

# Technical Systems Audits QA 101 Session

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#### **QA 101 - TSAs**



# **Technical Systems Audits (TSAs)**

#### Let's break it into 3 parts...

- ✓ What is a TSA and why do we do them?
- ✓ How do you conduct a good and effective TSA? Tips for conducting audits!
- ✓ Technical Systems Audit Workgroup: What is it and what are we doing?





# 40 CFR Part 58, Appendix A Section 2.5 says in black and white...

2.5 Technical Systems Audit Program. Technical systems audits of each PQAO shall be conducted at least every 3 years by the appropriate EPA Regional Office and reported to the AQS. If a PQAO is made up of more than one monitoring organization, all monitoring organizations in the PQAO should be audited within 6 years (two TSA cycles of the PQAO). As an example, if a state has five local monitoring organizations that are consolidated under one PQAO, all five local monitoring organizations should receive a technical systems audit within a 6-year period. Systems audit programs are described in reference 10 of this appendix.

"Reference 10" is...



The Quality Assurance
Handbook for Air Pollution
Measurement Systems,
Volume II

Otherwise known as

"The QA Handbook"

If you don't know this by now, Remedial QA is down the hall...

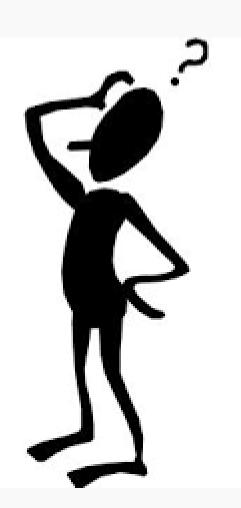


Quality Assurance Handbook for Air Pollution Measurement Systems

Volume II

Ambient Air Quality Monitoring Program





# What does it say?

# Section 15.3 Technical Systems Audit

"A technical systems audit is an onsite review and inspection of a monitoring organization's ambient air monitoring program to assess its compliance with established regulations governing the collection, analysis, validation, and reporting of ambient air quality data."



# The QA Handbook states that a TSA should address and report on the following key areas:

- Planning
- Field Operations
- Laboratory Operations
- Quality Assurance/ Quality Control
- Data Management
- Reporting





# **Planning**

- Network Design
- Monitoring Strategy
- Representativeness
- Meeting Monitoring Requirements
- Funding Needs
- Resources (Staffing, Equipment)



# **Field Operations**

- Use of approved analyzers and samplers for monitoring objective (FRM,FEM)
- Use of analyzers and samplers according to FRM/FEM requirements
- Following documented sampling procedures
- Proper siting of monitoring stations, samplers, and probes
- Maintenance capacity
- Cross-training
- Site housekeeping
- Age of equipment
- Site safety concerns





# **Laboratory Operations**

- Use of appropriate analytical equipment
- Following documented analytical procedures
- Cross-training
- Maintenance capabilities
- Housekeeping
- Age of equipment
- Sample storage





# **Quality Assurance and Quality Control**

- Approved and updated QMP and QAPP
- Consistent with EPA's Quality System
- Independence
- Proper collocated sampling
- QC checks (zero/precision/span checks, calibrations, etc) conducted properly
- QC checks conducted at the correct frequency
- Documented QA data reviews
- Separate instruments and standards for QA
- Review of electronic traces
- Audits



# **Data Management**

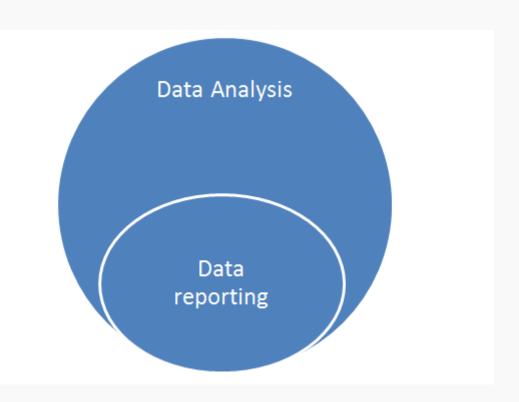
- Data acquisition system
- Data backup
- Data flow SOP or flowchart
- Organization (can documentation actually be found?)
- Minute data
- Archival (paper and electronic)





