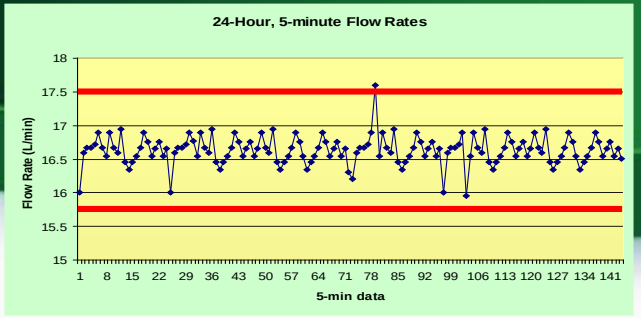
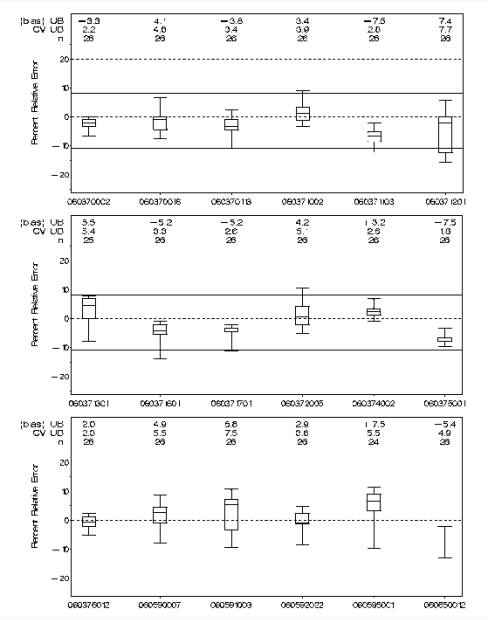


Quality System For the Ambient Air Monitoring Program



Thanks

Ambient Air QA Team

Dennis Crumpler
Greg Noah
Mike Papp
Solomon Ricks
Mark Shanis
Jenia Tufts
Tim Hanley

EPA Regions

Bob Judge -R1
Kia Hence -R3
Doug Jager/Stephanie McCarthy –R4
Mathew Plate – R9

Others

Melinda Ronca-Battista- Northern Arizona University

Training Agenda

- Start out slow….
  - QA Policy/Regs/Guidance-*(3/28/16 Reg Changes)*
  - Documentation- E-logbooks
- and then it gets rough!
  - Criteria Pollutants
    - PM2.5/PM10- *Dennis Crumpler/Tim Hanley*
      - ***Break 10:15***
    - Gases – *Mark Shanis*
    - AA-PGVP – *(Mike Papp for Solomon Ricks)*
      - ***-- Lunch 12:00***
    - Pb- *Greg Noah*
  - Assessments
    - Data Quality Indicator Statistics -*Melinda Ronca Battista*
      - ***Break 2:30***
    - Regional Assessments- *Bob Judge, Kia Hence, Doug Jager, Mat Plate*
    - Technical Systems Audits – *Stephanie McCarthy/Greg Noah*
    - Data Certification- *Mike Papp*

Q&A----Today and Tomorrow-Write Questions Down!

A Mandate for Quality- The Clean Air Act

"(2) Establishment of a national network to monitor, collect, and compile data with quantification of certainty in the status and trends of air emissions, deposition, air quality, surface water quality, forest condition, and visibility impairment and to ensure the comparability of air quality data collected in different States and obtained from different nations."

How do we quantify certainty and ensure comparability?

Q:\COMP\ENVIR1\CLEANAIR.001

Sec. 103 CLEAN AIR ACT 10

(c) AIR POLLUTANT MONITORING, ANALYSIS, MODELING, AND INVENTORY RESEARCH.—In carrying out subsection (a), the Administrator shall conduct a program of research, testing, and development of methods for sampling, measurement, monitoring, analysis, and modeling of air pollutants. Such program shall include the following elements:

(1) Consideration of individual, as well as complex mixtures of, air pollutants and their chemical transformations in the atmosphere.

(2) Establishment of a national network to monitor, collect, and compile data with quantification of certainty in the status and trends of air emissions, deposition, air quality, surface water quality, forest condition, and visibility impairment, and to ensure the comparability of air quality data collected in different States and obtained from different nations.

(3) Development of improved methods and technologies for sampling, measurement, monitoring, analysis, and modeling to increase understanding of the sources of ozone percursors, ozone formation, ozone transport, regional influences on urban ozone, regional ozone trends, and interactions of ozone with other pollutants. Emphasis shall be placed on those techniques which—

(A) improve the ability to inventory emissions of volatile organic compounds and nitrogen oxides that contribute to urban air pollution, including anthropogenic and natural sources;

(B) improve the understanding of the mechanism through which anthropogenic and biogenic volatile organic compounds react to form ozone and other oxidants; and

(C) improve the ability to identify and evaluate region-specific prevention and control options for ozone pollution.

(4) Submission of periodic reports to the Congress, not less than once every 5 years, which evaluate and assess the effectiveness of air pollution control regulations and programs using monitoring and modeling data obtained pursuant to this subsection.

(d) ENVIRONMENTAL HEALTH EFFECTS RESEARCH.—(1) The Administrator, in consultation with the Secretary of Health and Human Services, shall conduct a research program on the short-term and long-term effects of air pollutants, including wood smoke, on human health. In conducting such research program the Administrator—

(A) shall conduct studies, including epidemiological, clinical, and laboratory and field studies, as necessary to identify and evaluate exposure to and effects of air pollutants on human health;

(B) may utilize, on a reimbursable basis, the facilities of existing Federal scientific laboratories and research centers; and

(C) shall consult with other Federal agencies to ensure that similar research being conducted in other agencies is coordinated to avoid duplication.

