Documents and Records Management

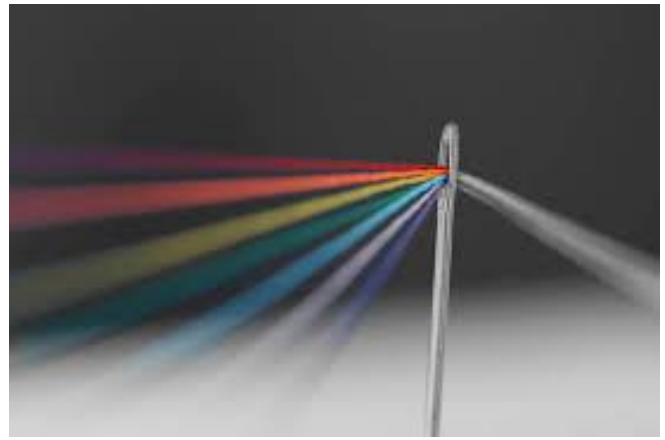
REGION 4 QUALITY ASSURANCE TRAINING

SEPTEMBER 2019

ATHENS, GEORGIA

Agenda

- General discussion on some additional elements of a QA program
  - Document Control
  - Records Management
- Explain why good documentation is fundamental to a solid QA Program, and a key component of all the above elements

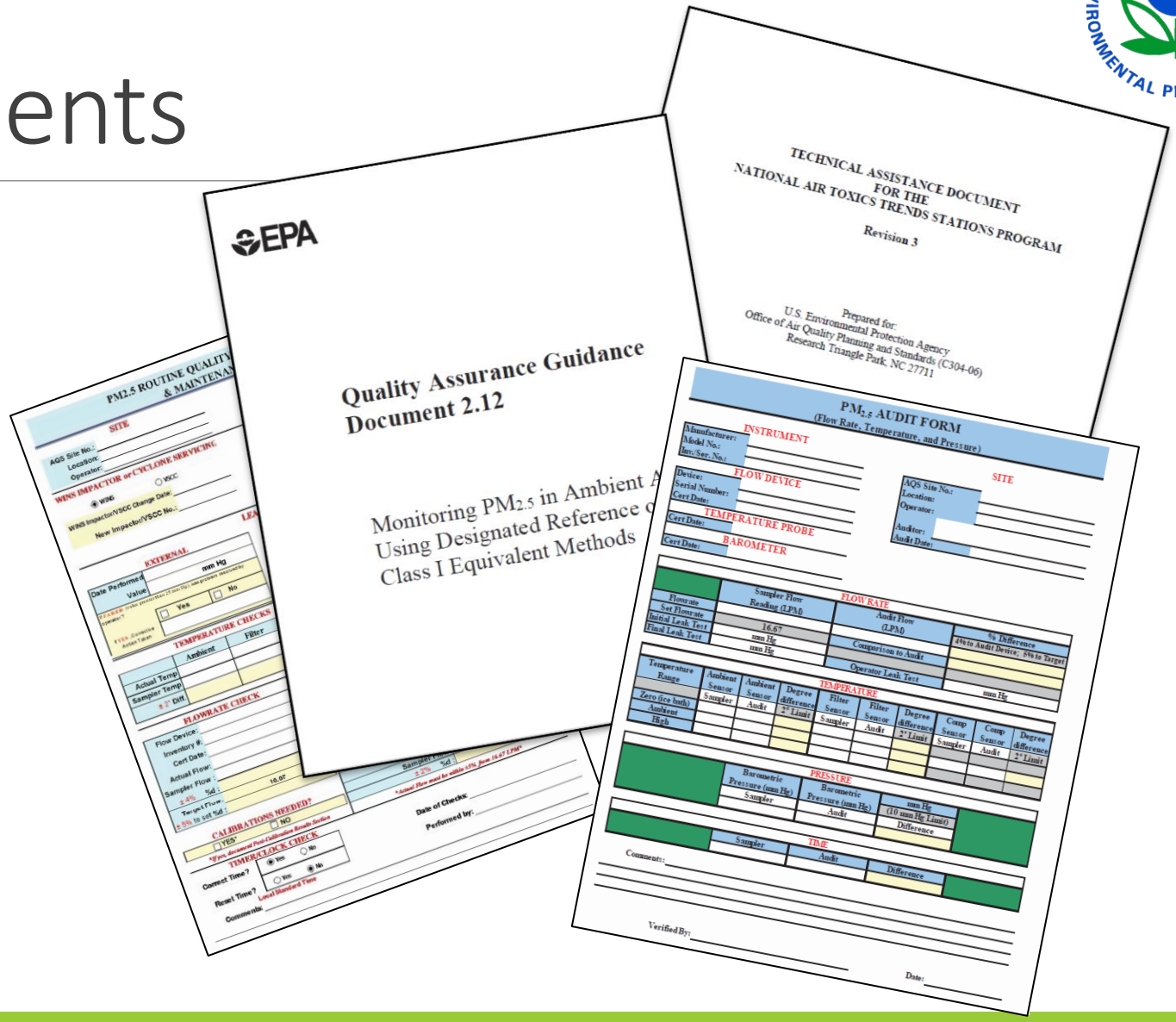


Document Control

The purpose of document control is to provide current versions of documents to all project personnel