# Reporting

- Data in AQS
- Timely reporting
- Correct flagging
- Correct null coding
- Metadata
- Certification
- AIRNow





#### References

#### 40 CFR Part 58, Appendix A, Section 2.5

Regulations - Requirements that *must* be followed

#### **QA Handbook**

Guidance and details on how best to perform a complete and effective audit

#### **TSA Guidance Document**

In development by the TSA workgroup – Considered best practice for conducting a TSA

#### Who Audits Who?



#### Back to 40 CFR Part 58, Appendix A:

"Technical systems audits of each PQAO shall be conducted at least every 3 years by the appropriate EPA Regional Office and reported to the AQS."

The EPA Regional Offices have the responsibility to conduct Technical Systems Audits.



#### When Do We Do TSAs?



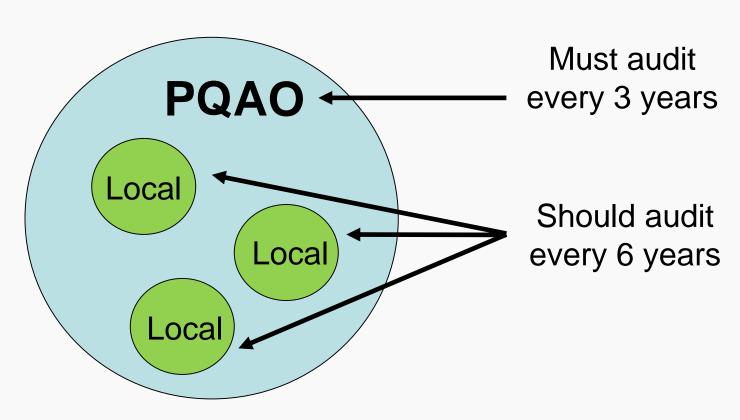


- The EPA Regional Offices are required to conduct TSAs on PQAOs in their respective regions at least every 3 years.
- If a PQAO is made up of more than one monitoring organization, all monitoring organizations in the PQAO should be audited within 6 years.
- EPA Regional staff may follow up with more frequent TSAs if deficiencies are noted that require attention

#### When Do We Do TSAs?



# Consolidated PQAO with 3 monitoring agencies



# How to Conduct Effective TSAs



- Tools!
- Pre-audit activities
- On-site assessment & interviews
- Post-site assessment activities

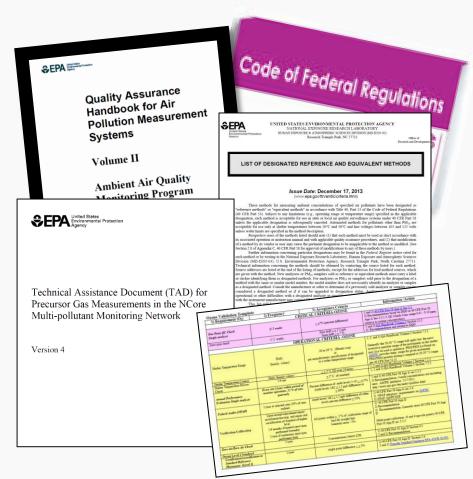
TSAs cover a lot of territory in a short amount of time! It is important to be prepared and organized!





#### **Gather Your Tools**

- ✓ CFR
- ✓ QA Handbook
  - Validation Templates
- ✓ Guidance Documents
- ✓ FRM/FEM Designations
- ✓ Audit Forms
- ✓ AQS
- ✓ Time!!!



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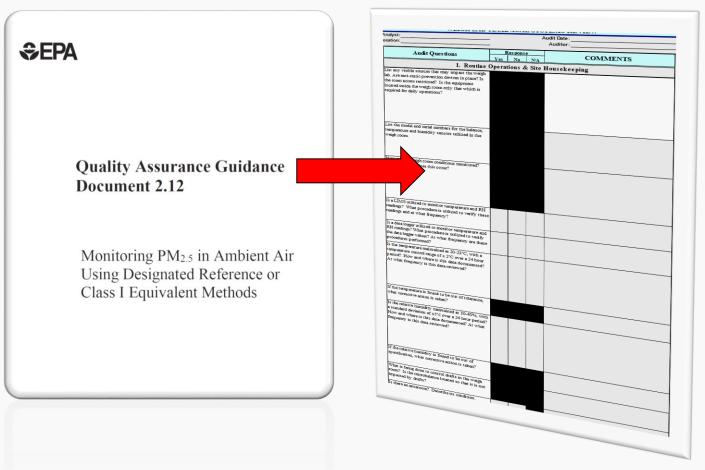


# TSA Questionnaire

- Use EPA
questionnaire
directly, or modify it
to your agency's
needs!



