Assessing the Quality of Your Lab's Test Results:

What We Learned at ARUP and How We Changed the Culture to Pursue Highest Quality

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Lab Quality Confab; October 21, 2014; New Orleans, LA

Learning Objectives

- Identify common quality problems in the clinical laboratory
- Apply available strategies to obtain a current state assessment of laboratory quality
- Implement key milestones to keep quality improvement moving forward
- Identify roadblocks to achieving highest quality

Speaker Financial Disclosure Information

- Grant/Research Support: **None**
- Salary/Consultant Fees: **None**
- Board/Committee/Advisory Board Membership: **None**
- Stocks/Bonds: **None**
- Honorarium/Expenses: **None**
- Intellectual Property/Royalty Income: **None**

The Illusion of 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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Quality Control: Getting back to basics

Frederick G Strathmann, PhD, DABCC (CC, TC)

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?

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

QC Strategy

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

October, 2012

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 in Master Control

Modify rules to ensure appropriate balance of control

Not too much, not too little

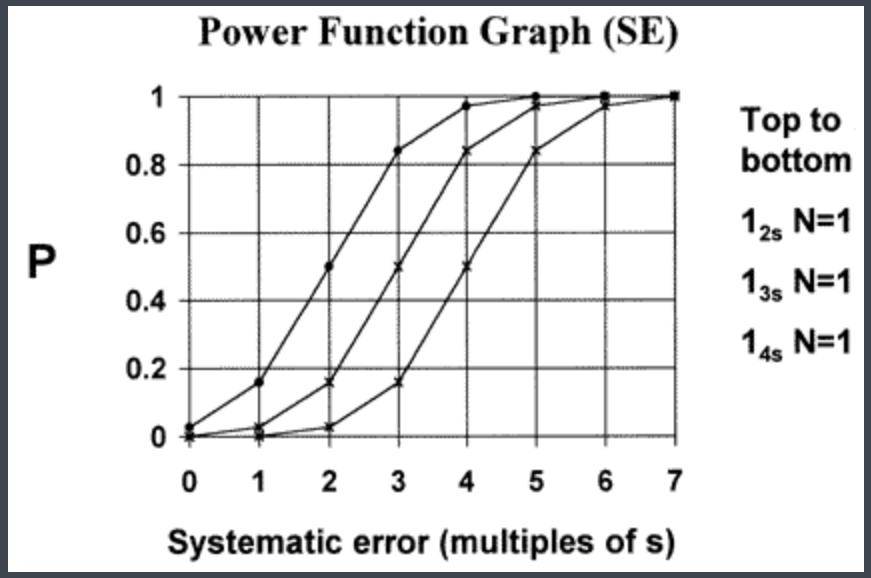
Adhere to good QC practice at all times

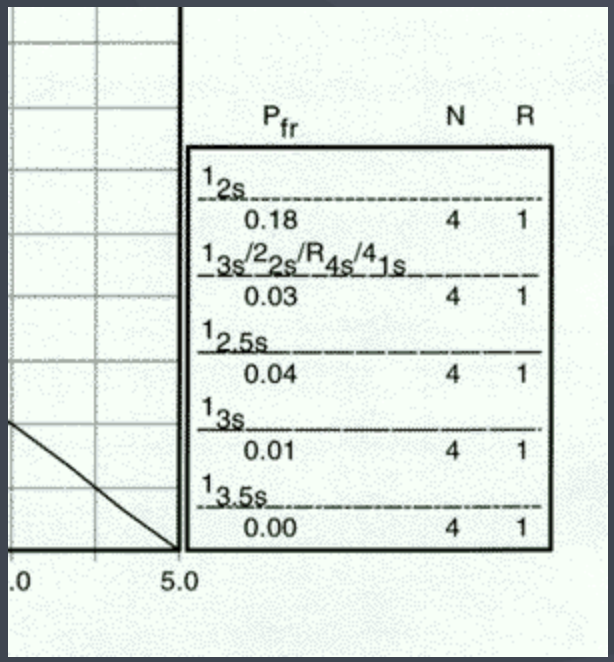
QC prepped with patient samples

No repeating of “out” QC

Root cause of failed QC

Rule performance





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- Read probability for error detection (P_{ed}) at point on power curve corresponding to critical-sized error
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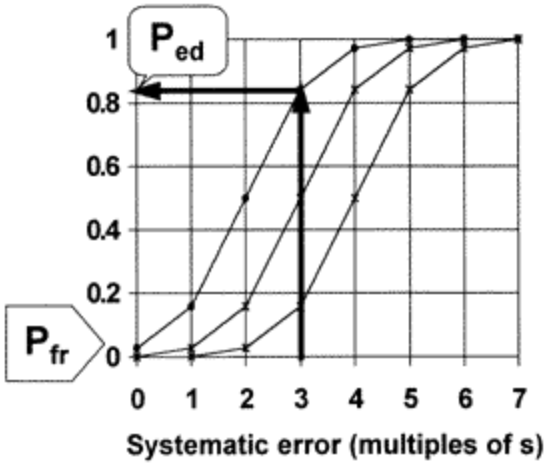


