Score	Prev Mont Z	Set CV	Curr Month CV	Prev Month CV	Expected Range
AS DMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	13.33	1.5	0.691375	-1.113333	-0.802381	10	5.186812	6.60	12.000-18.000
AS DMA	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	102	94.49	10.2	4.422419	-0.736275	-0.392157	10	4.680304	6.40	81.600-122.400
AS III	TEC Fractionation	861 AS UF LEVEL I	72778.1	14	21	22.69	2.1	2.472575	0.802721	1.838655	10	10.899259	8.37	16.800-25.200
AS MMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	14.03	1.5	0.980803	-0.65	-0.385714	10	6.993245	6.87	12.000-18.000
AS MMA	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	103	94.43	10.3	3.89576	-0.832039	-0.449376	10	4.125554	5.24	82.400-123.600
AS Organic	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	52	44.19	5.2	1.71584	-1.501923	-1.120879	10	3.882868	6.19	41.600-62.400
AS Organic	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	394	341.51	39.4	19.552464	-1.332234	-1.065706	10	5.725298	5.84	315.200-472.800
AS V	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	13	12.68	1.3	1.079413	-0.25	0.615385	10	8.516076	7.25	10.400-15.600
AS V	TEC Fractionation	861 AS UF LEVEL II	72778.2	18	98	95.40	9.8	4.631732	-0.265306	0.184767	10	4.855065	6.00	78.400-117.600
Antimony Blood	TEC ICP MS Dig	861 BLD DIG LEVEL I	68819.1	10	1.3	1.10	0.5	0.316228	-0.4	-0.6	38.461538	28.747979	0.00	0.300-2.300
Antimony Blood	TEC ICP MS Dig	861 BLD DIG LEVEL II	68819.2	10	6.4	5.50	1	0.527046	-0.9	-0.9	15.625	9.58266	9.96	4.400-8.400
Bismuth WB	TEC ICP MS Dig	861 BLD DIG LEVEL I	68819.1	8	1.9	1.88	0.5	0.353553	-0.05	-0.05	26.315789	18.856181	18.86	0.900-2.900
Bismuth WB	TEC ICP MS Dig	861 BLD DIG LEVEL II	68819.2	8	5.4	5.38	1	0.517549	-0.025	-0.4	18.518519	9.629622	0.00	3.400-7.400
Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL I	97695	8	0.56	0.53	0.1	0.138873	-0.35	0.929412	17.857143	26.450003	18.85	0.360-0.760
Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL I	83459	25	15	14.68	1.4	1.091253	-0.228571	0.069333	9.333333	7.433604	9.85	12.200-17.800
Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL II	69152	22	3.3	3.37	0.53	0.211979	0.127221	0.410172	16.060606	6.285089	9.53	2.240-4.360
Copper, Free	TEC ICP MS Dig	861 CU FREE NIST	1643E	19	2.28	2.25	0.3	0.102026	-0.108772	-0.22963	13.157895	4.53981	4.88	1.680-2.880
CU Weight	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	26	2	2.52	2	0.557706	0.259808	0.363409	100	22.134564	23.27	-2.000-6.000
CU Weight	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	26	3	2.78	1	0.753833	-0.218077	0.210455	33.333333	27.097549	18.77	1.000-5.000
FE Weight	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	26	2	2.62	2	0.636045	0.308077	0.398571	100	24.312198	28.78	-2.000-6.000
FE Weight	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	26	3	2.77	1.2	0.74372	-0.191026	0.285227	40	26.841642	24.21	0.600-5.400
Hep Copper Cont	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	26	81.5	81.38	28.2	18.042157	-0.004364	0.37637	34.601227	22.171098	22.63	25.100-137.900
Hep Copper Cont	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	26	6.6	6.77	1.7	1.540487	0.099545	1.048107	25.757576	23.178779	21.58	2.300-10.900

Troubleshooting Workflow Developed – *By Me*



Troubleshooting Tools Developed – *With Staff*



Organizational Support

- QC Subcommittee formed from LIS SuperUsers
- SOP written based upon TTE Lab process
- Presentations to Group Managers
- Presentations to Supervisors
- Workshops organized for interested labs
  - Hands on with lab data

Organizational Current State

- Five full workshops with requests for more
  - Current State Assessment: Part I and Part II
- Follow-up workshops in preparation
  - Designing a QC Troubleshooting Plan: Part I and Part II
  - Pulling the trigger on your first change: Part I
  - Follow up post go-live: Part II

Where are we now?