#### **Individual Method Checklists**



Utilize
those
available
or make
your own!

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# Plan & Organize

- Review the agency's monitoring network
  - Does the agency have a PM<sub>10</sub> or PM<sub>2.5</sub> weigh lab?
  - Does the agency do trace-level or near-road monitoring?
  - Does the agency participate in NATTS or special purpose toxics monitoring?
  - Is there an analytical lab involved?
- Know the methods you are auditing!





#### **Balance Resources**

- How much time do you need to complete your audit?
  - Recommend at least one week per agency
- Based on the size & scope of the network, do you have the right team of auditors assembled?
- Talk to your management if you think you may need additional time or resources
- Complete as much prep work as you can in-house, in order to optimize time available in the field



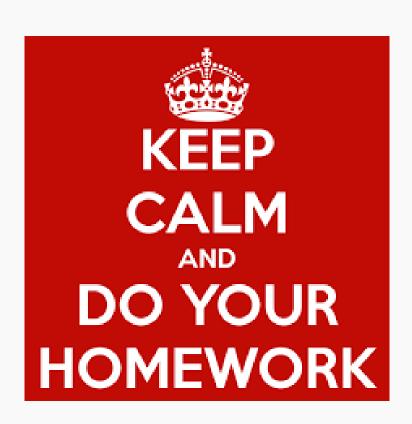
# **Communicate with the Agency**

- Schedule the audit with the agency
- Send the agency contact your TSA questionnaire a month or more in advance of the audit
- Request copies of their quality documents
- Request a copy or link to their annual network plan





#### **Document Review**



#### – QAPP and SOPs

- Are any of these documents more than 5 years old?
- Have they been approved by EPA? If not, why?
- Do the stated procedures meet method requirements?
   FRM/FEM specifications?
- Are there <u>details</u> within the documents?
- Earmark any "red flags" as future questions to be asked during the TSA



- Review the responses provided by the agency in the TSA questionnaire
  - Do the responses line up with the QAPP/SOPs you have reviewed?
  - Were any questions left blank?
  - Do any answers make you go "Hmmm?"
- Earmark answers (or blanks) in the questionnaire for follow-up





#### **Review Data!!**

- Pull the agency's data from AQS
  - AMP 350 (Raw Data Report)
  - AMP 251 (QA Raw Data Assessment Report)
  - AMP 256 (QA Data Quality Indicator Report)
  - AMP 430 (Data Completeness Report)
  - AMP 480 (Design Value Report)
  - AMP 503 (Extract Sample Blank Data)
  - AMP 504 (Extract QA Data)
  - AMP 600 (Certification Evaluation & Concurrence)
- Mark data that catch your eye!



Code change?

#### The AMP 350 Tells a Story

What malfunctioned?
Where is maintenance & recalibration?