(2) In conducting the research program under this subsection, the Administrator shall develop methods and techniques necessary

February 24, 2004

Quality System

E4- A structured and documented management system….. of an organization for ensuring quality in its work processes, products (items) and services.

A series of management activities – including planning, implementation, and assessment – necessary to provide confidence in the **quality** & **defensibility** of data.

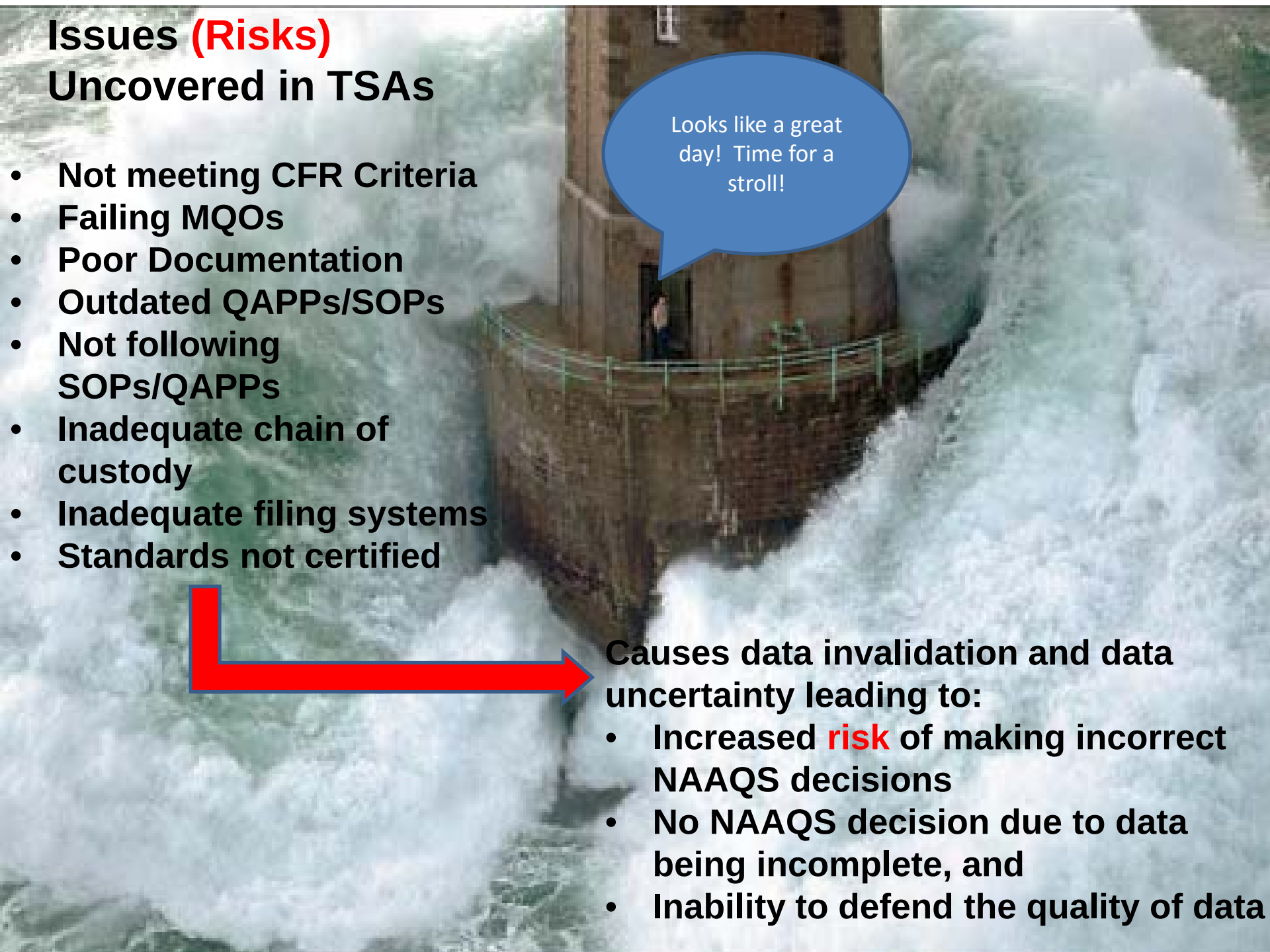
Some decisions will be inappropriate (wrong) due to
data uncertainty… (error)

…the difference between

your measurement (estimate)
and the “truth”

Premise 1 - All estimates have error so all decisions made with estimates have risks.
Premise 2- We can’t afford 100% certainty in our decisions

Issues (Risks) Uncovered in TSAs



- Not meeting CFR Criteria
- Failing MQOs
- Poor Documentation
- Outdated QAPPs/SOPs
- Not following SOPs/QAPPs
- Inadequate chain of custody
- Inadequate filing systems
- Standards not certified

Causes data invalidation and data uncertainty leading to:

- Increased risk of making incorrect NAAQS decisions
- No NAAQS decision due to data being incomplete, and
- Inability to defend the quality of data

Ambient Air Quality System

Quantifying and Controlling Uncertainty in Order to Minimize the risks of Decision Errors

