Quality Assurance - Audit Issues and Expectations

Mike Papp
Office of Air Quality Planning and Standards

MARAMA Air Monitoring Meeting
December 10, 2014

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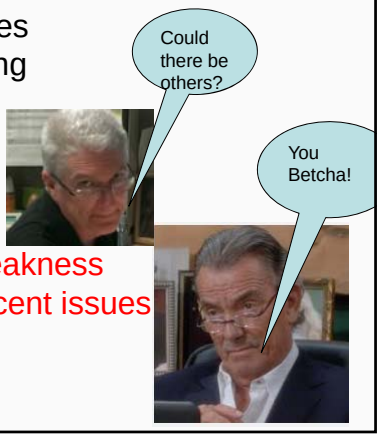
Recent Data Validation Issues

- Hayden AZ- No approved QAPP –Data not used
- Billings MT – QC Infractions for SO2 data
- PM2.5 Gravimetric Lab Issues- Data Invalidations (years)
  - Louisville, KY
  - Cook County, IL
  - Knoxville, TN
  - Atlanta, GA
  - Florida, DEP ?
  - Oregon, DEQ ?

Some of these issues were identified during TSAs



Based on Gravimetric Lab Issues
- Region 5 self-declared a FMFIA weakness
- Janet McCabe's identification of recent issues to the IG

40 CFR Part 58 Appendix A Section 1 General Information

"….Accordingly, EPA and monitoring agencies shall use a "weight of evidence" approach when determining the suitability of data for regulatory decisions. The EPA reserves the authority to use or not use monitoring data submitted by a monitoring organization when making regulatory decisions based on the EPA's assessment of the quality of the data. Generally, consensus built validation templates or validation criteria already approved in Quality Assurance Project Plans (QAPPs) should be used as the basis for the weight of evidence approach.

We're all in this together!

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Reasons for TSAs and Data Invalidation

- Why TSA's are critical for EPA
  - Can't observe the real world from behind a desk
  - A new set of eyes
  - Cross fertilization/communication
  - Keeps regional staff trained on the technology
  - Helps train monitoring org staff on the important things we are seeing across the country
  - Keeps us paying attention to your issues
- Why some monitoring orgs are having data quality issues
  - Requirements and guidance (EPA and QAPP) not followed
  - Equipment not meeting new requirements
  - Losing good personnel--not being replaced--- stretching remainder thin
  - Lacking time for proper equipment upkeep or data review
  - Replacements not being trained well or possibly no mentoring
  - Not paying attention or maybe not knowing to pay attention

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FACT

By the time we see data quality issues either through AQS or TSAs it's usually too late.

We need you looking at data quality real time

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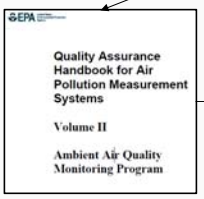
Bottom Line #1
Develop your quality system

#1 CFR
- Follow all requirements unless a tech memo available (AMTIC)



Monitoring Org QAPP and SOPs

TSAs start here

#2 QA Handbook
- Understand suggestions
- Understand the Validation Templates

#3 Monitoring Org QAPP
- Meets regs and includes Handbook suggestions or "approvable" equivalent.
- Regions on the hook to approve.
- QAPP/SOPs are the contract

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QAPPs & SOPs are like a contract…

- Your commitment to monitoring as written and approved
- Who compares your data results to QAPP objectives?
  - How often
- Who compares data results to SOP requirements?
  - How often?
- Who is your independent QA Manager?
  - What does he/she do?
- Do you have quality assurance staff?
  - What do they do?
- Does implementation staff have QA responsibilities?
  - What are they?
- Who attests and certifies the accuracy and validity of your data to EPA?