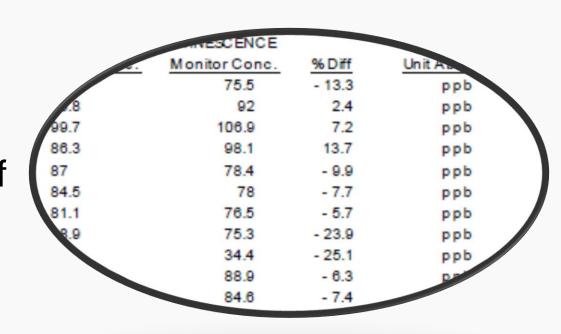
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2	4.7	4.1	4.1	5.5	5.2	2.6	. 1.3	2.0	2.9	2.2	1.9	1.0	.9	.7	.7	2	.8	. 6	. 6	.6	. 5	.6	, 8	1.0	24	5.5
3	1.5	. 9	.7	.7	. 6	. 6	.6	1.0	1.0	.7	.7	1.3	1.1	1.5	2.0	. 9	.5	.5	,5	.4	. 5	.5	.4	.5	24	1.9
4	1.5	.7	. 5	-4	.4	, 4	4	.4	.8	2,5	3.6	4.9	8.6	1.3	. 9	.8	.7	.7	.7	.8	.5	.4	.5	.4	24	8.6
5	2.6	1.0	.7	. 6	. 6	.6	7	.7	. 9	1.1	1.9	2.7	BF	AN .	AN	AM	AN	AN	AN	AN	AN	AN	AN	AN	12	2.7
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15	4.4	1.7	1.5	1.2	1,2	, 5	. 5	.6	2.3	4.3	4.4	4.7	8.5	13.2	12.9	10.1	8,1	8.3	5.7	2.1	. 8	5	.4	- 4	24	13.2
16	4.6	1.4	.7	.5	.5	.4	-6	.5	.4	1.0	4.9	8.5	8.8	6.2	5.3	4.9	17.6	21.7	6.7	2.6	1.6	1.7	2.0	2.2	24	21.7
17	4.0	1.5	. 9	.8	. 8	.7	. 6	. 5	.5	2.8	4.7	4.1	3.7	3.3	3.1	2.8	2.4	1.9	1.5	1.4	1.2	.1,1	1,1	1.0	24	4.7
18	3.6	1.9	1.5	1.1	. 6	. 9	. 9	.9	. 8	2.1	3.9	5.3	12.9	8.9	6.7	5.7	6.5	5.5	3.1	1.8	1.1	. 5	. 4	.3	24	12.9
19	3.7	1.1	.7	.7	.7	. 6	. 6	.5	.7	1.8	3.4	7.0	BF	10.0	6.7 .		3.3	3.0	2.9	2.8	2.3	2,1	1.7	1,6	23	10.0
20	3.8	2.5	1.8	1.6	1.7	1.0	.7	. 6	1.2	3.0	3.7	6.5	9.2	8.7	7.3	8.0	6.1	5.0	5.4	6,0	5.8	4.9	4.5	3.1	24	9.2
21	3.8	1.9	1.4	.9	.8	1.3	1.0	.9	1.4	1.6	2.4	4.7	7.8	10.7	6.6	5.1	4.2	2.5	1.9	1.7	1.2	.7	.5	. 5	24	10.7
22	3.1	1.2	. 8	.7	.8	.4	. 5	.5	.7	.6	1.0	7.4	28.6	18.1	9.2	4.3	2.5	1.5	1,3	1,3	1,5	3,2	4.0	2.9	24	28.6
23	4.1	4.7	12.5	13.1	8.0	2.5	2.0	1.0	.3	.3	.2	,1	.2	.1	.1	. 9	.1	.0	. 0	. 0	٥.	.1	.1	. 0	24	13.1
24	1.5	. 5	.3	.1	.0	. 0	. 2	.1	.3	- 6	-4	.3	.4	.1	.1	.1	- 0	, 0	.0	. 0	. 0	.0	.0	.0	24	1.5
25	3.2	1.3	1.1	2.3	3.2	3.2	3.6	3.9	5.0	3.5	3.5	10.4	6.3	4.4	4.3	4.4	4.9	2.8	2.6	1.8	1.9	1.4	. 9	. 8	24	10.4
26	2.4	1.0	. 6	-3	.3	. 4	.3	.6	. 6	1.4	2.2	2.1	2.7	3.3	2.1	1.7	2.1	2.8	4.6	5.5	1.9	1.2	1.4	2.2	24	5.5
27	3.6	1.1	.7	.4	-3	.1	. 2	. 2	-4	5.4	5.6	4.9	13.3	5.4	1.1	.5	.2	.1	.2	- 0	.0	.0	. 0	. 0	24	13.3
28	4.0	1.2	.9	- 6	.5	. 6	-4	.4	.5	.5	1.4	8.2	6.7	3.6	2.5	1.9	2.1	2.0	1.1	.5	.2	-1	.3	. 2	24	8.2
29	3.3	1.2	.7	-7	.6	.6	. 8	.6	1.4	1.7	2.1	23.0		27.1	23.7	14.1	10.0	14.7	4.1	2.4	1.4	1.4	1.9	4.3	24	27.1
30	7.9	4.0	2.8	2.5	2.4	2.2	2.3	3.6	6.4	5.3	4.6	3.6	2.6	2.4	2.4	4.4	7.2	2.3	1.2	1.0	. 9	.7	.4	.4	24	7.9