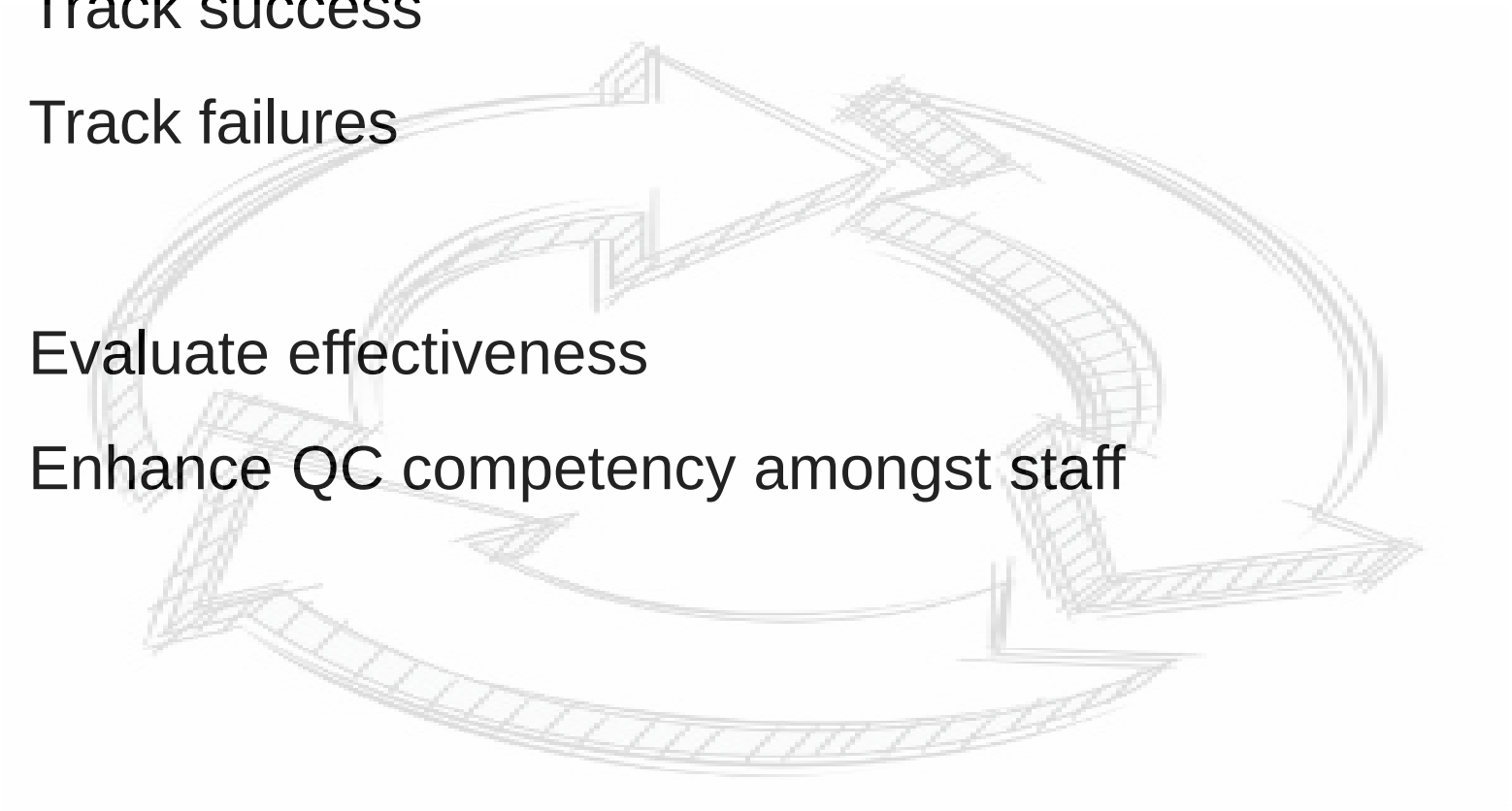
TTE Lab: Current State Assessment
1.5 yrs. post “go-live”

- External PT failures to nearly 0
  - Several assays identified for R&D rework
- Monthly QC review < 15 minutes
- Laboratory staff engaged in quality
  - Looking at LJ charts “because they’re interesting”
  - Amazing ideas about QC failures and what to do
  - Appreciation for what and why – “Patient in the tube”
- A nearly complete culture change