QC Goals

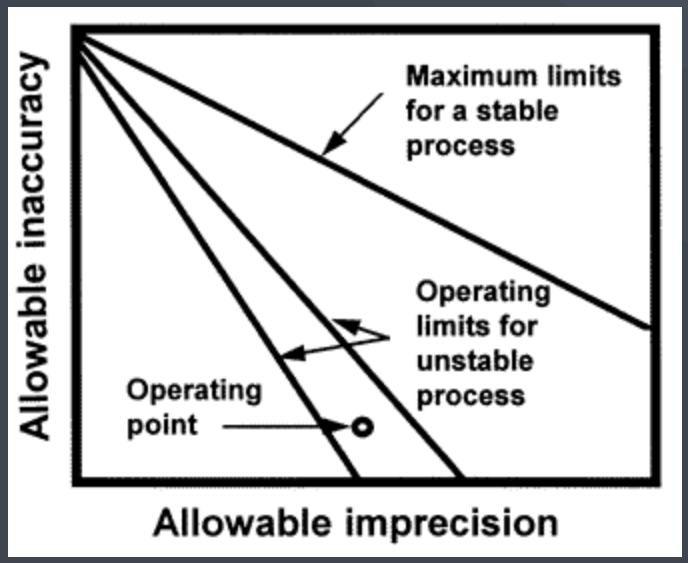
Total allowable error

Medical decision limits

Assay bias

Assay precision

Operational Process Specifications Chart



Example 1: Lead, WB

TEa = 10%

N = 4

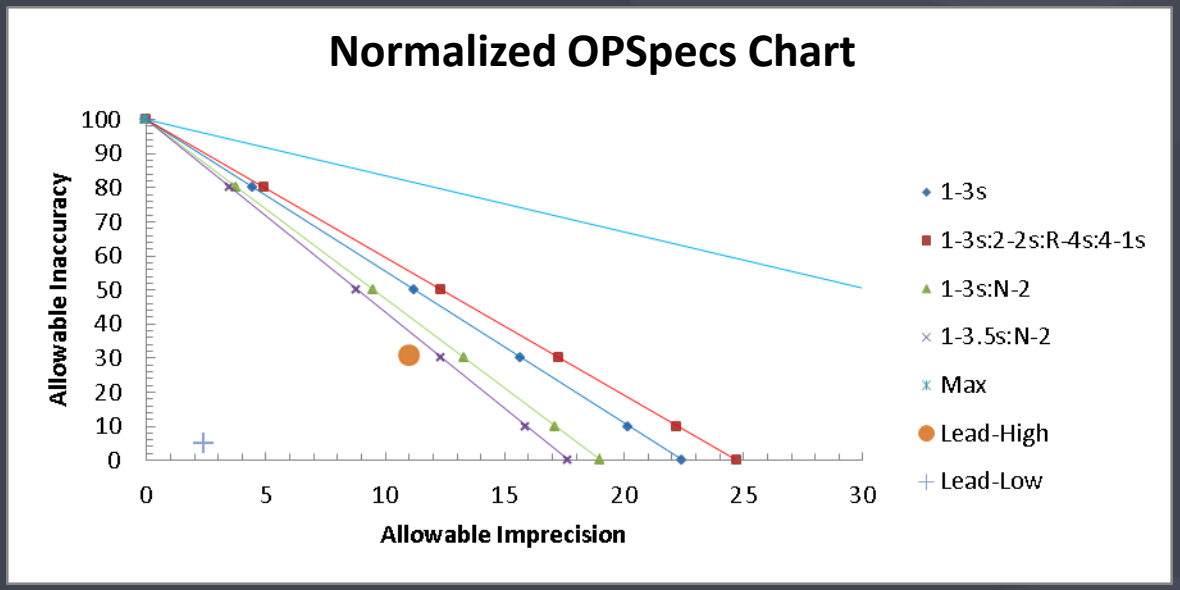
1-3s: 0.01 P_{fr} 90% P_{ed}

1-3s+: 0.03 P_{fr} 90% P_{ed}

N = 2

1-3s: 0.00 P_{fr} 90% P_{ed}

1-3.5s: 0.00 P_{fr} 90% P_{ed}



Example 2: Aluminum, U

TEa = 20%

N = 4

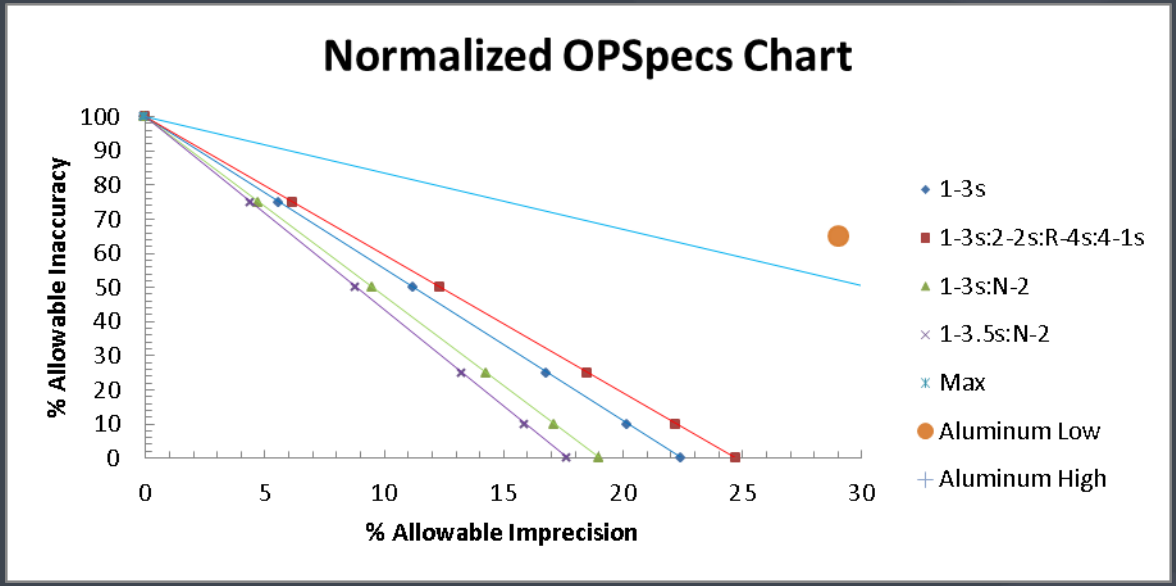
1-3s: 0.01 P_{fr} 90% P_{ed}

1-3s+: 0.03 P_{fr} 90% P_{ed}

N = 2

1-3s: 0.00 P_{fr} 90% P_{ed}

1-3.5s: 0.00 P_{fr} 90% P_{ed}



Example 2: Aluminum, U cont.

TEa = 50%

N = 4

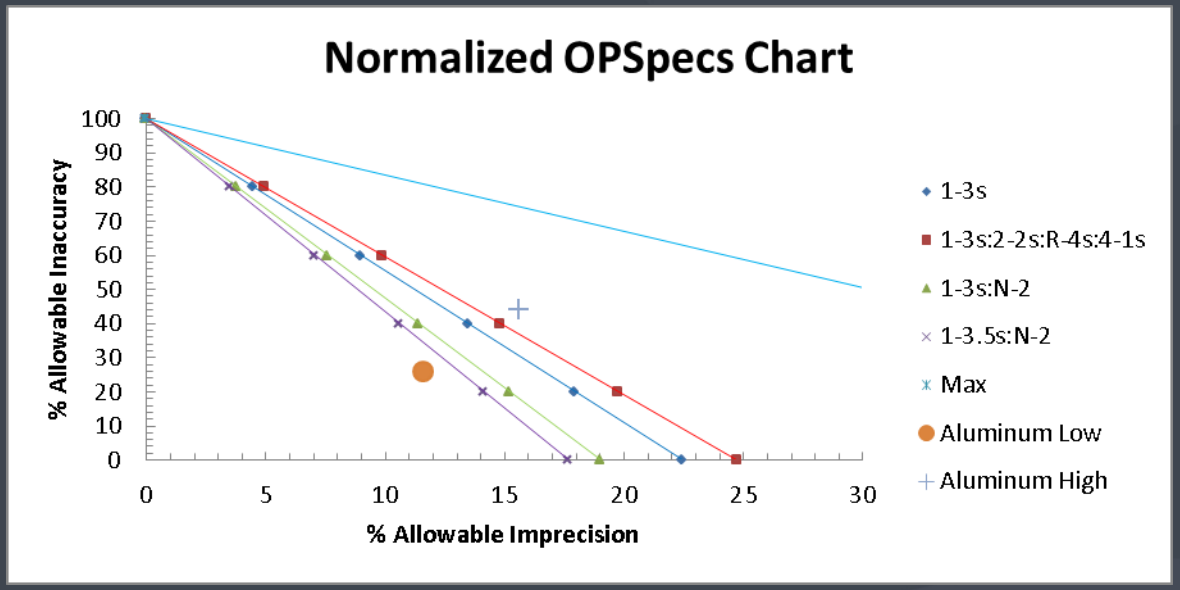
1-3s: 0.01 P_{fr} 90% P_{ed}

1-3s+: 0.03 P_{fr} 90% P_{ed}

N = 2

1-3s: 0.00 P_{fr} 90% P_{ed}

1-3.5s: 0.00 P_{fr} 90% P_{ed}



What's next?

Deeper analysis for all analytes in the lab

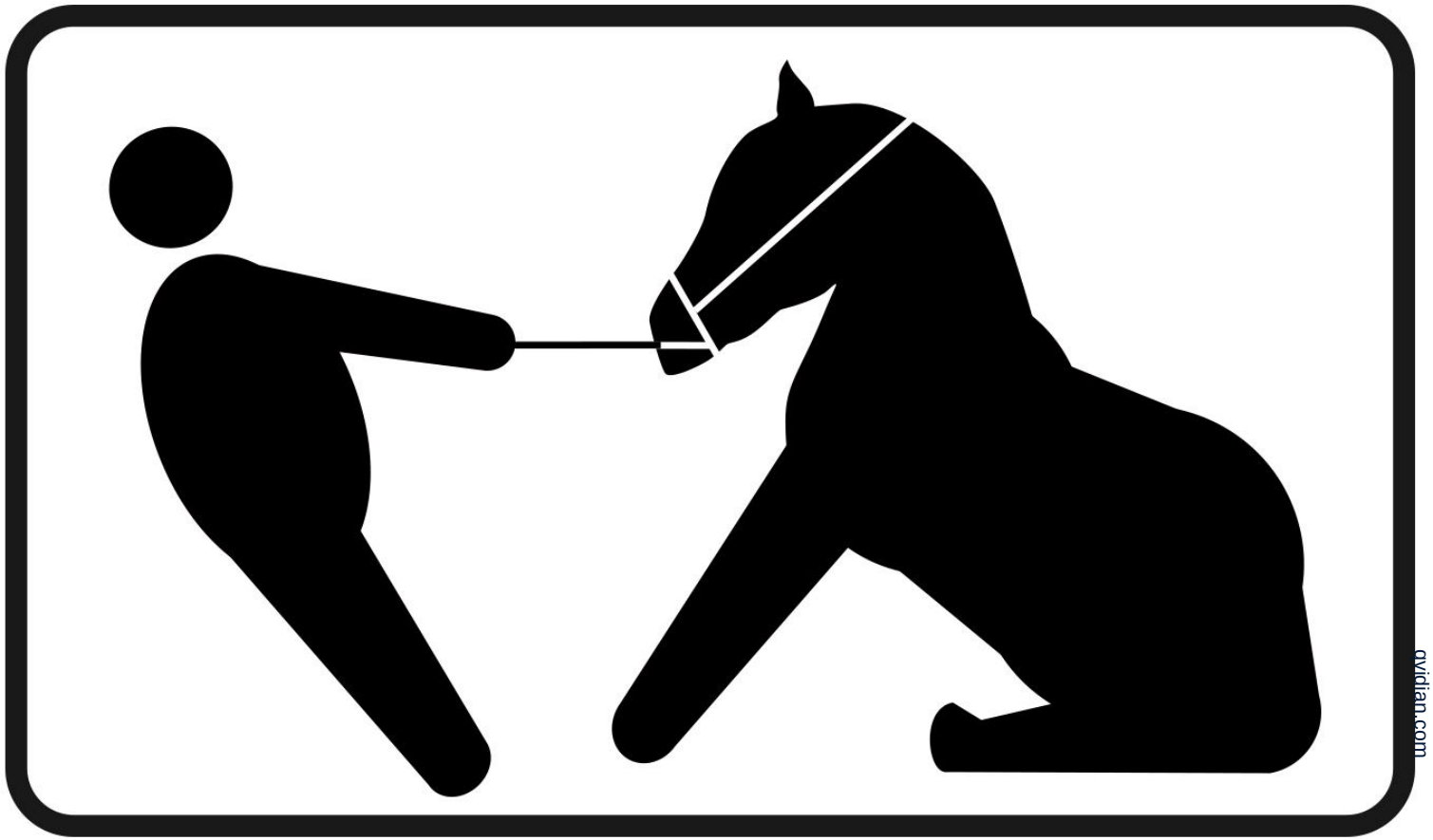
Standardization of comments and troubleshooting steps

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 understand how to change.
- Lots of *MY* ideas, lots of *MY* enthusiasm, no *STAFF* buy-in.