#### Mark charts needing further review at the agency!



#### QA/QC Data Review: AMP 251

- Look for high %d's!
- Reconcile against the AMP 350
- Can be hundreds of pages long for a large agency, though!





# Handy Tool: AMP 504 Sort the QA Data in Excel!

Action Type	Site	Param	POC	Date	Days	Method	Unit	Monitor Conc	Actual Conc	% Diff
1-Point QC	3002	44201	1	17-Jul-13	15	047	008	73.4	75	-2.1%
1-Point QC	3002	44201	1	22-Jul-13	5	047	008	74.4	75	-0.8%
1-Point QC	3002	44201	1	22-Jul-13	0	047	008	74.8	75	-0.3%
1-Point QC	3002	44201	1	31-Jul-13	9	047	008	73	75	-2.7%
1-Point QC	3002	44201	1	8-Aug-13	8	047	008	82.4	<b>75</b>	9.9%
1-Point QC	3002	44201	1	8-Aug-13	0	047	800	75	75	0.0%
1-Point QC	3002	44201	1	21-Aug-13	13	047	008	74.4	75	-0.8%
1-Point QC	3002	44201	1	9-Oct-13	49	047	008	105	75.6	38.9%
1-Point QC	3002	44201	1	9-Oct-13	0	047	008	74	75.6	-2.1%
1-Point QC	3002	44201	1	14-Oct-13	5	047	008	41.8	76.2	-45.1%
1-Point QC	3002	44201	1	14-Oct-13	0	047	008	75.8	75.8	0.0%
1-Point QC	3002	44201	1	30-Oct-13	16	047	008	75	75.8	-1.1%
1-Point QC	3002	44201	1	19-Nov-13	20	047	008	74	74.8	-1.1%

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# **Summary Hit List**



- Rank & prioritize your preliminary findings
- Pack your briefcase (and laptop!)
  - Agency's TSA questionnaire response
  - Agency's quality documents
  - Data packages
  - Blank checklists & field logbooks for audit notes
  - Other tools
    - Camera
    - Range finder and/or tape wheel
    - Compass



# **Audit Time!**



- Entrance briefing with management
- Take the office tour!
  - File Room
  - Repair shop
  - Certification/QA shop
  - Warehouse
  - Laboratory



#### Have a Scribe!



- Document your findings –
   be specific and detailed!
- Have teammates record observations, as well as take notes during interviews with staff
- Notes from all auditors can be combined postaudit to make report writing easier!



#### Staff Interviews

- Go over the TSA questionnaire
- Ask clarifying questions from SOP review
- Talk to the staff who actually do the work
- Listen closely
- Trust, but verify!





# **Agency Records Review**



- Ask to see certification records from each pollutant category
- Choose sites at random
- Have agency staff pull 3 years of records
- Expiration dates?
- Are standards traceable?
  - Photometers
  - Gas Calibrator Flows
  - Other flow devices (PM<sub>2.5</sub>, PM<sub>10</sub>, lead)
  - Thermometers
  - Barometers
  - Mass reference standards (check weights)