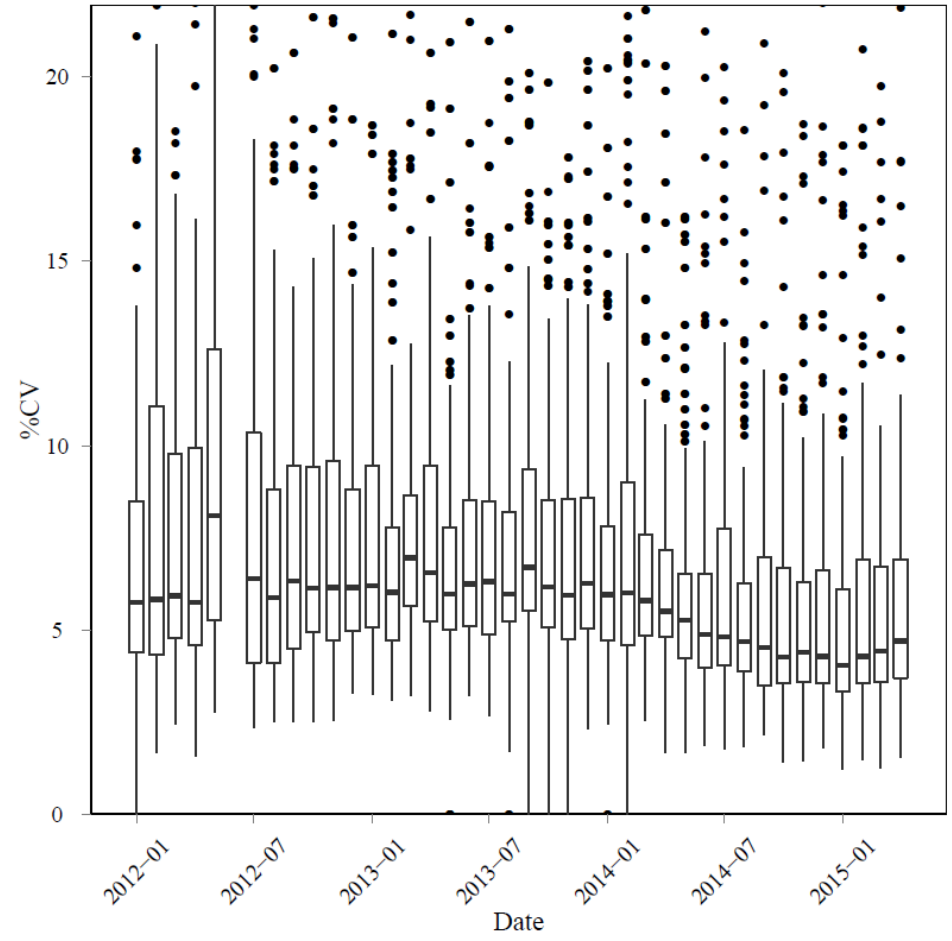
QC Strategy – Continuous Evaluation

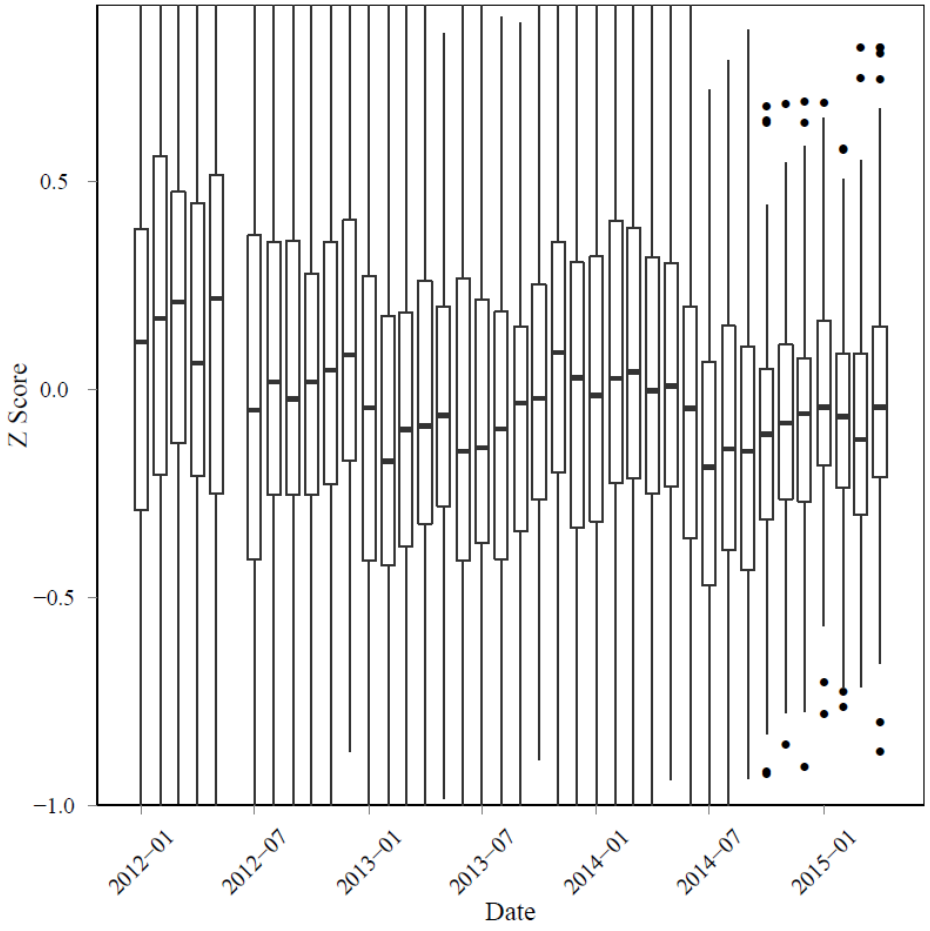
- Track success
- Track failures

- Evaluate effectiveness
- Enhance QC competency amongst staff

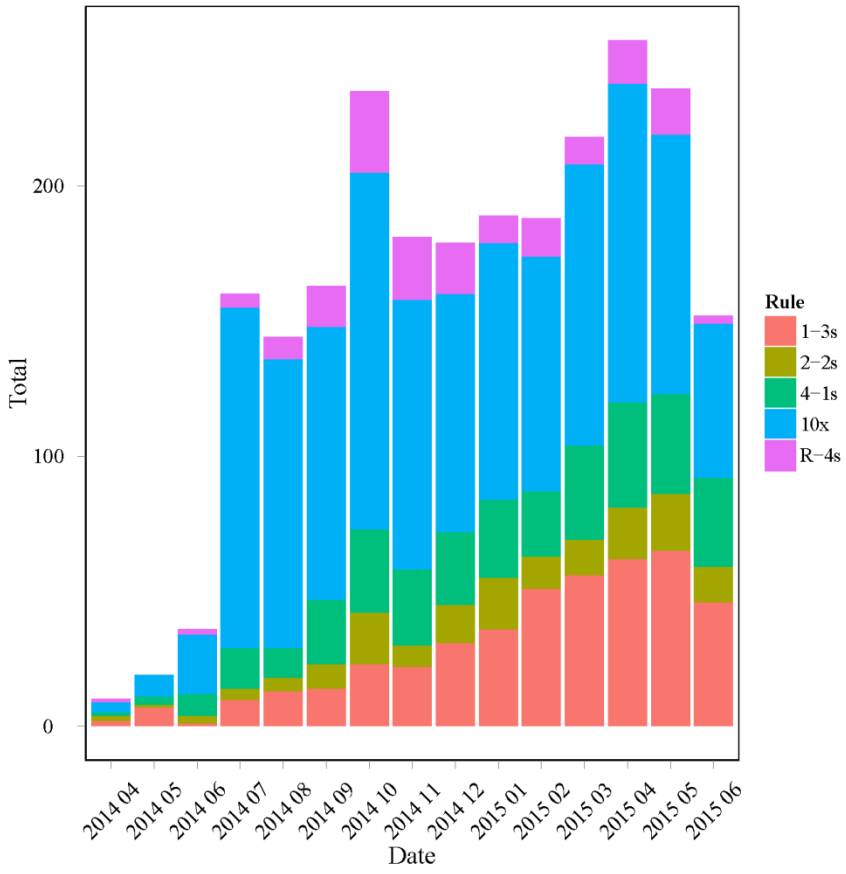


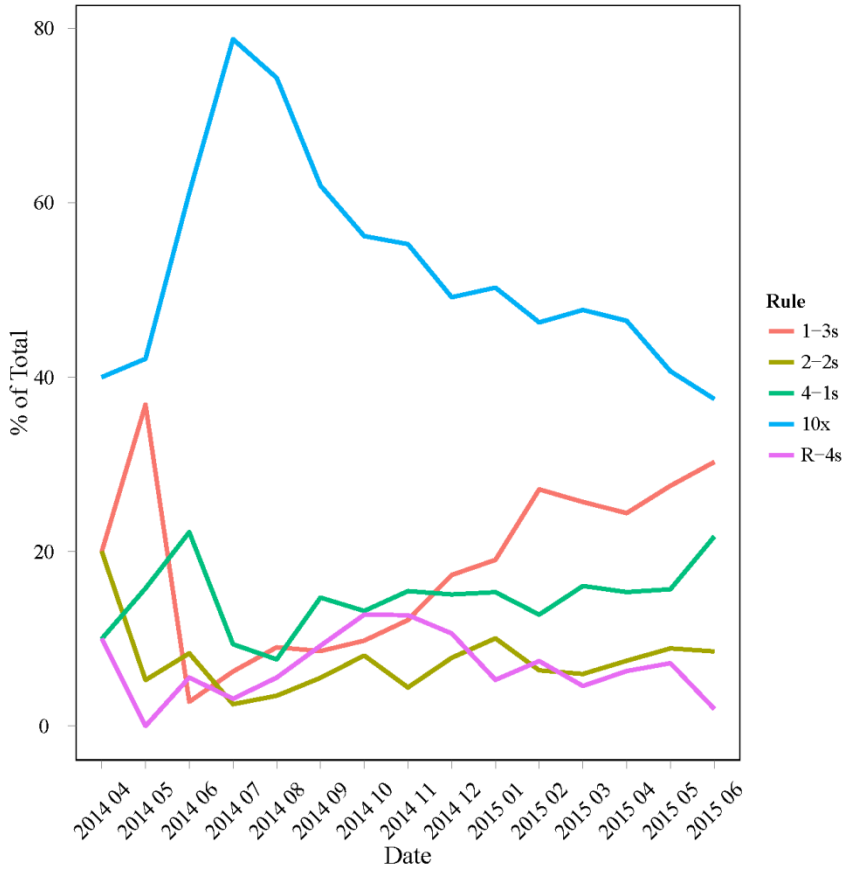
Quantifying Improvements in Quality





A Glimpse of What it Takes…





The Rewards: Then…

Test	Test Site	Control Name	Control Lot	N	Set Mean	Obv. Mean	Set SD	Obv. SD -	Z Score	Prev Mont Z	Set CV	Curr Month CV	Prev Month CV	Expected Range
AS DMA	TTE Fractionation	861 AS UF LEVEL I	72778.1	31	15	12.89	1.5	0.982267	-1.404301	-0.992308	10	7.483183	7.32	12.000-18.000
AS DMA	TTE Fractionation	861 AS UF LEVEL II	72778.2	31	102	93.12	10.2	7.021211	-0.870998	-0.279412	10	7.540273	7.62	81.600-122.400
AS III	TTE Fractionation	861 AS UF LEVEL I	72778.1	30	21	22.50	2.1	1.529364	0.712698	0.507326	10	6.79818	9.81	16.800-25.200
AS MMA	TTE Fractionation	861 AS UF LEVEL I	72778.1	30	15	14.15	1.5	1.569043	-0.566667	-0.425641	10	11.088644	9.10	12.000-18.000
AS MMA	TTE Fractionation	861 AS UF LEVEL II	72778.2	31	103	94.85	10.3	4.212115	-0.791106	-0.444984	10	4.440742	6.40	82.400-123.600
AS Organic	TTE Fractionation	861 AS UF LEVEL I	72778.1	31	52	44.54	5.2	1.974466	-1.434243	-1.26997	10	4.432825	4.10	41.600-62.400
AS Organic	TTE Fractionation	861 AS UF LEVEL II	72778.2	31	394	339.18	39.4	12.381584	-1.391354	-1.096658	10	3.650439	5.13	315.200-472.800
AS V	TTE Fractionation	861 AS UF LEVEL I	72778.1	31	13	13.01	1.3	1.113176	0.009926	0.328402	10	8.554403	7.95	10.400-15.600
AS V	TTE Fractionation	861 AS UF LEVEL II	72778.2	31	98	92.32	9.8	5.684077	-0.579987	-0.040816	10	6.157187	5.42	78.400-117.600
Copper, Free	TTE ICP MS Dig	861 CU FREE LEVEL I	83459	24	15	16.09	1.4	1.088844	0.779762	0.190476	9.333333	6.765283	10.31	12.200-17.800
Copper, Free	TTE ICP MS Dig	861 CU FREE LEVEL II	89152	22	3.3	3.71	0.53	0.165929	0.77187	0.098832	16.060606	4.473579	13.39	2.240-4.360
Copper, Free	TTE ICP MS Dig	861 CU FREE NIST	1643E	22	2.28	2.25	0.3	0.074001	-0.1	-0.382609	13.157895	3.288046	4.94	1.680-2.880