Uncertainty = **Natural (Population) Variability** + **Measurement Uncertainty**

Spatial/Temporal

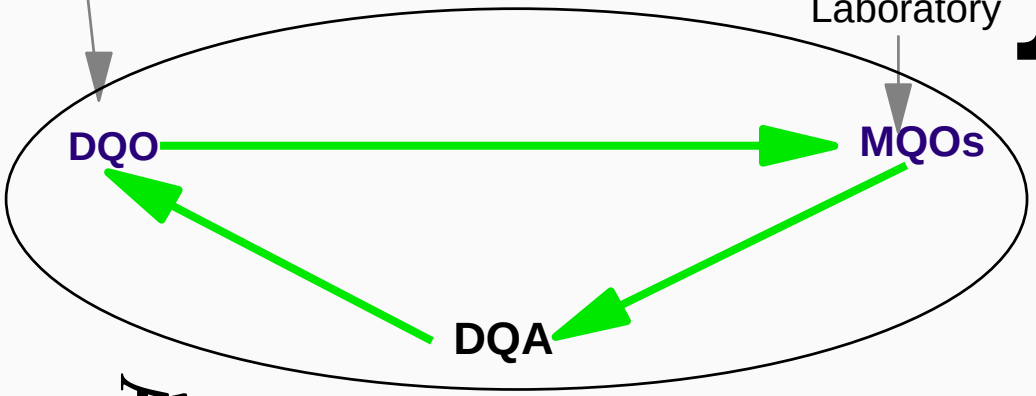
1. Representativeness

Preparation
Field
Laboratory

Data Quality Indicators

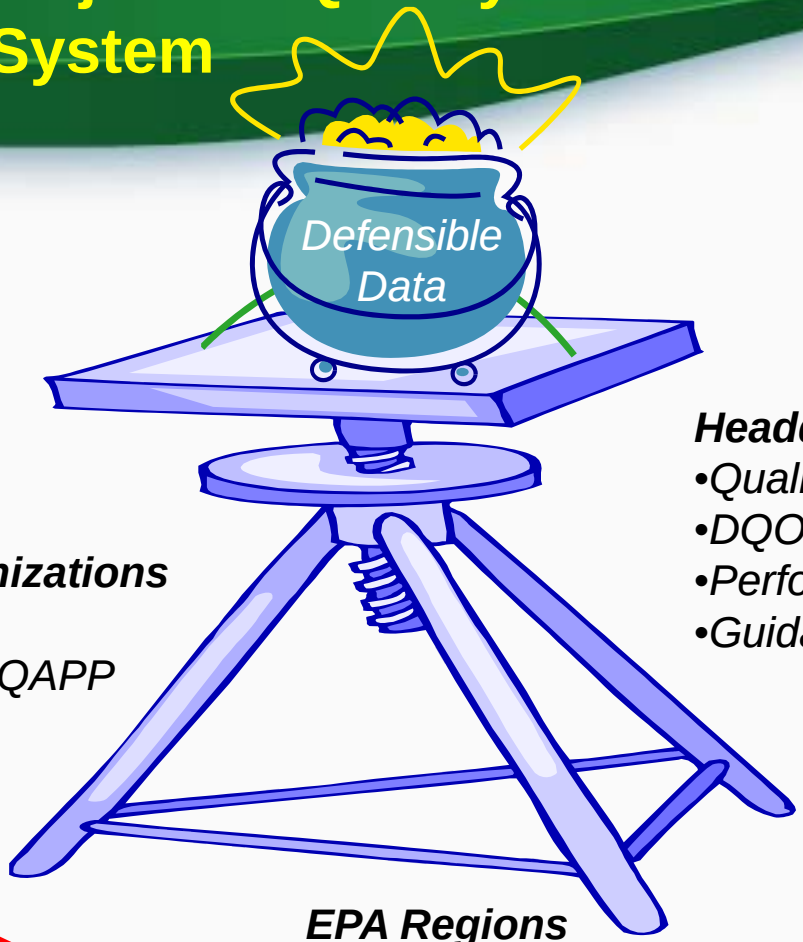
2.Precision*
3.Bias*
4. Completeness*
5. Comparability
6. Detectability*

* Defined in App A



The Quality System → Documented in the QAPP

Balanced/Objective Quality System



Headquarters –OAQPS
- *Quality System Requirements*
- *DQOs*
- *Performance Evaluation Programs*
- *Guidance/Technical Memos/QA EYE*

Monitoring Organizations
- *QMP*
- *Network Specific QAPP*
- *SOPs*
- *Quality Control*
- *Data Validation*