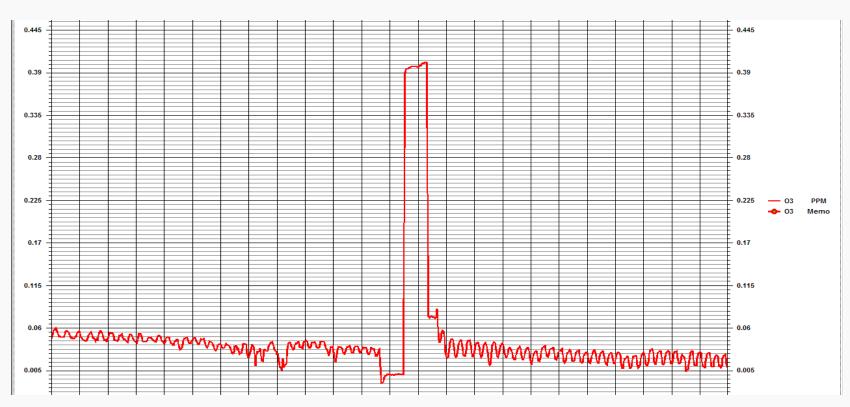
# **Agency Records Review**



- Ask to see records for all data marked during pre-audit activities
- QA/QC Records
  - Calibrations
  - Verifications
  - Maintenance
- Is there enough detail in the records that you can easily recreate events & justify null value codes?



#### **Review Minute Data!**



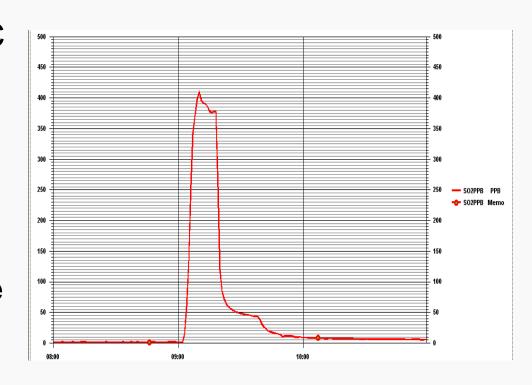
It will illuminate problems that daily summary (hourly) reports will mask!

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# **Review Minute Data!**

- Shows the stability of QC checks
  - Adherence to SOPs?
  - Good quality procedures?
- Opportunity to talk to QA staff and learn & observe their data handling procedures





### **Even More Records...**

- Logbooks
- Chain of custody forms
- If it's not documented, it didn't happen!





# **Visit Field Sites**

- Spread out!
  - Don't just visit the sites that are near the central office!
  - Visit multiple sites to get a well-rounded view of the network
    - District offices, different operators
  - Auditors can break into teams, if needed, in order to maximize time









# **Field Operations**

- Housekeeping
- Review logbooks
- Talk to the field technician!
  - Demonstrate procedures?
- Check sample lines
  - Proper plumbing?
  - Condensation free?
  - Approved materials?
- Evaluate Appendix E criteria
  - Take physical measurements!





# **Exit Briefing**



- Pre-meeting with audit team to review all issues identified
- Categorize findings and develop a briefing summary
  - Outline with speaking points can be used as a framework for building the TSA report later!
  - Organize findings so that conversation flows in the most logical manner
  - Have regulatory citations on hand
  - Remember your audience!
- Be prepared to discuss potential corrective actions with agency staff



# **Exit Briefing**



### Face-to-face exit briefing is preferred

- Important to have the right people in the room during the meeting
- Clearly communicate the audit findings
- Be factual, concise, and professional
- Have team scribe take notes during the briefing, so any follow-up questions or requests are documented



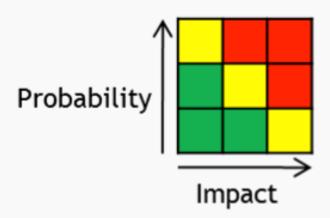
# A Few Words of Advice

- You can't account & plan for everything in a TSA
  - Findings revealed on-site (unplanned) may require additional records requests
  - Some findings may need additional research, analysis, or discussion with OAQPS
  - Discuss these pending issues during the exit briefing so there are no surprises!
  - Wrap up any post-audit information gathering within one week, if possible
- Follow-up conference call needed with agency to discuss outcome of additional analyses and/or to "close the loop" on outstanding issues



# Write the TSA Report

- Immediately start writing!!
  - Details will still be fresh in the notes
  - If possible, request from management a week to focus solely on drafting the report
- Gather all logbooks and notes from audit team
- Document areas not reviewed during the on-site assessment, if necessary
- Route the report through internal technical and administrative review prior to issuance





# The report should capture only the biggest ticket items!



- Define Findings Categories
- Rank the findings in order to illustrate significance
- Provide clear, specific language in the report
  - Be concise and remember the audience!
  - Cite the appropriate regulations, QAPPs, SOPs
- Establish the minimum expected corrective action