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Bottom Line #2
Implement your quality system

Use the validation templates and assess your results as soon as they are reported

Ozone Validation Template

1) Requirement (O_3)	2) Frequency	3) Acceptance Criteria	Information /Action
CRITICAL CRITERIA-OZONE			
One Point QC Check Single analyzer	*1/ 2 weeks*	≤ ±7% (percent difference)	1 and 2) 40 CFR Part 58 App A Sec 3.2 3) Recommendation based on DQO in 40 CFR Part 58 App A Sec 2.3.1.2. QC Check Conc range 0.01 - 0.10 ppm, relative to routine concentrations
Zero/span check	1/ 2 weeks	Zero drift ≤ ± 1.5 ppb Span drift ≤ ± 7 %	1 and 2) QA Handbook Volume 2 Section 12.3 3) Recommendation and related to DQO
OPERATIONAL CRITERIA -OZONE			
Shelter Temperature Range	Daily (hourly values)	20 to 30° C. (Hourly avg) or per manufacturers specifications if designated to a wider temperature range	1, 2 and 3) QA Handbook Volume 2 Section 7.2.2 Generally the 20-30 ° C range will apply but the most restrictive operable range of the instruments in the shelter may also be used as guidance. FRM/FEM list found on AMTIC provides temp. range for given instrument. FRM/FEM monitor testing is required at 20-30 ° C range per 40 CFR Part 53.32
Shelter Temperature Control	Daily (hourly values)	≤ ± 2° C SD over 24 hours	1, 2 and 3) QA Handbook Volume 2 Section 7.2.2
Shelter Temperature Device Check	1/6 mo	± 2° C of standard	1, 2 and 3) QA Handbook Volume 2 Section 7.2.2
Annual Performance Evaluation Single analyzer	*Every site 1/year within period of monitor operation, 25 % of sites quarterly*	Percent difference of audit levels 3-10 ≤ ±15% Audit levels 1&2 ± 1.5 ppb difference or ± 15%	1 and 2) 40 CFR Part 58 App A sec 3.2.2 3) Recommendation- 3-audit concentrations not including zero. AMTIC guidance 2/17/2011 http://www.epa.gov/ttn/amtic/cpreldoc.html
	1/year at selected sites 20% of sites	Audit levels 1&2 ± 1.5 ppb difference all other	1) 40 CFR Part 58 App A sec 2.4

*Observations that do not meet each and every criterion on the **Critical Criteria Table** should be invalidated unless there are compelling reason and justification for not doing so. The sample or group of samples for which one or more of these criteria are not met is invalid until proven otherwise.*

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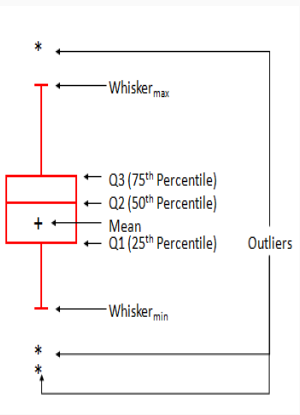
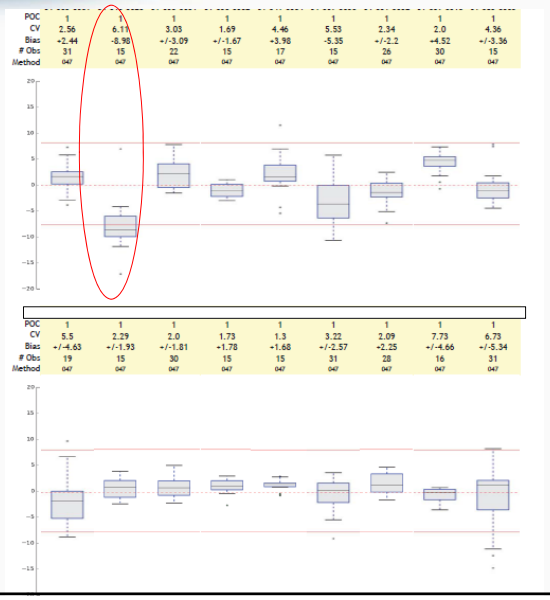
What we look at: Annual Box and Whisker Plots Ozone