Round 2

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The Beginning of Buy-in

- A few more failed PTs
- A supervisor and a lead forced 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

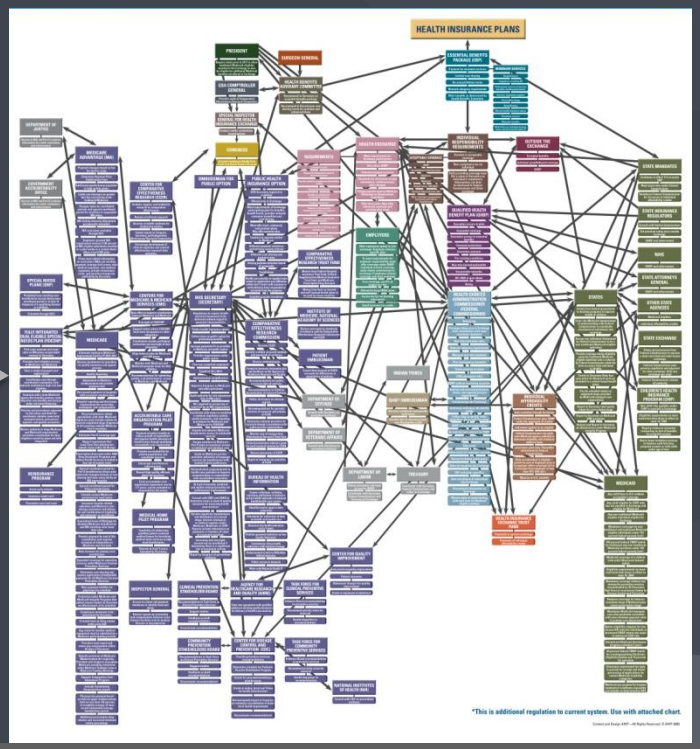
ARUP Nuts and Bolts Series

October 15, 2013

Common Mistake #1

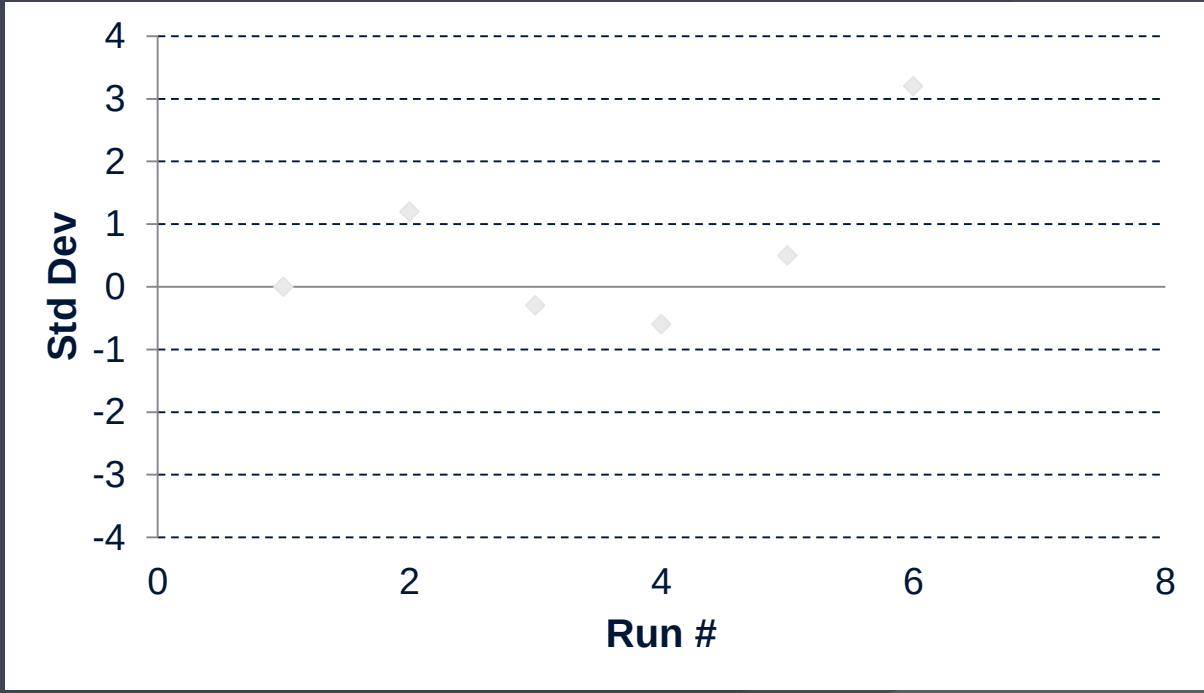
- Using a trigger with computer-based QC

> 2sd
> 2.5sd



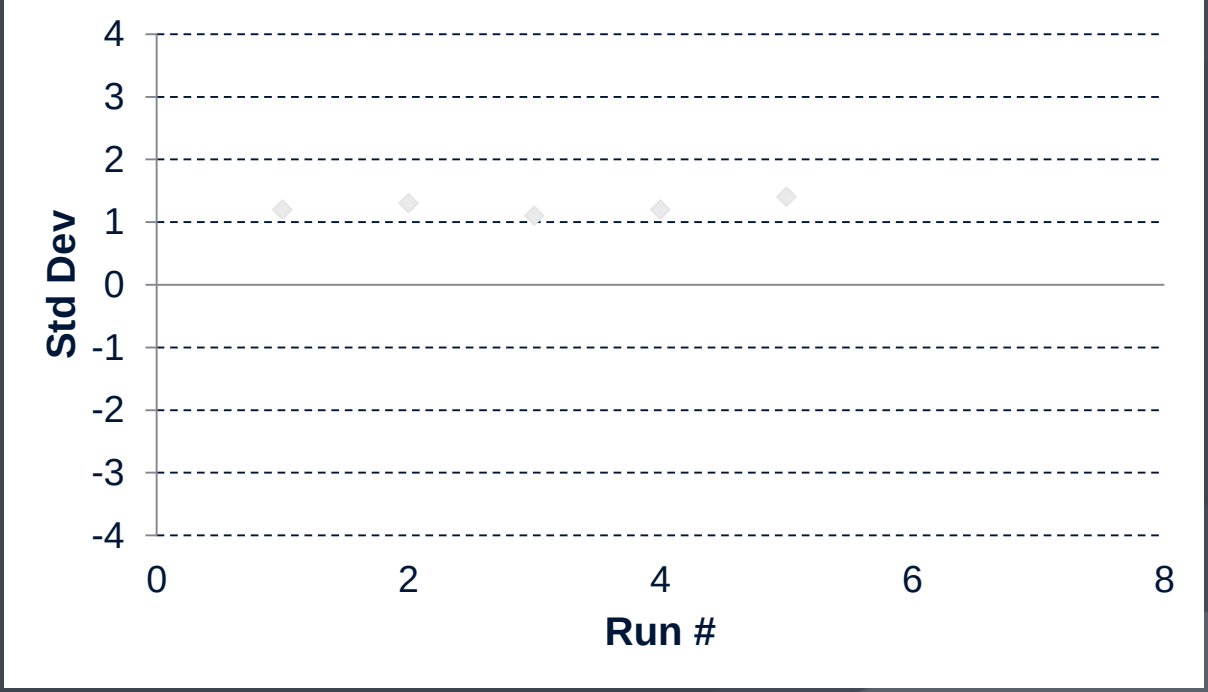
1-3s Rule

- Precision or Bias?



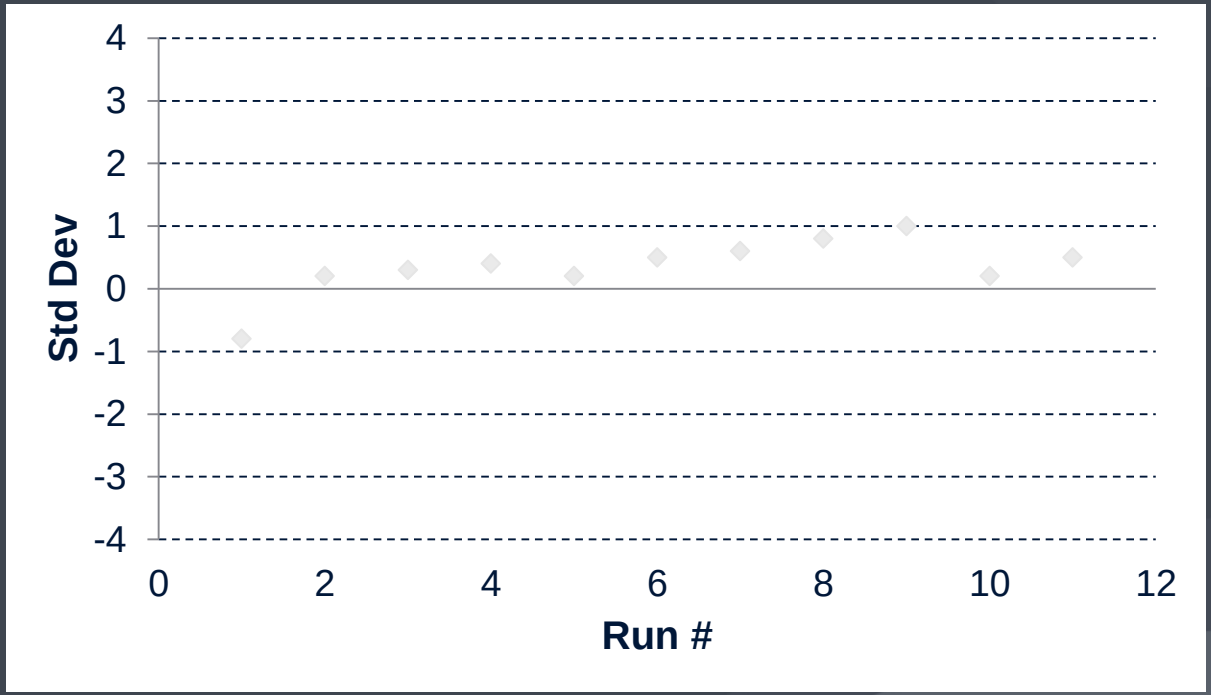
4_{1s} Rule

- Precision or Bias?