CU Weight	TTE ICP MS Dig	861 TISSUE LEVEL I	1577C	22	2	2.69	2	0.698546	0.344773	0.288591	100	25.97264	25.96	-2.000-6.000
CU Weight	TTE ICP MS Dig	861 TISSUE LEVEL II	TE050410	22	3	3.00	1	0.570284	0.003936	-0.295714	33.333333	18.986485	16.99	1.000-5.000
FE Weight	TTE ICP MS Dig	861 TISSUE LEVEL I	1577C	22	2	2.54	2	0.629929	0.271136	0.292308	100	24.73885	23.75	-2.000-6.000
FE Weight	TTE ICP MS Dig	861 TISSUE LEVEL II	TE050410	22	3	2.82	1.2	0.671116	-0.151515	-0.327885	40	23.81379	18.72	0.600-5.400
Hep Copper Cont	TTE ICP MS Dig	861 TISSUE LEVEL I	1577C	22	81.5	94.73	28.2	25.790186	0.469213	0.067859	34.601227	27.224418	23.98	25.100-137.900
Hep Copper Cont	TTE ICP MS Dig	861 TISSUE LEVEL II	TE050410	22	5.6	7.12	1.7	1.300158	0.895722	0.2493	30.357143	18.253656	19.77	2.200-9.000
Hep Fe Content	TTE ICP MS Dig	861 TISSUE LEVEL I	1577C	22	11.6	11.54	5	2.083417	-0.011818	0.019231	43.103448	18.052454	22.93	1.600-21.600
Hep Fe Content	TTE ICP MS Dig	861 TISSUE LEVEL II	TE050410	22	93	83.48	35	24.69326	-0.272078	-0.622088	37.634409	29.580818	24.03	23.000-163.000
QC Cu Liver	TTE ICP MS Dig	861 TISSUE LEVEL I	1577C	22	317	351.51	31.8	17.058591	1.092204	0.282952	9.968454	4.852896	5.06	253.800-380.200
QC Cu Liver	TTE ICP MS Dig	861 TISSUE LEVEL II	TE050410	22	19	23.74	3	1.120229	1.580303	1.080952	15.789474	4.718561	8.70	13.000-25.000
QC Fe Liver	TTE ICP MS Dig	861 TISSUE LEVEL I	1577C	22	226.3	232.18	42.4	34.049515	0.138615	-0.077925	18.736191	14.665309	12.71	141.500-311.100
QC Fe Liver	TTE ICP MS Dig	861 TISSUE LEVEL II	TE050410	22	1536	1470.20	250	129.118834	-0.2632	-0.695138	16.276042	8.782399	11.76	1036.000-2036.000
Aluminum, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	59409.1	35	5.9	5.71	2.5	2.395724	-0.074286	0.875294	42.372881	41.925178	46.48	0.900-10.900
Aluminum, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	59409.2	34	19.9	18.71	2.5	2.634811	-0.477647	-0.101935	12.562814	14.0844	11.04	14.900-24.900
Aluminum, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	59409.3	34	40.3	38.18	4	3.72925	-0.530882	-0.408333	9.925558	9.788452	9.71	32.300-48.300