What we look at: AMP256 Reports

AIR QUALITY SYSTEM

AMP256

DATA QUALITY INDICATOR REPORT

One Point Quality Control

Jun. 16, 2014

App A? Y

POC	MT	Begin Date	End Date	# Required	# Observation	% Complete	CV UB	Bias UB
1	S	01-APR-12	31-OCT-12	15	31	100	2.56	+/- 2.44
1	S	01-APR-12	31-OCT-12	15	15	100	6.11	8.98
1	S	01-APR-12	31-OCT-12	15	22	100	3.03	+/- 3.09
1	S	01-APR-12	31-OCT-12	15	15	100	1.69	+/- 1.67

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Another Look- Same Data
The DASC Tool

O_3 Assessments

Site ID: {Enter Site ID} | Pollutant type: O_3 | CV_{ub} (%) | Bias (%)

Meas Val (Y)	Audit Val (X)	d (Eqn. 1)	25th Percentile	d^2	|d|	$\|d\|^2$
85.1	91.1	-6.586	-8.750	43.378	6.586	43.378
81.6	91.1	-10.428	75th Percentile	108.745	10.428	108.745
83.4	92.4	-9.740	-5.262	94.873	9.740	94.873
84	92.4	-9.091		82.645	9.091	82.645
87.4	92.4	-5.411		29.282	5.411	29.282
78.4	92.4	-15.152	Outlier	229.568	15.152	229.568
85.4	92.4	-7.576		57.392	7.576	57.392
85.4	92.4	-7.576		57.392	7.576	57.392
80.6	88	-8.409		70.713	8.409	70.713
83.5	88	-5.114		26.149	5.114	26.149
83.5	88	-5.114		26.149	5.114	26.149
80.8	88	-8.182		66.942	8.182	66.942
81.5	88	-7.386		54.558	7.386	54.558
93.5	88	6.250	Outlier	39.063	6.250	39.063
84.8	88	-3.636		13.223	3.636	13.223

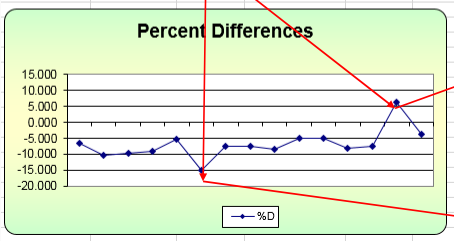
n	S_d	S_{d2}	$\Sigma\|d\|$	"AB" (Eqn 4)
15	4.557	52.464	115.651	7.71
n-1	Σd	Σd^2	$\Sigma\|d\|^2$	"AS" (Eqn 5)
14	-103.151	1000.072	1000.072	2.78

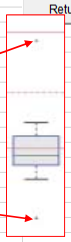
Bias (%) (Eqn 3): 8.98 — Both Signs Positive: FALSE

CV (%) (Eqn 2): 6.11 — Signed Bias (%): -8.98 — Both Signs Negativ: TRUE

Upper Probability Limit: 2.06 — Lower Probability Limit: -15.81

Return to Main Menu | Print Worksheet





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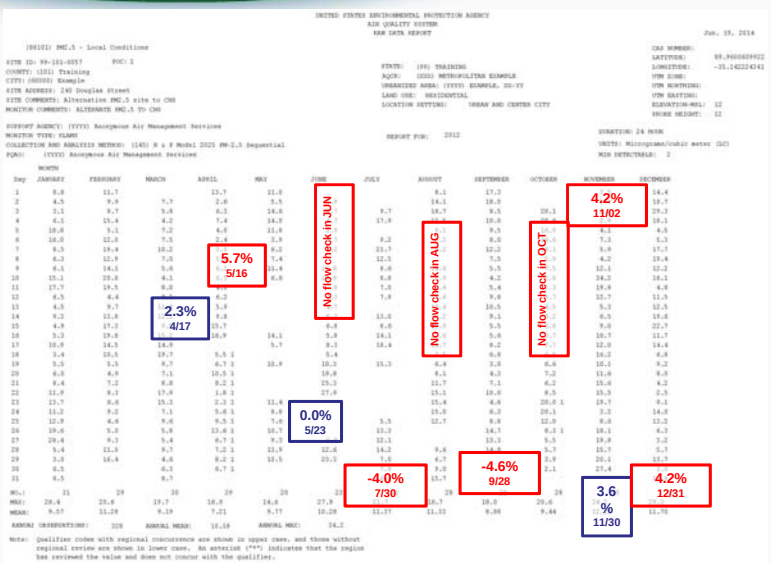
What we look at:
Monthly PM2.5 Flow Checks