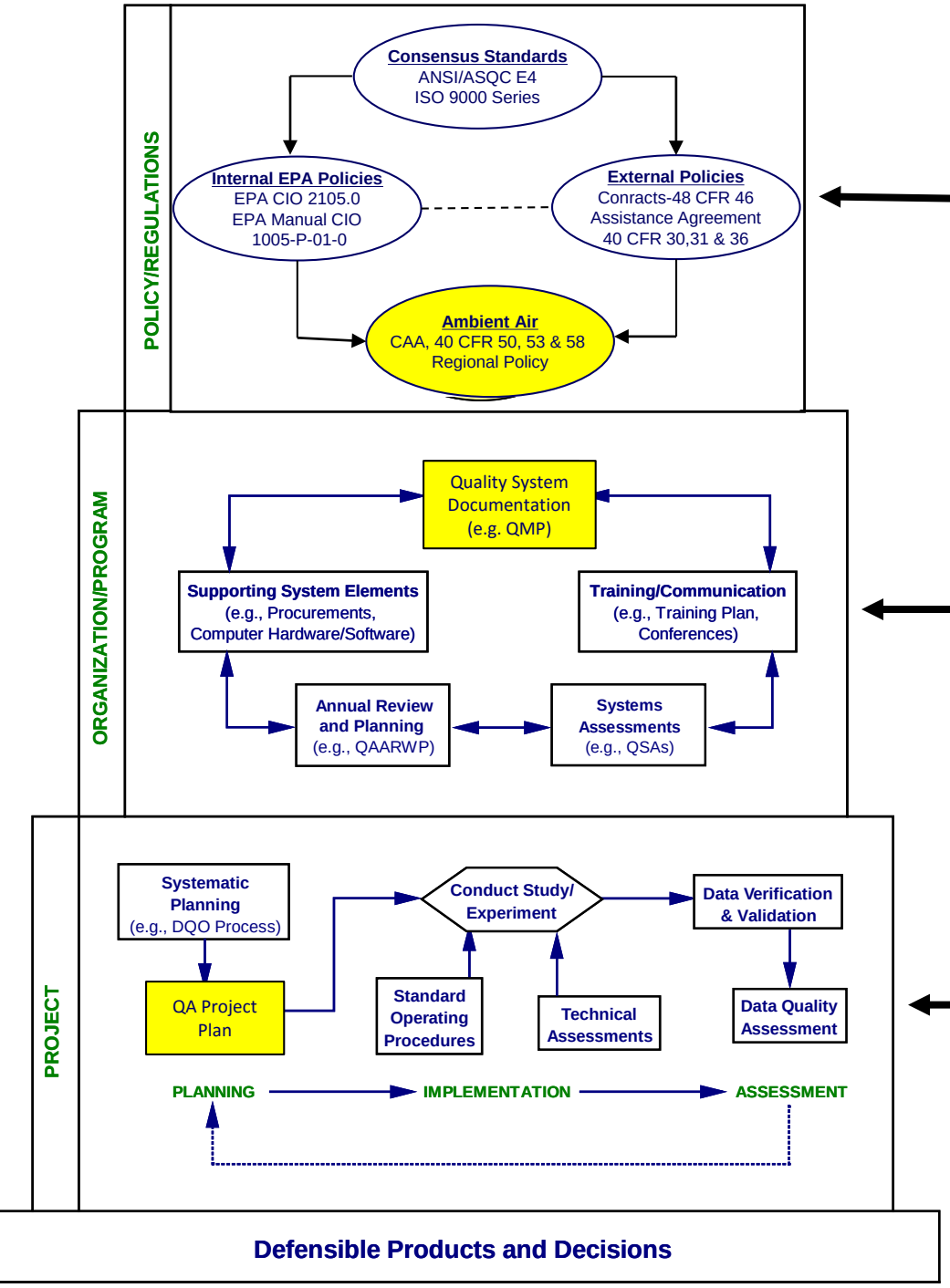
communication

communication

EPA Regions
- *QMP/QAPP Approval*
- *Technical Systems Audits*
- *Performance Evaluation Programs*
- *Technical Assistance*

QA Policy, Regulations and Guidance

National Ambient Air Monitoring Conference August 2016



Policy & Regulations

Program

Project

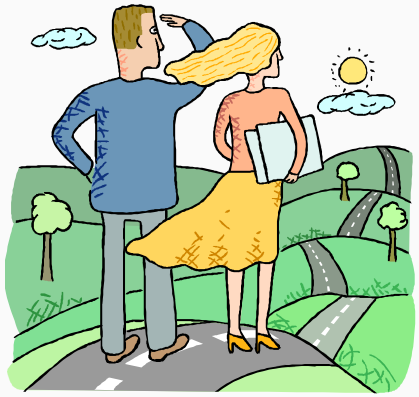
Defensible- able to withstand any reasonable challenge

40 CFR Pt. 58 App. A QA Requirements

- **Section 1**
  - General Info
  - PQAO
  - Applicability
  - Definitions
- **Section 2**
  - QMPs/QAPPs*
  - Independent quality management function*
  - DQOs- (EPA)
  - NPAP/PEP
  - TSAs-(EPA Regions)
  - NIST Traceable Standards

* EPA QA Policy

- **Section 3**
  - Quality Control and Assessment
- **Section 4**
  - QA Stats
- **Section 5-**
  - Reporting Req.



AMBIENT AIR QC

Title Change
Pg 17280- Title

Quality Assurance Requirements for Monitors used in Evaluations of National Ambient Air Quality Standards

Appendix A Formatting

- One stop shop for each pollutant
  - 4 gaseous pollutant about the same
  - PM pollutants separate
- Section 4,5, 6 virtually the same as before

Appendix A Format

1. GENERAL INFORMATION
   - 1.1 Applicability
   - 1.2 Primary Quality Assurance Organization Moved up
   - 1.3 Definitions (precision, bias etc)
   - 1.4 Measurement Quality Checks
   - 1.5 Assessments and Reports.

2. QUALITY SYSTEM REQUIREMENTS
   - 2.1 Quality Management Plans and Quality Assurance Project Plans.
   - 2.2 Independence of Quality Assurance.
   - 2.3. Data Quality Performance Requirements.
   - 2.4 National Performance Evaluation Programs.
   - 2.5 Technical Systems Audit Program.
   - 2.6 Gaseous and Flow Rate Audit Standards.
   - 2.7 Primary Requirements and Guidance.

3. MEASUREMENT QUALITY CHECK REQUIREMENTS (Modified)
   - 3.1 Gaseous Analyzers of SO_2, NO_2, O_3, and CO.
     - 3.1.1 One-Point Quality Control Check for SO_2, NO_2, O_3, and CO.
     - 3.1.2 Annual performance evaluation for SO_2, NO_2, O_3, and CO
     - 3.1.3 National Performance Audit Program (Added)
   - 3.2 $PM_{2.5}$
     - 3.2.1 Flow Rate Verification
     - 3.2.2 Semi-Annual Flow Rate Audit
     - 3.2.3 Collocated Sampling.
     - 3.2.4 $PM_{2.5}$ Performance Evaluation Program (PEP) Procedures.
   - 3.3 PM_{10}
     - 3.3.1 Flow Rate Verification for Low Volume Samplers
     - 3.3.2 Flow Rate Verification for High Volume Samplers
     - 3.3.3 Semi-Annual Flow Rate Audit.
     - 3.3.4 Collocated Sampling for Manual PM_{10}
   - 3.4 Pb Methods
     - 3.4.1 Flow Rate Verification for Low Volume Samplers
     - 3.4.2 Flow Rate Verification for High Volume Samplers
     - 3.4.3 Semi-Annual Flow Rate Audit.
     - 3.4.4 Collocated Sampling for TSP
     - 3.4.5 Collocated Sampling for Pb-PM_{10}
     - 3.4.6 Pb Analysis Audits
     - 3.4.7 Performance Evaluation Program (PEP) Procedures