Aluminum, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	59409.4	25	110	104.12	11	6.716398	-0.534545	-0.229249	10	6.450832	9.15	88.000-132.000
Chromium, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	59409.1	30	3	3.06	0.8	0.407417	0.070833	0.407258	26.666667	13.328796	19.14	1.400-4.600
Chromium, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	59409.2	33	9.6	9.78	1	0.820869	0.184848	0.348429	10.416667	8.389184	8.41	7.600-11.600
Chromium, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	59409.3	28	17.3	17.37	1.5	1.218942	0.047619	0.095238	8.67052	7.016937	6.16	14.300-20.300
Chromium, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	59409.4	27	30.2	29.94	2.6	1.934136	-0.10114	0.254808	8.609272	6.46068	6.92	25.000-35.400
Cobalt, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	59409.1	185	0.7	0.37	0.3	0.226314	-1.107071	-1.165692	42.857143	61.518637	84.53	0.100-1.300
Cobalt, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	59409.2	152	4.3	4.15	0.5	0.362656	-0.296053	-0.262745	11.627907	8.734541	8.11	3.300-5.300
Cobalt, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	59409.3	138	13.9	13.77	1.4	0.908864	-0.095238	0.016097	10.071942	6.601919	7.82	11.100-16.700
Cobalt, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	59409.4	103	26.6	26.55	2.6	1.83024	-0.019417	0.144444	9.774436	6.803686	7.41	21.400-31.800
Copper, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	59409.1	181	68.1	72.98	5.1	3.975585	0.957534	0.705987	7.488987	5.447244	5.54	57.900-78.300
Copper, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	59409.2	169	138.2	143.91	10.4	8.912952	0.549158	0.531627	7.525326	5.776444	5.39	117.400-159.000
Copper, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	59409.3	151	190.6	198.26	14.3	10.379765	0.535544	0.345881	7.502623	5.235476	4.99	162.000-219.200
Copper, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	59409.4	107	332.1	345.17	24.9	19.601447	0.524828	0.381857	7.497742	5.67881	5.19	282.300-381.900