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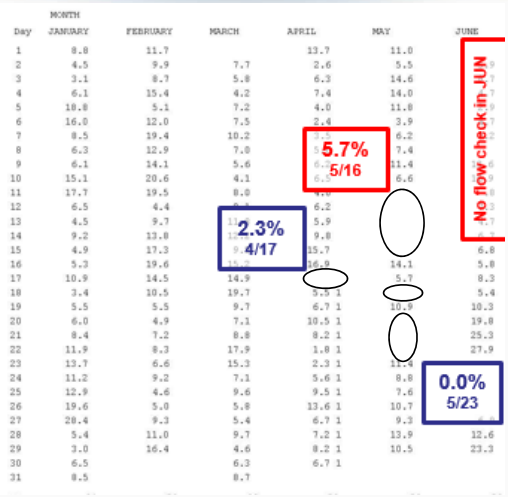
What Questions Are We Asking



Day	MONTH JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE
1	8.8	11.7		13.7	11.0	
2	4.5	9.9	7.7	2.6	5.5	
3	3.1	8.7	5.8	6.3	14.6	
4	6.1	15.4	4.2	7.4	14.0	
5	10.8	5.1	7.2	4.0	11.8	
6	16.0	12.0	7.5	2.4	3.9	
7	8.5	19.4	10.2		6.2	
8	6.3	12.9	7.0		7.4	
9	6.1	14.1	5.6		11.4	
10	15.1	20.6	4.1		6.6	
11	17.7	19.5	8.0			
12	6.5	4.4		6.2		
13	4.5	9.7		5.9		
14	9.2	13.8		9.8		
15	4.9	17.3		15.7		6.8
16	5.3	19.6		16.9	14.1	5.8
17	10.9	14.5	14.9		5.7	8.3
18	3.4	10.5	19.7	5.5 1		5.4
19	5.5	5.5	9.7	6.7 1	10.9	10.3
20	6.0	4.9	7.1	10.5 1		19.8
21	8.4	7.2	8.8	8.2 1		25.3
22	11.9	8.3	17.9	1.8 1		27.9
23	13.7	6.6	15.3	2.3 1		
24	11.2	9.2	7.1	5.6 1	8.8	
25	12.9	4.6	9.6	9.5 1	7.6	
26	19.6	5.0	5.8	13.6 1	10.7	
27	28.4	9.3	5.4	6.7 1	9.3	
28	5.4	11.0	9.7	7.2 1	13.9	12.6
29	3.0	16.4	4.6	8.2 1	10.5	23.3
30	6.5		6.3	6.7 1		
31	8.5		8.7			

- Why no flow checks reported in some months?
- Why no null codes for missing data?
- Was some of the data invalidated due to out of speck flow rate?
  - Why not back to the last check?
- If data was considered acceptable is the compelling evidence documented?