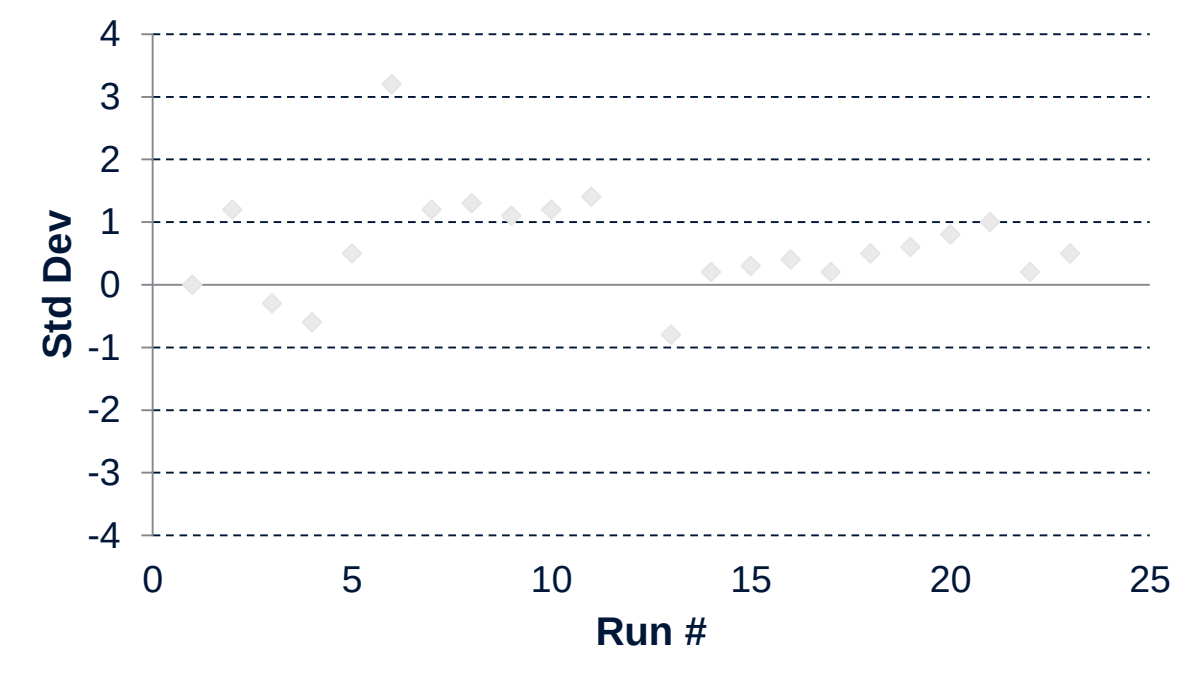
10x Rule

- Precision or Bias?



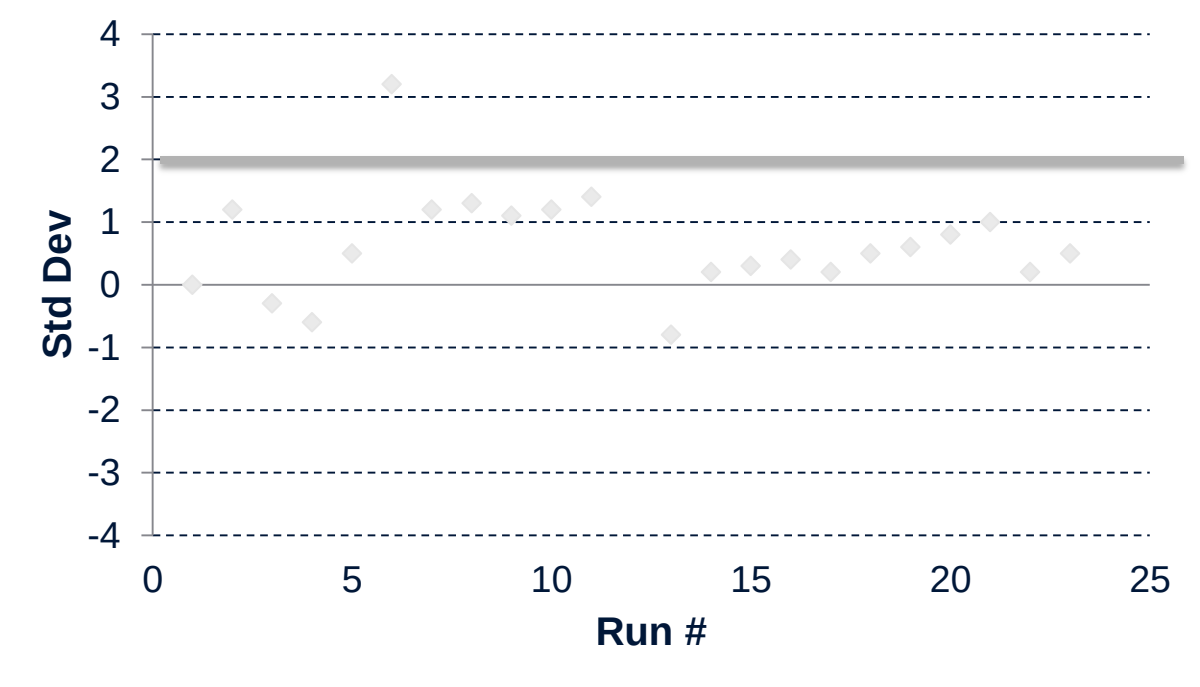
#1 Using a Trigger Rule

Few if any failures equals high quality…



#1 Using a Trigger Rule

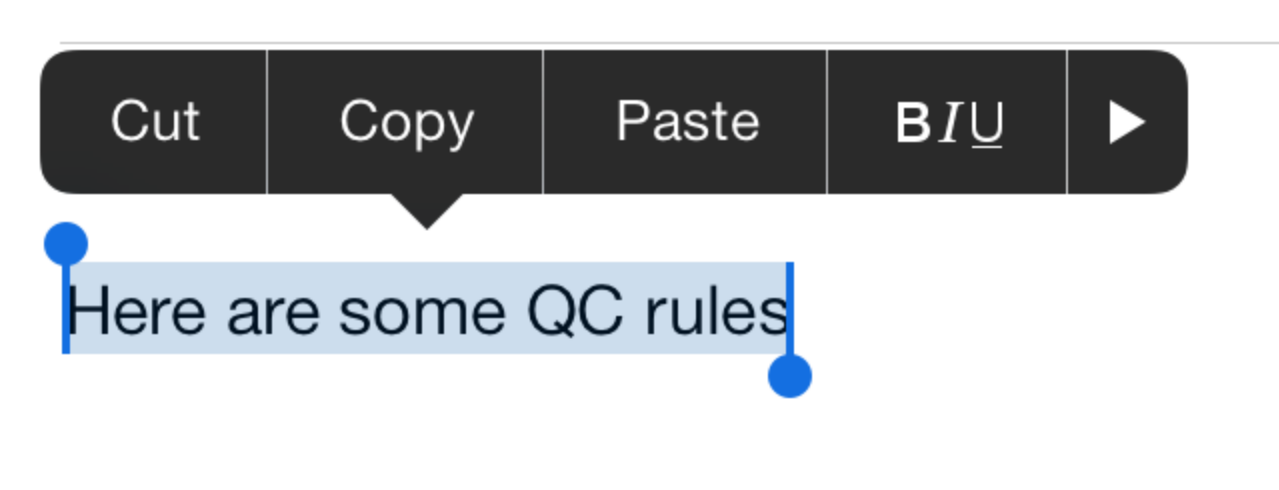
Few if any failures equals high quality…



Robots need work too…

Common Mistake #2

- Cut and paste QC rules



#2 Cut and Paste QC Rules

If it works for them it should work for us…

- Probability of error detection
- Probability of false rejection
- Effectiveness of rule combinations