The Rewards: …Now

Test	Test Site	Control Name	Control Lot	N	Set Mean	Obv. Mean	Set SD	Obv. SD	Z Score	Prev Month Z	Set CV	CV	Prev Month CV	Expected Range	
QC MG RBC RPT	TTE Misc Bench	861 MG RBC RPT	D5082010	55.0	1.9	1.9	0.2	0.1	-0.3	-0.1	10.3	5.4	6.6	1.540-2.340	
QC MG RBC RPT	TTE Misc Bench	861 MG RBC RPT	D5082010	60.0	1.9	1.9	0.2	0.1	-0.1	-0.1	10.3	6.5	6.6	1.540-2.340	
Nickel, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	1008031	20.0	1.9	1.9	0.4	0.4	-0.1	-0.3	20.8	23.3	24.8	1.120-2.720	
Mang, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	1008031	27.0	1.0	0.9	0.1	0.1	-0.3	-0.6	10.3	11.7	7.7	0.770-1.170	
IODINE_SER	TTE ICP MS Ser	861 SERUM LEVEL I	1008031	27.0	44.6	44.9	1.7	1.4	0.2	0.0	3.7	3.2	3.2	41.280-47.960	
Chromium, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	1008031	44.0	1.3	1.2	0.3	0.2	-0.2	-0.1	23.3	17.9	14.3	0.690-1.890	
Aluminum, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	1008031	44.0	4.0	3.3	2.0	1.6	-0.3	-0.3	49.5	49.0	44.7	0.040-8.040	
Selenium, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	1008031	60.0	13.2	13.1	1.1	0.8	-0.1	0.0	8.5	6.5	7.9	10.990-15.470	
Cobalt, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	1008031	137.0	1.3	1.3	0.1	0.1	0.0	-0.3	9.2	6.5	6.8	1.070-1.550	
Zinc, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	1008031	140.0	14.6	14.7	1.5	1.1	0.1	0.0	10.2	7.4	8.1	11.610-17.570	
Copper, Serum	TTE ICP MS Ser	861 SERUM LEVEL I	1008031	141.0	12.4	12.4	0.7	0.5	0.0	-0.3	5.4	4.0	4.2	11.090-13.770	
Nickel, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	1008032	20.0	5.2	5.0	0.5	0.5	-0.3	-0.2	9.7	10.8	8.8	4.180-6.180	
IODINE_SER	TTE ICP MS Ser	861 SERUM LEVEL II	1008032	27.0	273.1	276.4	11.3	9.5	0.3	0.1	4.1	3.5	3.0	250.530-295.730	
Mang, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	1008032	29.0	6.9	6.9	0.4	0.4	-0.1	0.1	5.8	6.4	4.9	6.150-7.750	
Aluminum, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	1008032	42.0	26.7	26.3	3.1	2.6	-0.1	-0.1	11.6	10.2	9.5	20.470-32.870	
Chromium, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	1008032	47.0	2.7	2.8	0.5	0.3	0.1	0.2	18.5	10.6	7.7	1.710-3.710	
Selenium, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	1008032	67.0	222.9	221.4	10.9	8.9	-0.1	-0.1	4.9	4.0	5.0	201.110-244.710	
Cobalt, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	1008032	143.0	13.9	13.9	0.6	0.5	0.0	-0.3	4.7	3.5	3.9	12.610-15.210	
Copper, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	1008032	157.0	114.6	114.9	4.6	4.2	0.1	-0.2	4.0	3.6	3.1	105.320-123.840	
Zinc, Serum	TTE ICP MS Ser	861 SERUM LEVEL II	1008032	160.0	116.9	117.3	5.8	4.6	0.1	-0.2	4.9	3.9	4.0	105.410-128.450	
Nickel, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	1008033	16.0	10.4	10.6	0.6	0.7	0.2	-0.3	5.8	6.8	5.8	9.210-11.610	
IODINE_SER	TTE ICP MS Ser	861 SERUM LEVEL III	1008033	28.0	534.8	542.9	19.7	16.7	0.4	0.1	3.7	3.1	2.4	495.400-574.240	
Mang, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	1008033	29.0	13.6	13.5	0.7	0.6	0.0	0.2	5.2	5.7	3.9	12.150-14.950	
Aluminum, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	1008033	41.0	54.8	53.5	5.9	3.5	-0.2	0.1	10.8	6.6	6.6	42.960-66.560	
Chromium, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	1008033	50.0	5.7	5.7	0.5	0.3	-0.1	0.2	8.7	5.1	5.7	4.720-6.720	
Selenium, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	1008033	66.0	449.0	443.8	23.1	22.4	-0.2	0.0	5.2	5.1	4.6	402.730-495.290	
Cobalt, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	1008033	148.0	27.8	27.6	1.3	1.0	-0.2	-0.2	4.7	3.6	4.0	25.180-30.420	