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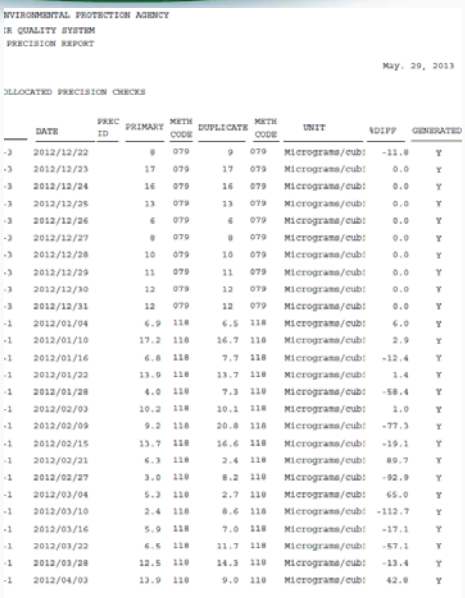
What we look at: Collocated Precision



NVIRONMENTAL PROTECTION AGENCY
IR QUALITY SYSTEM
PRECISION REPORT

May. 29, 2013

OLLOCATED PRECISION CHECKS

	DATE	PREC ID	PRIMARY	METH CODE	DUPLICATE	METH CODE	UNIT	%DIFF	GENERATED
-3	2012/12/22		8	079	9	079	Micrograms/cubi	-11.8	Y
-3	2012/12/23		17	079	17	079	Micrograms/cubi	0.0	Y
-3	2012/12/24		16	079	16	079	Micrograms/cubi	0.0	Y
-3	2012/12/25		13	079	13	079	Micrograms/cubi	0.0	Y
-3	2012/12/26		6	079	6	079	Micrograms/cubi	0.0	Y
-3	2012/12/27		8	079	8	079	Micrograms/cubi	0.0	Y
-3	2012/12/28		10	079	10	079	Micrograms/cubi	0.0	Y
-3	2012/12/29		11	079	11	079	Micrograms/cubi	0.0	Y
-3	2012/12/30		12	079	12	079	Micrograms/cubi	0.0	Y
-3	2012/12/31		12	079	12	079	Micrograms/cubi	0.0	Y
-1	2012/01/04		6.9	118	6.5	118	Micrograms/cubi	6.0	Y
-1	2012/01/10		17.2	118	16.7	118	Micrograms/cubi	2.9	Y
-1	2012/01/16		6.8	118	7.7	118	Micrograms/cubi	-12.4	Y
-1	2012/01/22		13.9	118	13.7	118	Micrograms/cubi	1.4	Y
-1	2012/01/28		4.0	118	7.3	118	Micrograms/cubi	-58.4	Y
-1	2012/02/03		10.2	118	10.1	118	Micrograms/cubi	1.0	Y
-1	2012/02/09		9.2	118	20.8	118	Micrograms/cubi	-77.3	Y
-1	2012/02/15		13.7	118	16.6	118	Micrograms/cubi	-19.1	Y
-1	2012/02/21		6.3	118	2.4	118	Micrograms/cubi	89.7	Y
-1	2012/02/27		3.0	118	8.2	118	Micrograms/cubi	-92.9	Y
-1	2012/03/04		5.3	118	2.7	118	Micrograms/cubi	65.0	Y
-1	2012/03/10		2.4	118	8.6	118	Micrograms/cubi	-112.7	Y
-1	2012/03/16		5.9	118	7.0	118	Micrograms/cubi	-17.1	Y
-1	2012/03/22		6.5	118	11.7	118	Micrograms/cubi	-57.1	Y
-1	2012/03/28		12.5	118	14.3	118	Micrograms/cubi	-13.4	Y
-1	2012/04/03		13.9	118	9.0	118	Micrograms/cubi	42.8	Y

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What we are asking: Collocated Precision

Did anyone investigate these results?