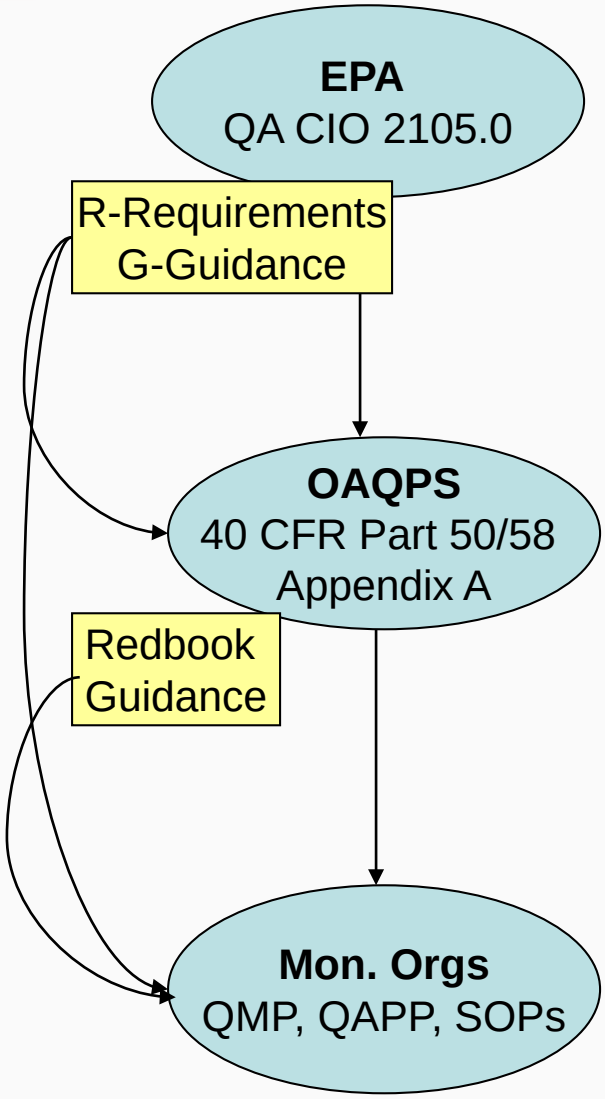
Important Reg Changes

- PSD sent PSD back to App B
  - Defined QA responsibilities based on permitting organization
  - Described how NPAP/PEP will work for PSD
    - Optional if data not used for NAAQS purposes.
- Removed QA Requirements for:
  - $PM_{10-2.5}$ and Pb at non-source NCore.
- PQAOs
  - Added oversight language

    “the agency identified as the PQAO (usually the state agency) will be responsible for overseeing that the Appendix A requirements are being met by all consolidated locals within the PQAO”
  - Think about whether consolidation is appropriate
    - Are all locals within a PQAO producing the same quality data?
    - All QAPPS should mention all locals within a PQAO

Regulations vs Guidance

- Regulations
  - Must be followed
  - Usually minimum requirements.. more is better
- Guidance
  - More details on regulations
  - Provides additional suggestions or strongly suggests
  - Are not mandatory, but you need an acceptable alternative
  - You can help- QA Handbook Revision Workgroup



Monitoring Organization Documentation QMPs, QAPPS and SOPs

- **Quality Management Plan (QMP) **** → **Ford**
  - Describes orgs quality system
  - Establishes capability/commitment