- *How many of you KNOW your QC is working?*

#2 Cut and Paste QC Rules

The more the merrier…

- Lab 1
  - 1-3s
- Lab 2
  - 1-3s/4-1s
- Lab 3
  - 1-3s/2-2s/4-1s/R-4s/10x

Efficiency & Effectiveness of QC

0% bias; 2% CV

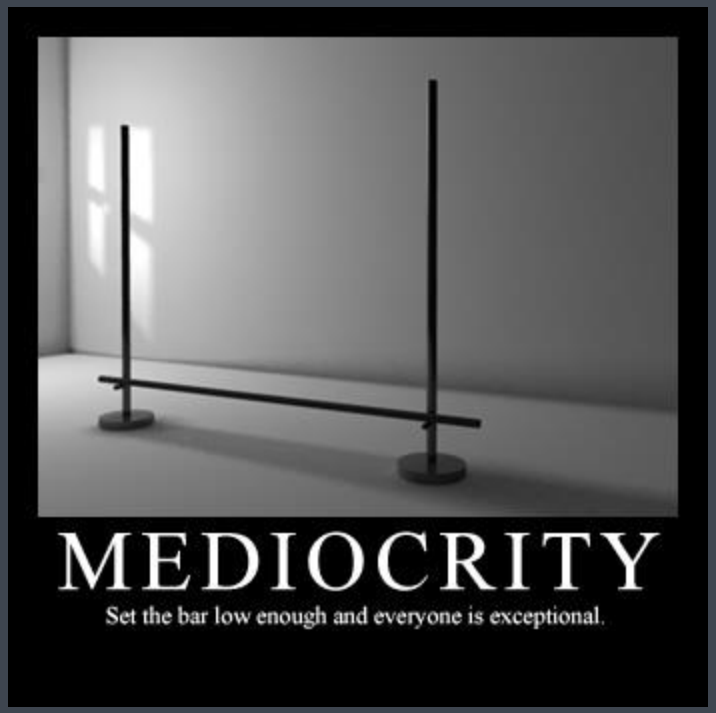
Rule	Pfr	Ped	N	R
1-3.5s	0	0.066	2	1
1-3s	0	0.86	2	1
1-3s/2-2s/R-4s	0.01	0.94	2	1
1-2.5s	0.04	1	4	1
1-3s/2-2s/R-4s/4-1s/8x	0.03	1	4	2

3% bias; 3% CV

Rule	Pfr	Ped	N	R
1-3.5s	0	0.01	2	1
1-3s	0	0.02	2	1
1-3s/2-2s/R-4s	0.01	0.03	2	1
1-2.5s	0.04	0.13	4	1
1-3s/2-2s/R-4s/4-1s/8x	0.03	0.18	4	2

Common Mistake #3

- Unrealistic QC acceptance criteria



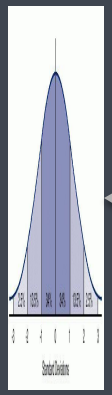
Example

- Historically, we've set our acceptance criteria to match NY PT acceptance criteria.
  - +/- 4 ug/dL at < 10 ug/dL (40%)

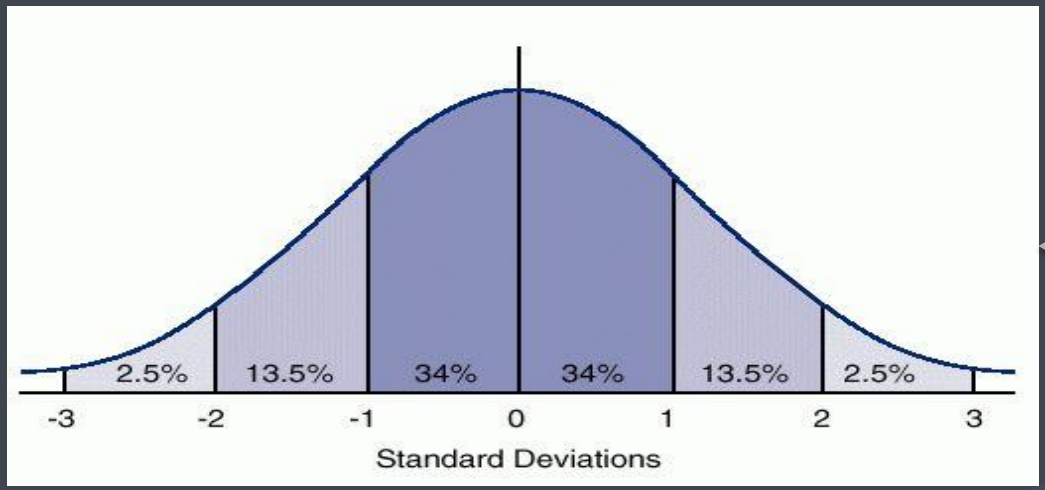
- Last month the CV for our 10ug/dL control was 5%

#3 Unrealistic QC Targets

Wider is better…



Instrument performance



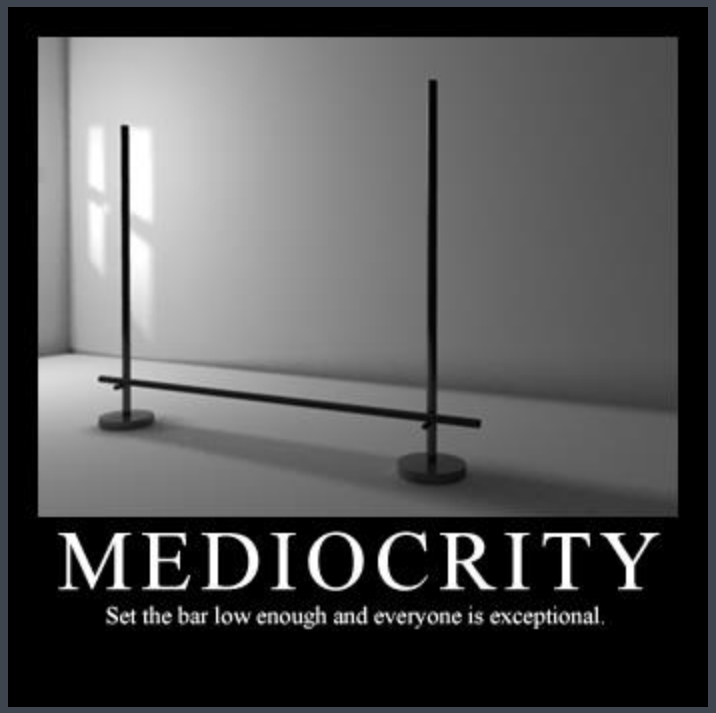
Lab expectations

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



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
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
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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