One of the pair is < 3 ug/m3 but the pairs still look odd

	DATE	PREC ID	PRIMARY	METH CODE	DUPLICATE	METH CODE	UNIT	%DIFF	GENERATED
-1	2012/01/28		4.0	118	7.3	118	Micrograms/cubi	-58.4	Y
-1	2012/02/03		10.2	118	10.1	118	Micrograms/cubi	1.0	Y
-1	2012/02/09		9.2	118	20.8	118	Micrograms/cubi	-77.3	Y
-1	2012/02/15		13.7	118	16.6	118	Micrograms/cubi	-19.1	Y
-1	2012/02/21		6.3	118	2.4	118	Micrograms/cubi	89.7	Y
-1	2012/02/27		3.0	118	8.2	118	Micrograms/cubi	-92.9	Y
-1	2012/03/04		5.3	118	2.7	118	Micrograms/cubi	65.0	Y
-1	2012/03/10		2.4	118	8.6	118	Micrograms/cubi	-112.7	Y
-1	2012/03/16		5.9	118	7.0	118	Micrograms/cubi	-17.1	Y
-1	2012/03/22		6.5	118	11.7	118	Micrograms/cubi	-57.1	Y
-1	2012/03/28		12.5	118	14.3	118	Micrograms/cubi	-13.4	Y
-1	2012/04/03		13.9	118	9.0	118	Micrograms/cubi	42.8	Y

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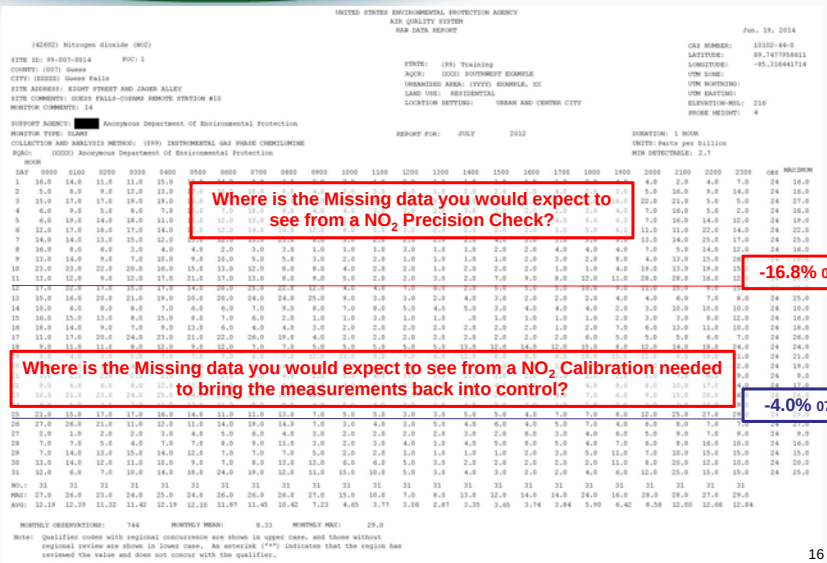
What we look at: NO2 with 1-Point QC



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What we look at: Check and Calibration Gas Standards

- Are they within certification period?
- Are pressure >200 psig for calibrations.
- It has been shown that some concentrations become unstable at low pressures.
- Agency participating in Protocol Gas Verification Program?

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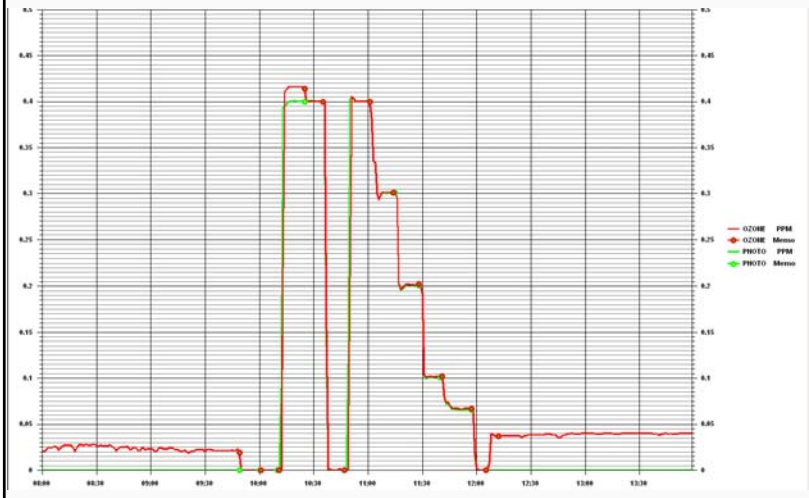
What we look at: Calibration points

Are they graphed?
Do they appear as "walkable stairsteps"?