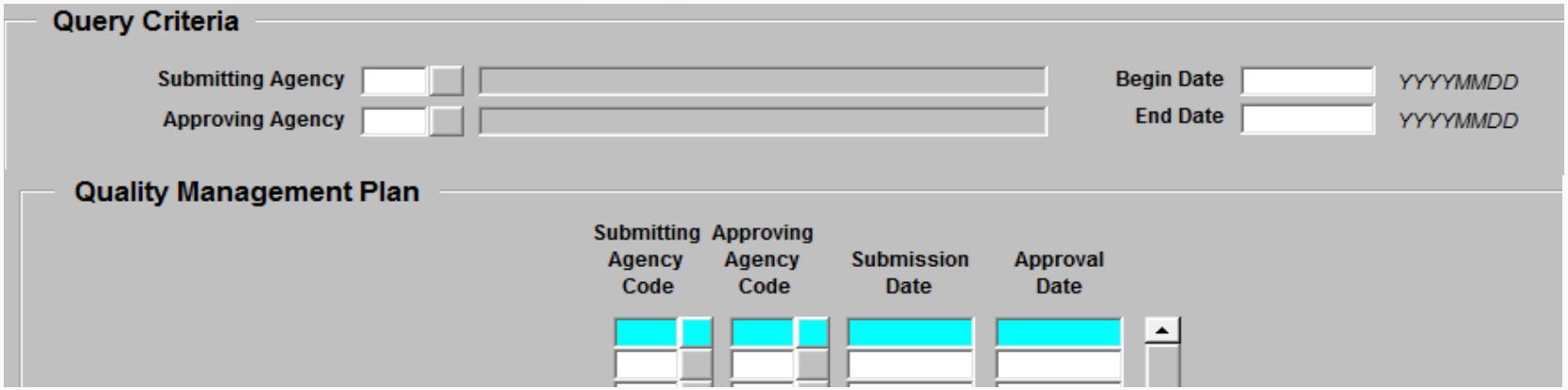
Quality is Job 1

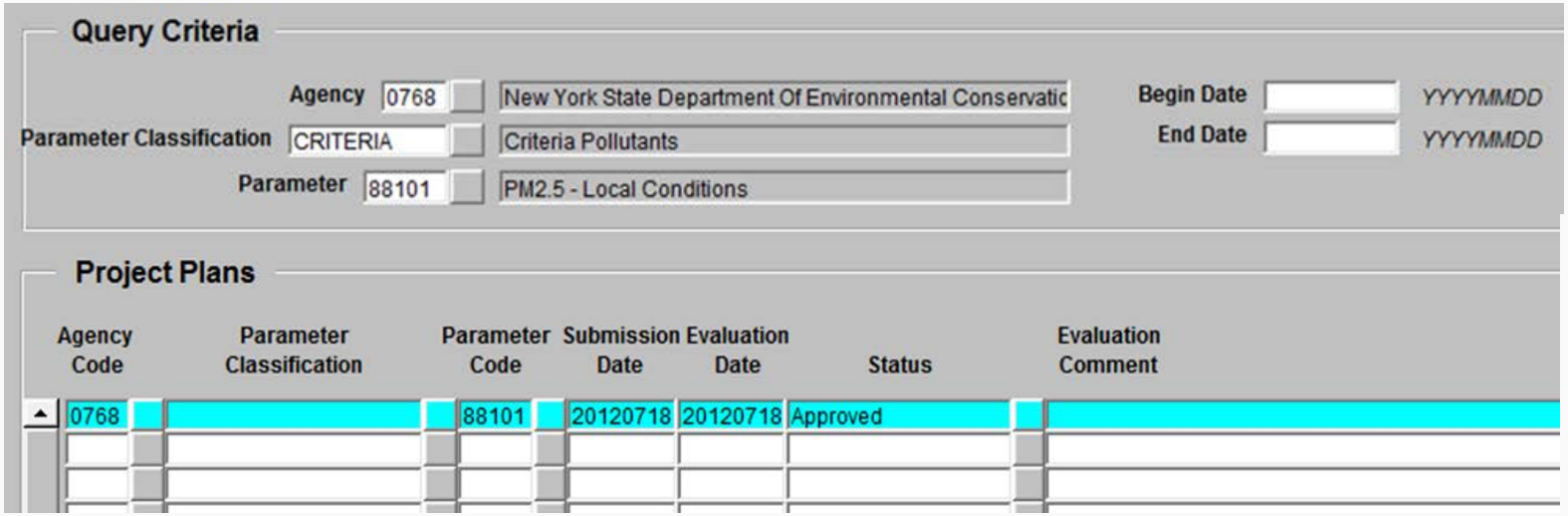
- **QA Project Plan (QAPP)**** → **Mustang**
  - Identifies the reasons for collecting data and for collecting it in a specific way
  - Documents how the data are collected and how quality is maintained
  - Is now part of data certification. **QAPP should be updated every 5 years. ≤5 (G); 6-10 (Y); >10 R**

- **Standard Operating Procedures (SOP)** → **Engine**
  - Ensures consistency
    - From day to day
    - From one person to the next

**** Required to be Reported to AQS including courtesy submission to Regions that allow QAPP self-approval**

QMP and QAPP Entries to AQS





QAPP Data on AQS

https://aqs.epa.gov/aqsweb/codes/data/QAPP.html

Quality Assurance Project Plans (QAPPS)

Sorted On: Agency Code

Last Updated on 7/23/2014 at 14:13:48

Download Delimited Version of the Code Table

Return to TTN Code Pages

Page: 1 of 4

First Page Previous Page **Next Page** **Last Page**

< Agency Code >	< Agency Desc >	< Parameter Code >	< Parameter Desc >	< Parameter Class >	< Status >	< Submission Date >	< Evaluation Date >
		42401	Sulfur dioxide	None	Approved	2013-02-27	2013-02-27
		42101	Carbon monoxide	None	Approved	2013-02-27	2013-02-27
		88101	PM2.5 - Local Conditions	None	Approved	2013-02-27	2013-02-27
		44201	Ozone	None	Approved	2013-02-27	2013-02-27
		42401	Sulfur dioxide	None	Approved	2010-01-15	2010-11-02
		14129	Lead (TSP) LC	None	Approved	2010-01-16	2010-11-02
		88101	PM2.5 - Local Conditions	None	Approved	1999-01-01	1999-01-01
		85129	Lead PM10 LC FRM/FEM	None	Approved	2010-01-16	2010-11-02
		81102	PM10 Total 0-10um STP	None	Approved	2010-01-15	2010-11-02
		44201	Ozone	None	Approved	2010-01-15	2010-11-02
		12128	Lead (TSP) STP	None	Approved	2010-01-16	2010-11-02

QMPs will be posted soon

Independence of Quality Assurance

The monitoring organization must provide for a quality assurance management function:

The management system that determines and implements the quality policy defined in a monitoring organization's QMP

- must have sufficient technical expertise and management authority to conduct independent oversight
- should be organizationally independent of environmental data generation activities.