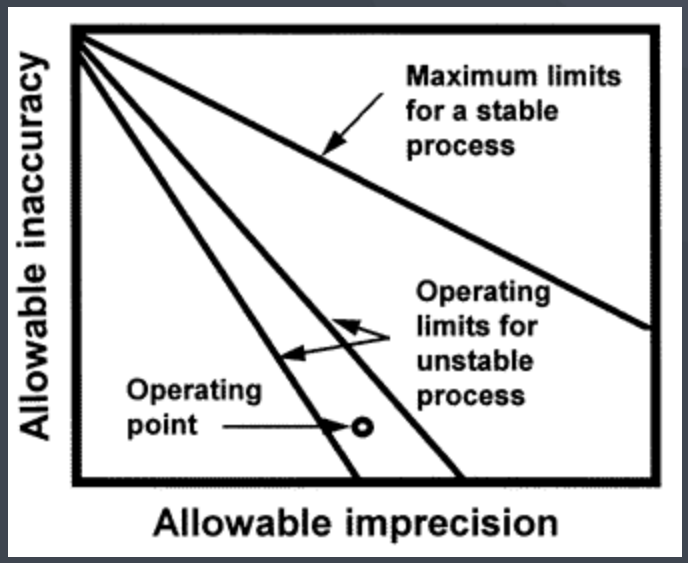
Total allowable error

Medical decision limits

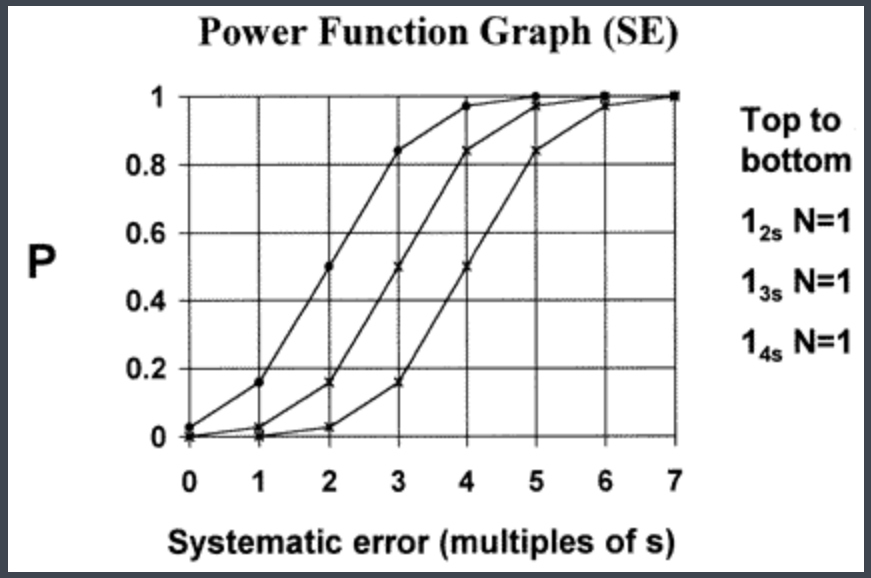
Assay bias

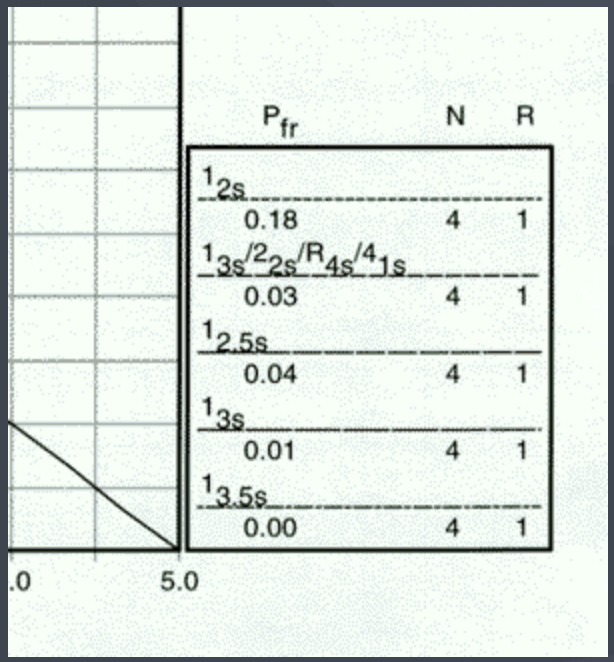
Assay precision

Operational Process Specifications Chart



Necessary Component #2





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- Read probability for error detection (P_{ed}) at point on power curve corresponding to critical-sized error
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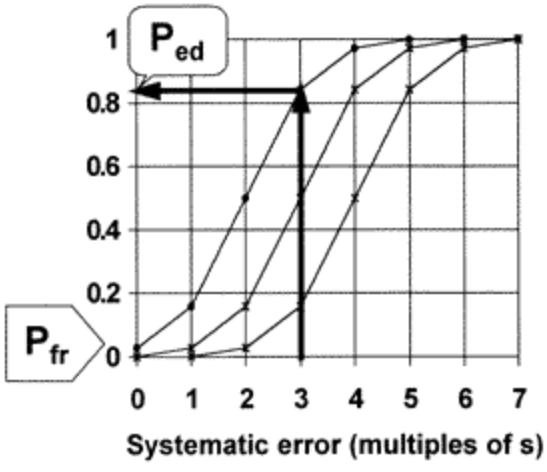


Almost…Not Quite

nickn87.umwblogs.org

crymore.net

Strategy #1

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	3.89578	-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	19.552484	-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	8.516076	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	37835	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	7.433604	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	0.137221	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	4.53961	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	0.265227	40	26.841842	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	16.042157	-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	26	5.6	5.77	1.7	1.550487	0.099548	1.040107	30.357143	26.909772	21.38	2.200-9.000

Strategy #2

Ask the staff

Poor performing assays

Assays not working well

too busy

Solving problems individually

Lack of staffing

procedural inflexibility

short on time

pulling long hours

short term solutions

Instruments not functioning properly

very rushed

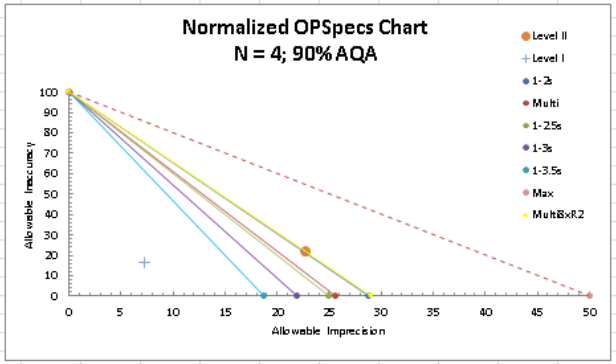
limited amount of automation

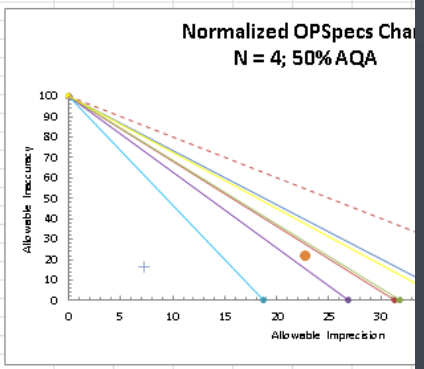
Personal opinion

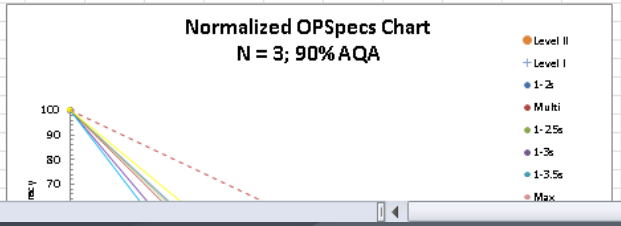
always very rushed

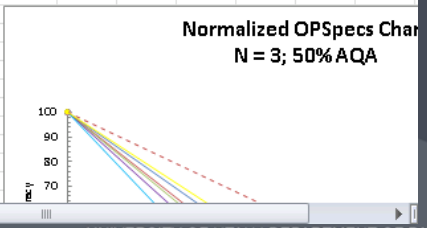
Quality Control Overhaul

	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				





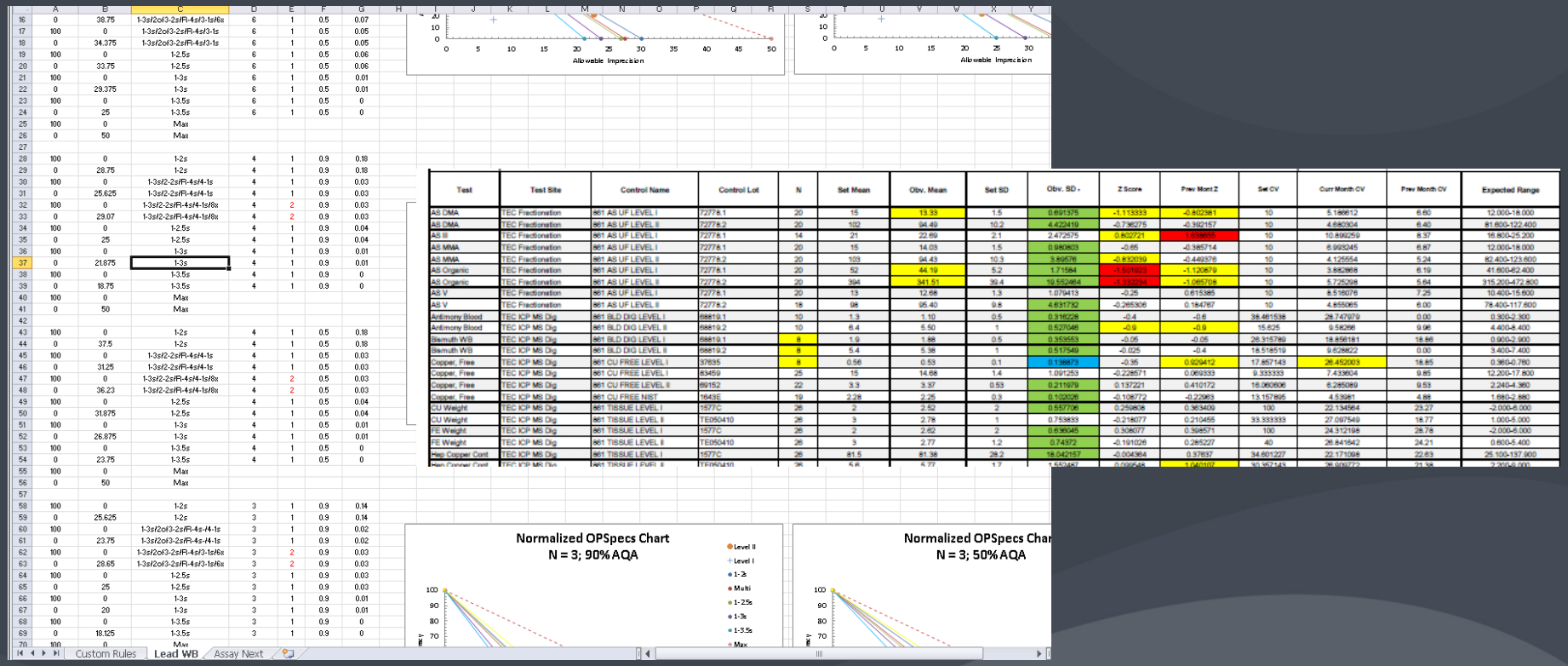




Custom Rules | Lead WB | Assay Next

Improvement Area #1

QC rules evaluated on a continuous basis



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	1.238095	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	19.582464	-1.330254	-1.065706	10	5.735298	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	0.139873	-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	7.433604	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	0.100026	-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	29.27	-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	0.309077	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	26.900722	21.38	2.200-9.000