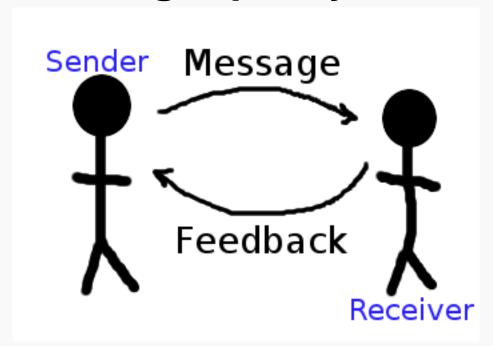
# **Next Steps**



- TSA does not end with issuance of report!
- Review agency response and Corrective Action Plan
- Track completion of corrective action items and assess efficacy
- Continue to communicate with agency & provide support until all identified issues have been successfully closed out



# Continued communications and followthrough are critical to ensure success and high quality data!



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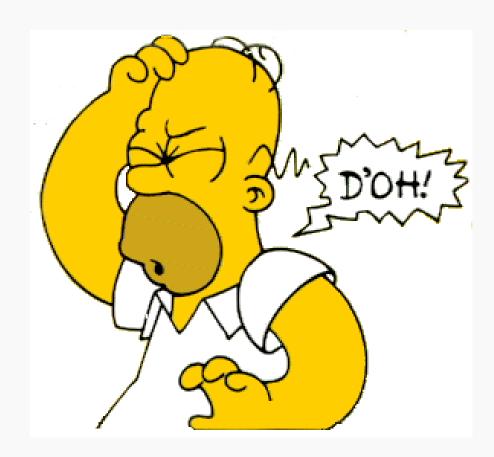
# Final Step: Enter the TSA close-out information in AQS!

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					1096	0251	20110929					
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					1096	0635	20120927					
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We have had general TSA Guidance in the QA Handbook for a while, but...

At the Atlanta National Monitoring Conference we found... Regionally, we're all doing different things





# So, we created the Technical Systems Audit Workgroup!

## All 10 EPA regional offices invited to participate

#### Goal of the TSA Workgroup:

To develop a more consistent national TSA approach by:

- Developing audit guidance to guide all auditors in a consistent approach – Technical Systems Audit Guidance Document
- Building auditor expertise
- Developing audit tools
- Discussing audit follow-up
- Providing a forum to discuss audit findings and actions





# What's going on right now?

### Meet every three weeks

# Major focus right now is developing the TSA Guidance Document (TSAGD)

- Discussed how each region does TSAs according to section
- Completed rough drafts of all Sections
- Developing a new Excel-based TSA Questionnaire
- Regional participation in writing the sections
- Plan to include audit templates specific to pollutants and/or networks
- Looking to have a draft by end of the year





# Where are we going in the future?

- Development of statistical tools to analyze monitoring and QC data
- Conduct webinars for auditors to develop auditing skills
- Provide a forum to discuss TSA audits with a national group of auditors





# At the end of the day, what do we want?

- All regions to use a consistent audit approach
- A guidance document for TSAs that documents requirements and best practices we can all follow
- Trained, technical auditors that can efficiently assess a network
- An independent forum where auditors can ask questions about auditing and techniques
- Consistent follow-up after audits to solve issues discovered in the audit

Finally, and most importantly, we want to ensure quality data is being generated from our monitoring networks!

### **TSA Benefits**



# TSAs aren't just for EPA...

- One of the best practices an air agency can implement is to conduct internal systems audits on a routine basis!
- Include in QAPP
- States, locals, and tribal QA Staff



### **TSA Benefits**



## Mimic the EPA!

- Use same approach as the federal TSA!
- Develop a TSA audit form based on your agency's quality system requirements
- Develop audit schedule
  - Recommend annual audits, at minimum
- Document findings in reports routed through chain-ofcommand



#### **TSA Benefits**



## **Internal TSA Benefits**

- Illustrates areas where supplemental training may be beneficial
- Prevents data loss
- Improves overall data quality
- Enhances quality system
- Small issues won't become big issues!
- Significantly reduces EPA findings during the regulatory TSA!