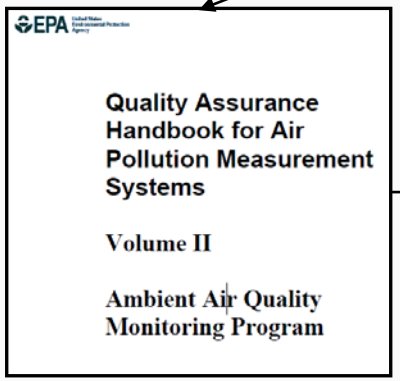
It's why we implement National Performance Evaluation Programs

Ya gotta be able to make the tough calls! and be consistent

Bottom Line #1
Develop your quality system

#1 CFR

- Follow all requirements unless a technical memo available (AMTIC)



Monitoring Organization QMP QAPP and SOPs

TSAs start here

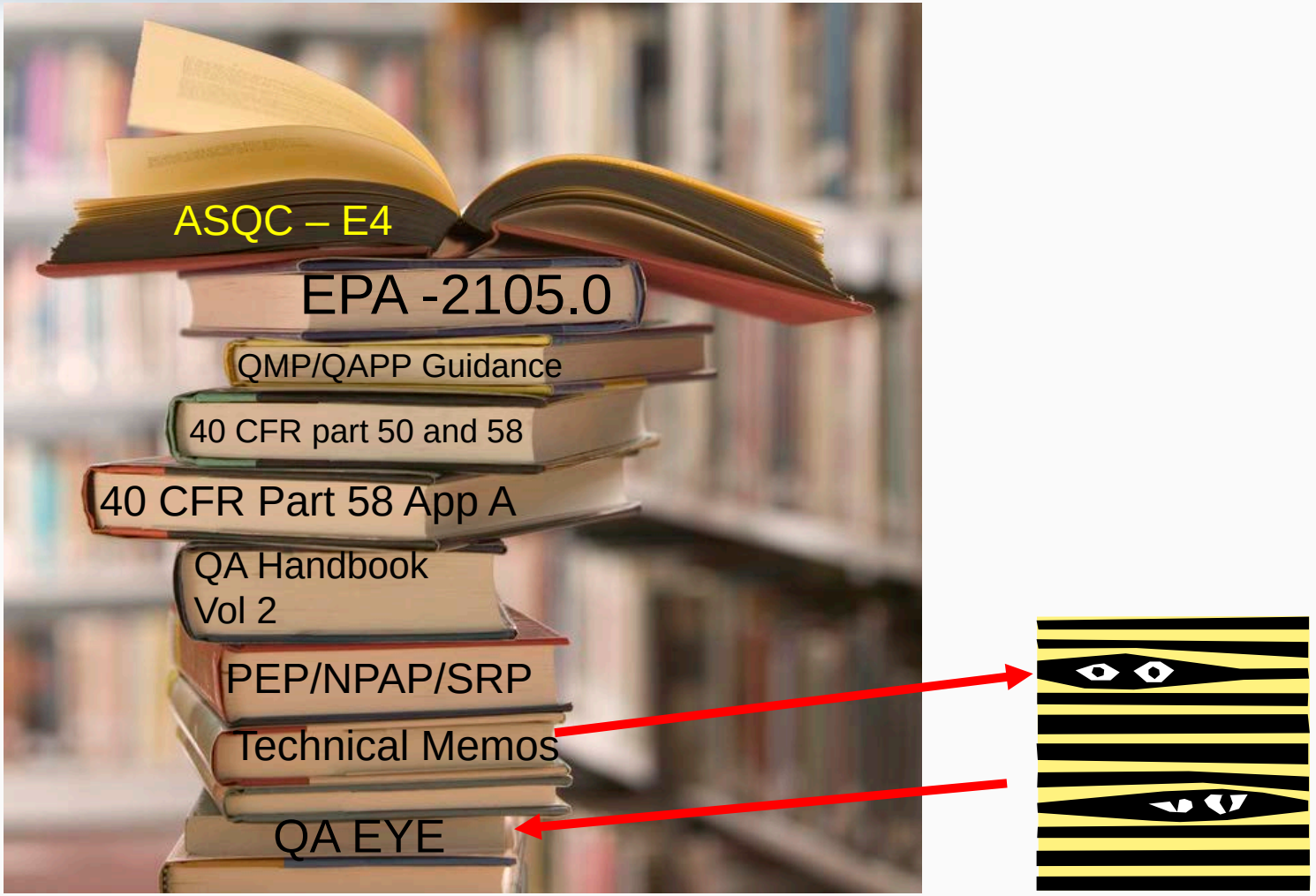
#2 QA Handbook

- Understand suggestions
- Understand the Validation Templates

#3 Monitoring Org QMP/QAPP/SOP

- Meets regs and includes Handbook suggestions or “approvable” equivalent.
- Regions on the hook to approve.
- QAPP/SOPs are the contract

Summer Reading List
What should be in your Library?