Improvement Area #2

QC troubleshooting plan optimization

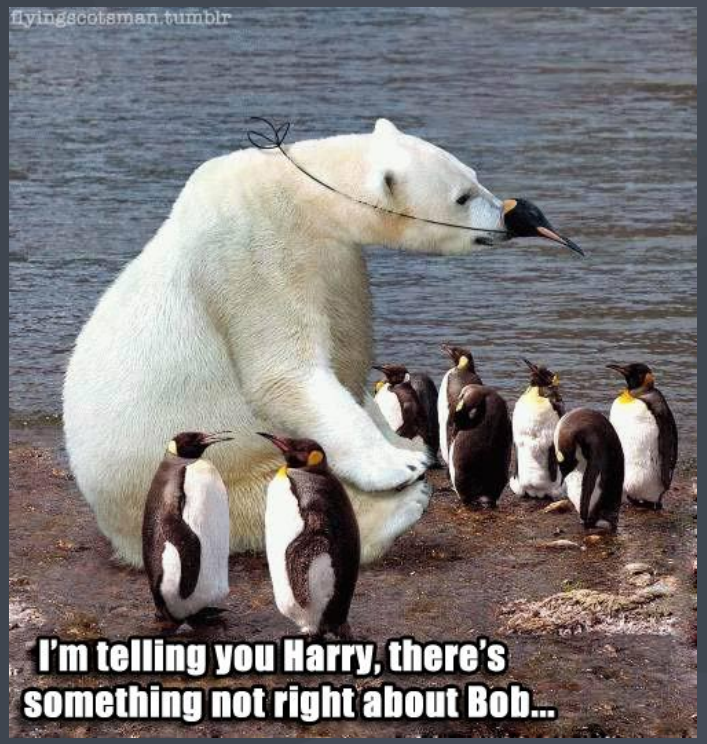
- Track success
- Track failures

- Evaluate effectiveness
- Enhance technical competency amongst staff

Improvement Area #3

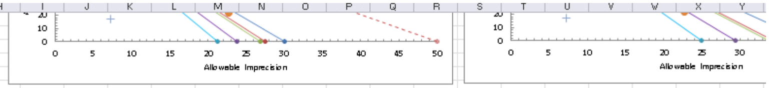
Assay improvements

- Identify the real problems
- Fix the problems you have
- Balance or combine SO conversions with improvements



And Then it Happened

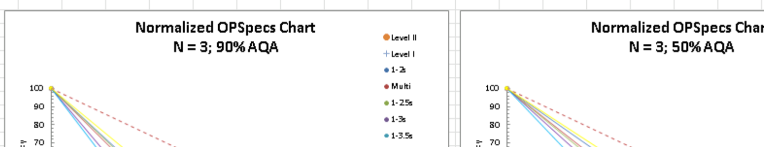
Current State Assessment Completed



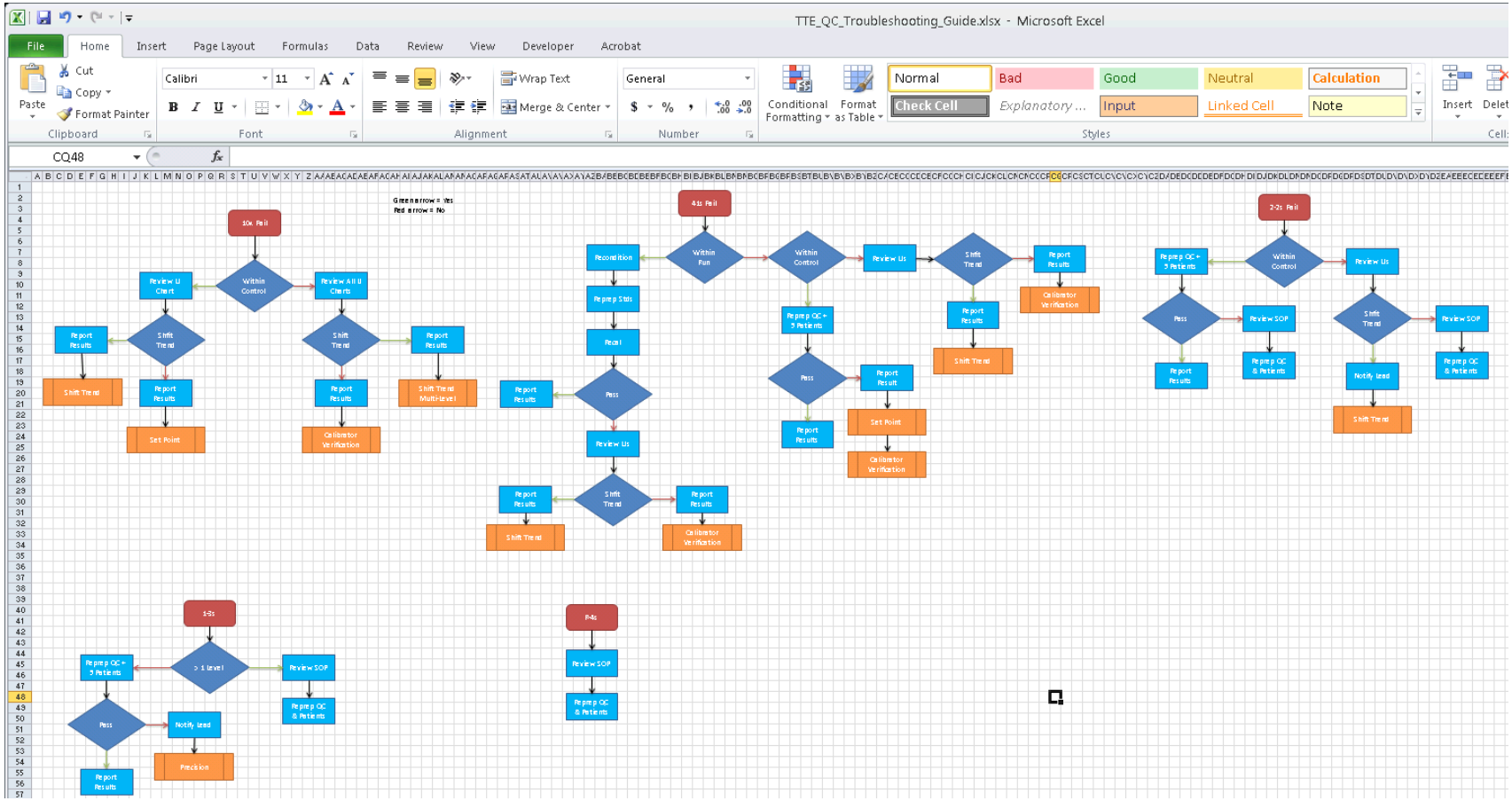
	A	B	C	D	E	F	G
16	0	38.75	1-3s/2of3-2s/R-4s/3-1s/6x	6	1	0.5	0.07
17	100	0	1-3s/2of3-2s/R-4s/3-1s	6	1	0.5	0.05
18	0	34.375	1-3s/2of3-2s/R-4s/3-1s	6	1	0.5	0.05
19	100	0	1-2.5s	6	1	0.5	0.06
20	0	33.75	1-2.5s	6	1	0.5	0.06
21	100	0	1-3s	6	1	0.5	0.01
22	0	29.375	1-3s	6	1	0.5	0.01
23	100	0	1-3.5s	6	1	0.5	0
24	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

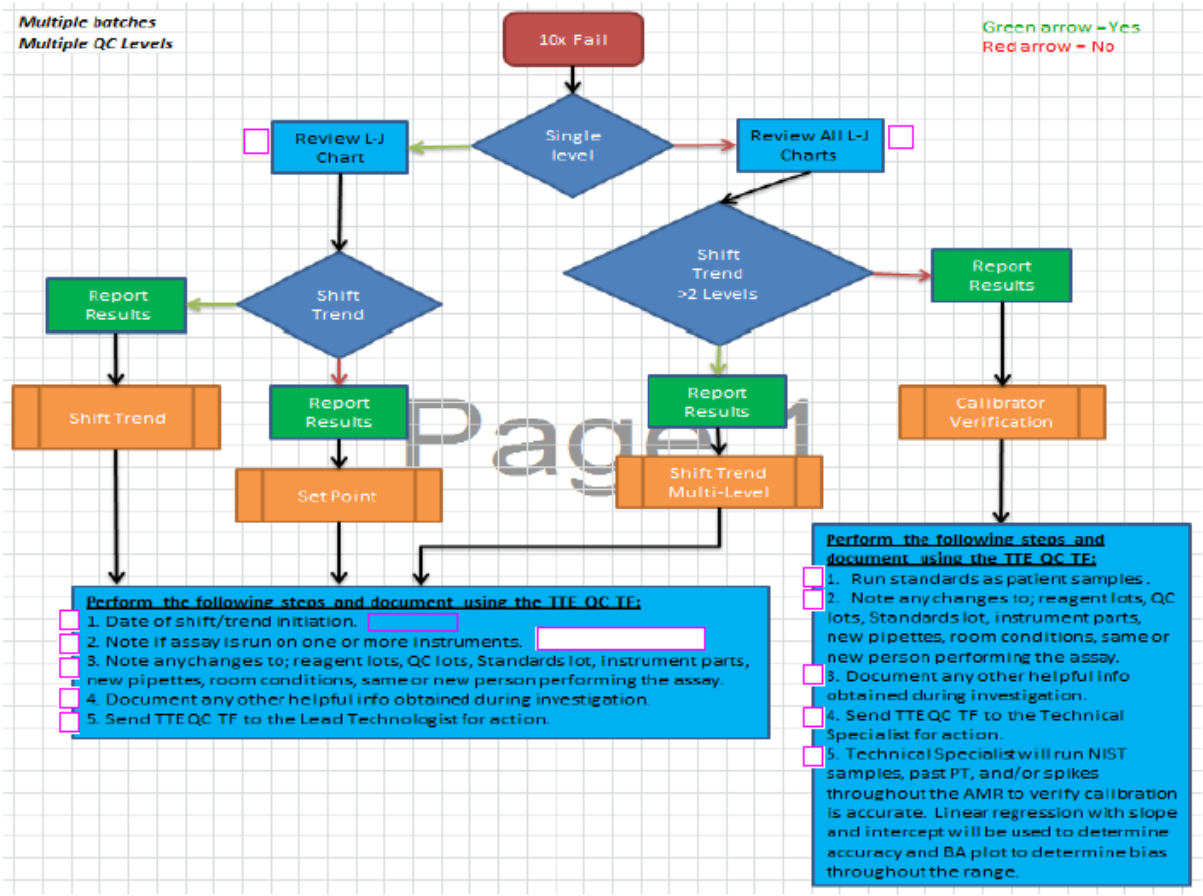
Test	Test Site	Control Name	Control Lot	N	Set Mean	Obv. Mean	Set SD	Obv. SD .	Z Score	Prev Mont Z	Set CV	Curr Month CV	Prev Month CV	Expected Range
AS DMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	13.33	1.5	0.691375	-1.113333	-0.802381	10	5.186612	6.60	12.000-18.000
AS DMA	TEC Fractionation	861 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	1.636655	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	16.85	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	0.137221	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	16.77	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