Copper, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	1008033	154.0	228.0	227.4	9.5	8.1	-0.1	-0.1	4.2	3.6	3.4	208.930-247.010	
Zinc, Serum	TTE ICP MS Ser	861 SERUM LEVEL III	1008033	163.0	231.8	230.4	11.2	8.9	-0.1	-0.1	4.8	3.9	4.2	209.400-254.120	
Nickel, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	1008034	20.0	15.9	15.8	0.8	0.8	-0.1	-0.3	5.0	5.4	4.7	14.340-17.540	
Mang, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	1008034	25.0	20.3	20.3	0.8	1.0	0.0	-0.2	3.9	4.9	3.5	18.660-21.860	
IODINE_SER	TTE ICP MS Ser	861 SERUM LEVEL IV	1008034	27.0	819.0	826.0	29.6	28.7	0.2	0.1	3.6	3.5	2.2	759.830-878.230	
Aluminum, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	1008034	41.0	82.3	81.1	9.3	8.3	-0.1	-0.2	11.3	7.9	6.0	63.650-100.950	
Chromium, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	1008034	58.0	8.1	8.1	0.6	0.4	0.0	0.2	7.4	5.2	5.3	6.920-9.320	
Selenium, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	1008034	61.0	635.3	636.1	29.4	26.3	0.0	-0.3	4.6	4.2	4.0	576.510-694.030	
Cobalt, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	1008034	127.0	39.4	39.6	1.7	1.4	0.1	-0.3	4.4	3.5	3.9	35.940-42.900	
Copper, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	1008034	134.0	324.2	325.7	12.7	11.1	0.1	-0.3	3.9	3.4	3.7	298.880-349.520	
Zinc, Serum	TTE ICP MS Ser	861 SERUM LEVEL IV	1008034	138.0	330.3	330.6	15.4	11.7	0.0	-0.2	4.7	3.6	4.4	299.410-361.210	
AS DMA	TTE Fractionation	861 AS UF LEVEL II	102334	19.0	96.7	98.6	4.4	3.5	0.4	0.2	4.6	3.7	5.1	87.770-105.570	New column 1/11/2015
AS MMA	TTE Fractionation	861 AS UF LEVEL II	102334	20.0	13.0	12.2	1.2	1.0	-0.7	-1.3	9.0	8.8	6.6	10.630-15.310	New column 1/11/2015
AS DMA	TTE Fractionation	861 AS UF LEVEL I	102334	20.0	13.2	13.3	0.7	0.7	0.1	-0.1	5.3	5.7	4.7	11.820-14.620	New column 1/11/2015
AS V	TTE Fractionation	861 AS UF LEVEL II	102334	20.0	93.1	94.2	4.2	4.1	0.3	0.1	4.5	4.5	4.1	84.670-101.510	New column 1/11/2015
AS V	TTE Fractionation	861 AS UF LEVEL I	102334	21.0	12.4	12.0	0.9	0.8	-0.5	0.0	6.8	6.8	7.0	10.710-14.110	New column 1/11/2015
AS Organic	TTE Fractionation	861 AS UF LEVEL I	102334	21.0	36.2	36.3	1.7	1.5	0.0	0.2	4.8	4.3	3.6	32.750-39.710	New column 1/11/2015
AS MMA	TTE Fractionation	861 AS UF LEVEL II	102334	21.0	93.0	95.4	4.5	3.7	0.5	-0.2	4.8	4.0	3.4	84.100-101.980	New column 1/11/2015
AS Organic	TTE Fractionation	861 AS UF LEVEL II	102334	21.0	316.0	316.8	15.1	12.1	0.1	0.5	4.8	3.9	4.0	285.890-346.170	New column 1/11/2015
AS III	TTE Fractionation	861 AS UF LEVEL I	102334	22.0	22.0	23.5	2.2	2.0	0.7	0.3	10.0	8.7	8.2	17.630-26.390	New column 1/11/2015
Arsenic Blood	TTE ICP MS WB	861 As Blood Conf I	1150281	34.0	11.8	11.6	0.6	0.5	-0.4	-0.5	5.3	4.3	5.1	10.540-13.020	Range Adjusted 1/5/2015
Arsenic Blood	TTE ICP MS WB	861 As Blood Conf II	1150282	34.0	73.8	74.7	2.5	2.3	0.3	-0.2	3.4	3.1	2.4	68.830-78.830	Range Adjusted 1/5/2015
Arsenic Blood	TTE ICP MS WB	861 As Blood Conf 3	1150283	33.0	151.8	153.9	4.6	4.1	0.4	-0.2	3.0	2.7	3.1	142.560-161.000	Range Adjusted 1/5/2015
Arsenic Blood	TTE ICP MS WB	861 As Blood Conf 4	1150284	34.0	209.5	214.0	7.7	6.4	0.6	-0.1	3.7	3.0	3.2	194.130-224.850	Range Adjusted 1/5/2015
Iodine, U	TTE ICP MS Um	861 IODINE URINE I	1189871	26.0	51.4	50.8	1.5	1.4	-0.4	-0.2	3.0	2.7	1.9	48.260-54.460	
Iodine, U	TTE ICP MS Um	861 IODINE URINE II	1189872	27.0	291.8	290.3	6.9	5.6	-0.2	0.0	2.4	2.0	1.5	278.050-305.570	
Iodine, U	TTE ICP MS Um	861 IODINE URINE III	1189873	29.0	594.1	592.6	14.3	11.2	-0.1	-0.1	2.4	1.9	1.6	565.500-622.700	