Red line =
Ozone Analyzer

Green line =
Photometer
Response

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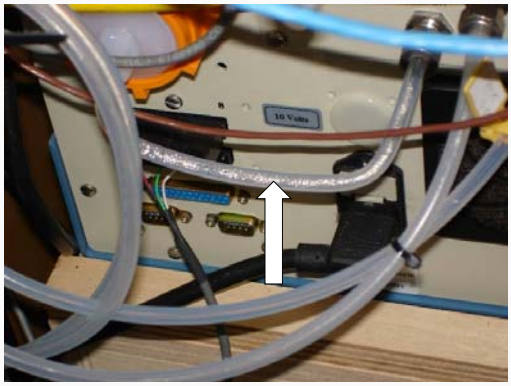
What we look at in the field

Water in Probe Lines

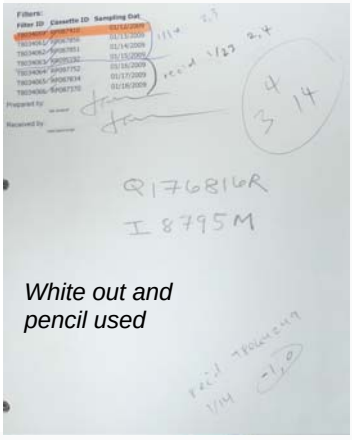


Unapproved Material (Tygon tubing) in Sampling Train

What we look at in the field

Contaminated Manifolds and Inlets

Problematic Chain of Custody (not defensible)



White out and pencil used

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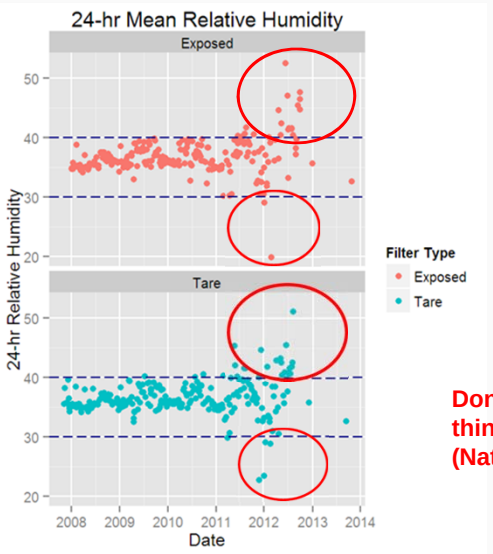
Real World TSA Findings - Lab



Relative humidity 24-hr mean must be 30% - 40% RH

- 40 CFR Part 50, App.L Sec 8.2.3

Electronic strip chart shows weighing conditions outside of the stated range

Resulted in invalidation of data points over multiple years

Don't weigh; if lab has a problem think about (have) alternatives (National PM2.5 contract)

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Expectations

- A quality system that's implemented as described in the QAPP and SOPs
  - Expect a QAPP to be revised every 5 years
- Adherence to regulations and documentation/ agreement on those regs that are not followed
- Following guidance and/or development of requirements deemed equivalent
- Data in AQS that reflects the validation requirements described in your in QAPP
- Documentation providing compelling evidence for keeping or invalidating data.
- Cooperation on audits. We have the same objectives.
- Addressing findings through corrective action in a timely manner
- TSAs will be reported to AMTIC.

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AQS TSA Entry

- Performing Agency
- Monitoring Agency
- Begin Date
- End Date
- Closeout Date

Date that all corrective actions have been taken. No date denotes findings exist and corrective actions not completed

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