Troubleshooting Workflow Developed – *By Me*



Troubleshooting Tools Developed – *With Staff*

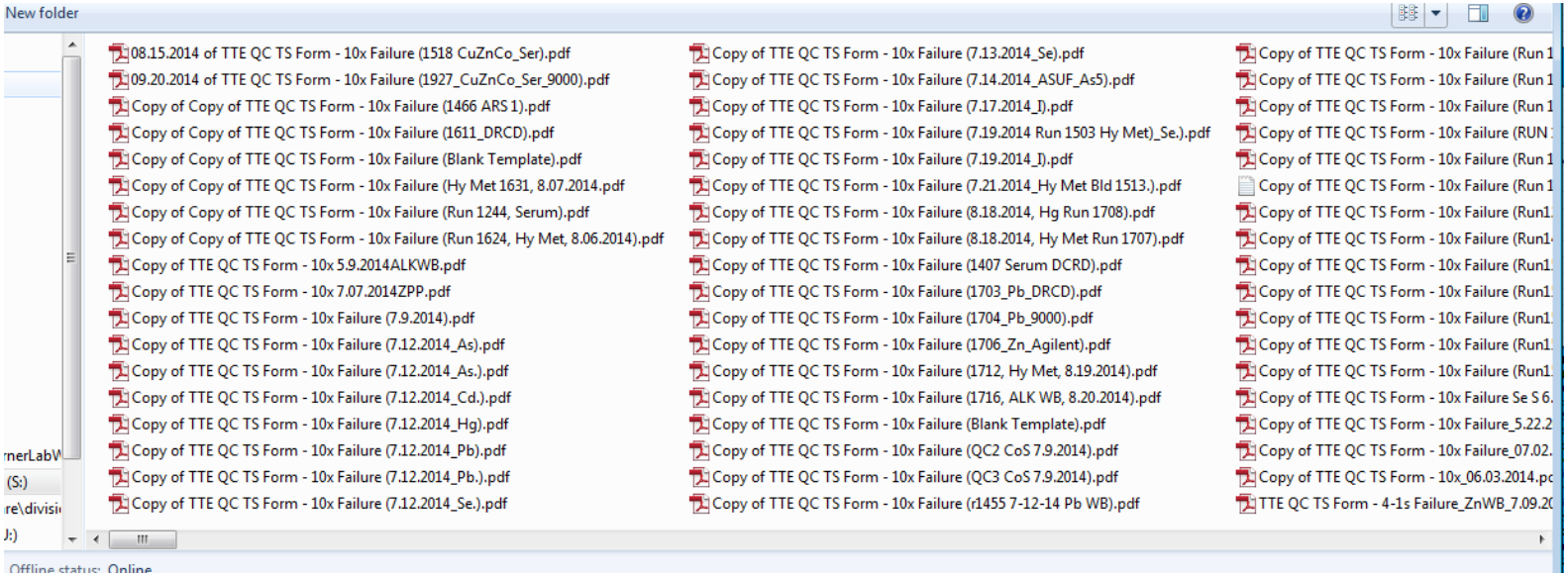


Organizational Support

- 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

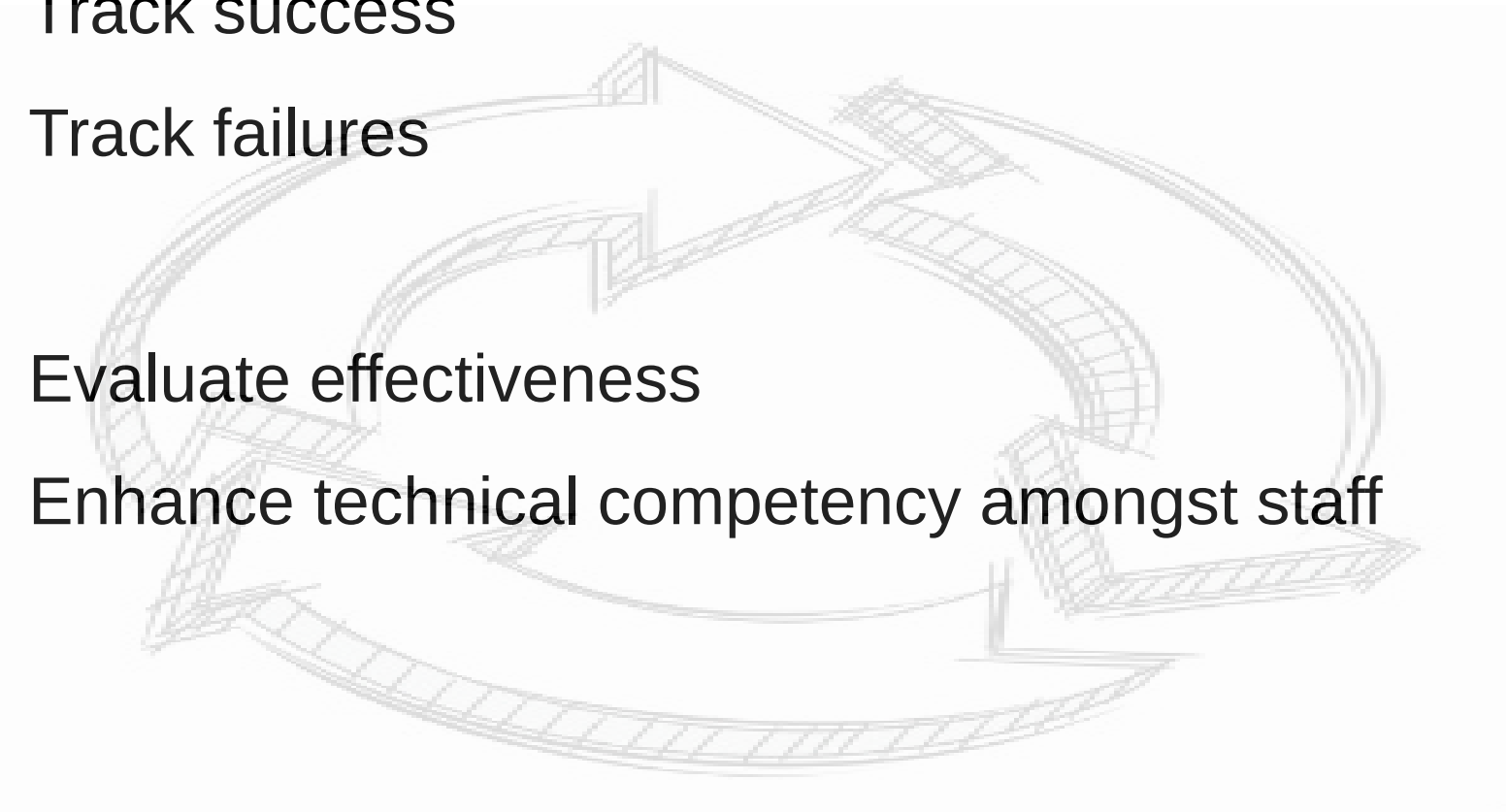
Illusion of Quality - Indeed

- It can be painful to be the leader…



Fix it. Keep fixing it.

- Track success
- Track failures



- Evaluate effectiveness
- Enhance technical competency amongst staff

Where are we now?

TTE Lab: Current State Assessment
6 mo. post "go-live"

- Not 1 failed PT
- 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

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

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.