What I learned from all of this.

- It is not enough to state the obvious.
- It is not enough to provide tools for change.
- Even though staff “should know this stuff” they don’t always know how to apply it.
- Someone has to drive – preferably someone with a backbone.
- Everyone has to be involved somehow.
- Never give up – Never surrender

Roadblocks to Quality

- Roadblocks to Quality
  1. Lab culture & bench disconnect
  2. One-size-fits-all QC rules
  3. Unclear troubleshooting processes
  4. Lack of QC life-cycle and metrics to track improvements

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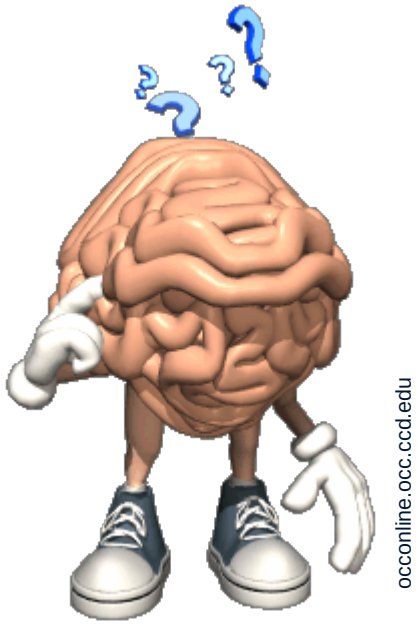

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