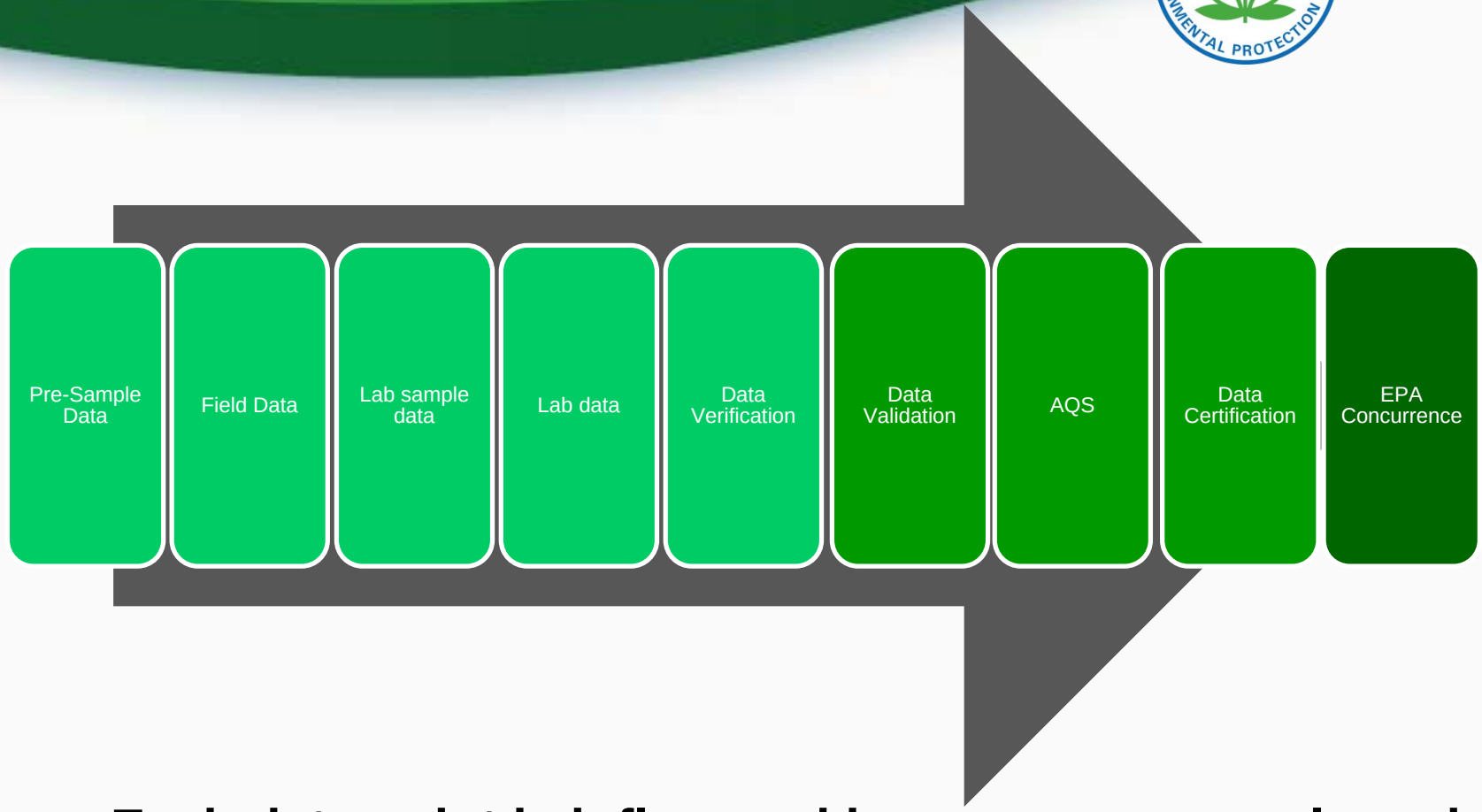
Documents and Records

Document, Document, Document….

File, File, File….

If it’s not documented, it did not happen!

Data flows…



Each data point is influenced by numerous people and processes. Thorough documentation is needed to ensure accurate data validation and data defensibility.

Documents/Records Questions?

What are your records?

- QMP/QAPPS/SOPs
- Training and certifications
- Logbooks
- Forms
  - Calibrations/Precision/QC-Checks
  - Maintenance
- Electronic and/or Paper Charts
  - Minute data
- Chain-of-Custody (CoC) forms
- Databases
- See QA Handbook (Table 5-1)

Are they organized?

- Documented filing procedure (QMP)
- Could someone find what they were looking for with little effort?

Where are your records?

- In the field, in the office
- Within the office, are they in one central location, or spread out across many offices?
- Avoid records being stored in the offices of individual employees

Are your records safe?

- Electronic back-up and in two systems/media
- Official files write-protected?

Do your records have enough detail to recreate an unusual event without staff having to add information years later?

The 5 Documentation W's

- **Who** is performing the work?
  - All data records should be signed and dated
- **What** pollutant, procedure, analyzer, calibrator?
  - Equipment IDs, makes & models
- **When** is the activity occurring?
  - Time and date, please!
- **Where** is the data being collected?
  - Identify the location of the site/data acquisition
- **Why** is the activity needed?
  - Be specific! Is it time for an annual recalibration per SOP, or has an instrument malfunctioned?

- Bound
- Page numbered
- Entries should be written in ink, signed, and dated.
- Corrections should be made with a single line through the incorrect entry, the site operator's initials, and the date of the correction.
- Do not leave large blank spaces in logbooks.
- Place an X in space that is unused.
- Do not back-fill!
- You can enter past information in your logbook, but enter it with today's date (and an explanation)!

Recommend that logbooks be scanned on some routine frequency; protects the written information, especially in the event of a disaster

What about Electronic Logbooks????

Electronic Logbooks Key Attributes

- **Integrity** - The system must ensure the integrity of the records it manages
- **Metadata/Identity** - Identify each record sufficiently to enable authorized personnel to retrieve, protect, and carry out the disposition of the records in the system
- **Backup** -The system must allow for records to be backed up to protect against information loss
- **Organization/Delegations-** The e-logbook system should be documented in a manner that identifies roles and responsibilities
- **Retrievability** -The system must retrieve records and be able top permit easy retrieval in a timely fashion
- **Auditability-**The system should be developed and documented in a manner that it can be tested (hardware and software) and reviewed.
- **e-Signatures/Legal signatures**
- **Information Security/Locking**
- **Data entry/data revision/correction**
- **Version Control**- E-logbooks will change and be revised over time. Version control of e-logbook software must be maintained

https://www3.epa.gov/ttn/amtic/files/policy/Electronic__Logbook_Final_%204_20_16.pdf

Information must be legally defensible!