Types of Documents

- QMP
- QAPPs
- SOPs
- EPA QA Handbook
- EPA Technical Assistance Documents
- Instrument User Manuals
- QA/QC Forms



A document control system should be established to identify, **by number and date**, each written procedure, or revisions thereof, so that the exact procedure used at any time (past or present) can be determined

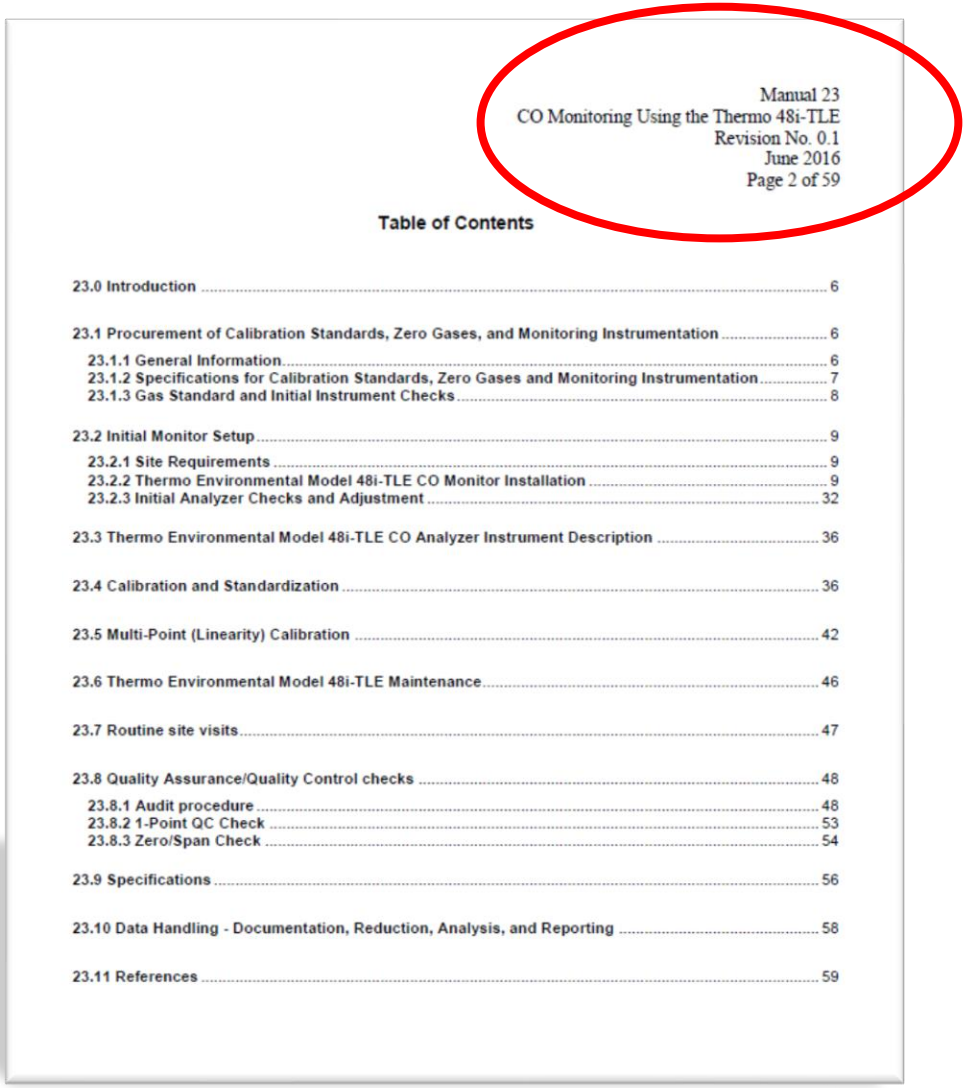
Without document control, each project participant could have a different version of the SOP or QC forms

This could result in data that is not comparable and/or does not meet project objectives

Document Control System

A mechanism to catalog, store, and retrieve documents in a secure and efficient way. Includes:

- Document Index
  - Section and revision numbers
  - Date
  - Page number and total pages
- An easy way to make and record changes
- A distribution system

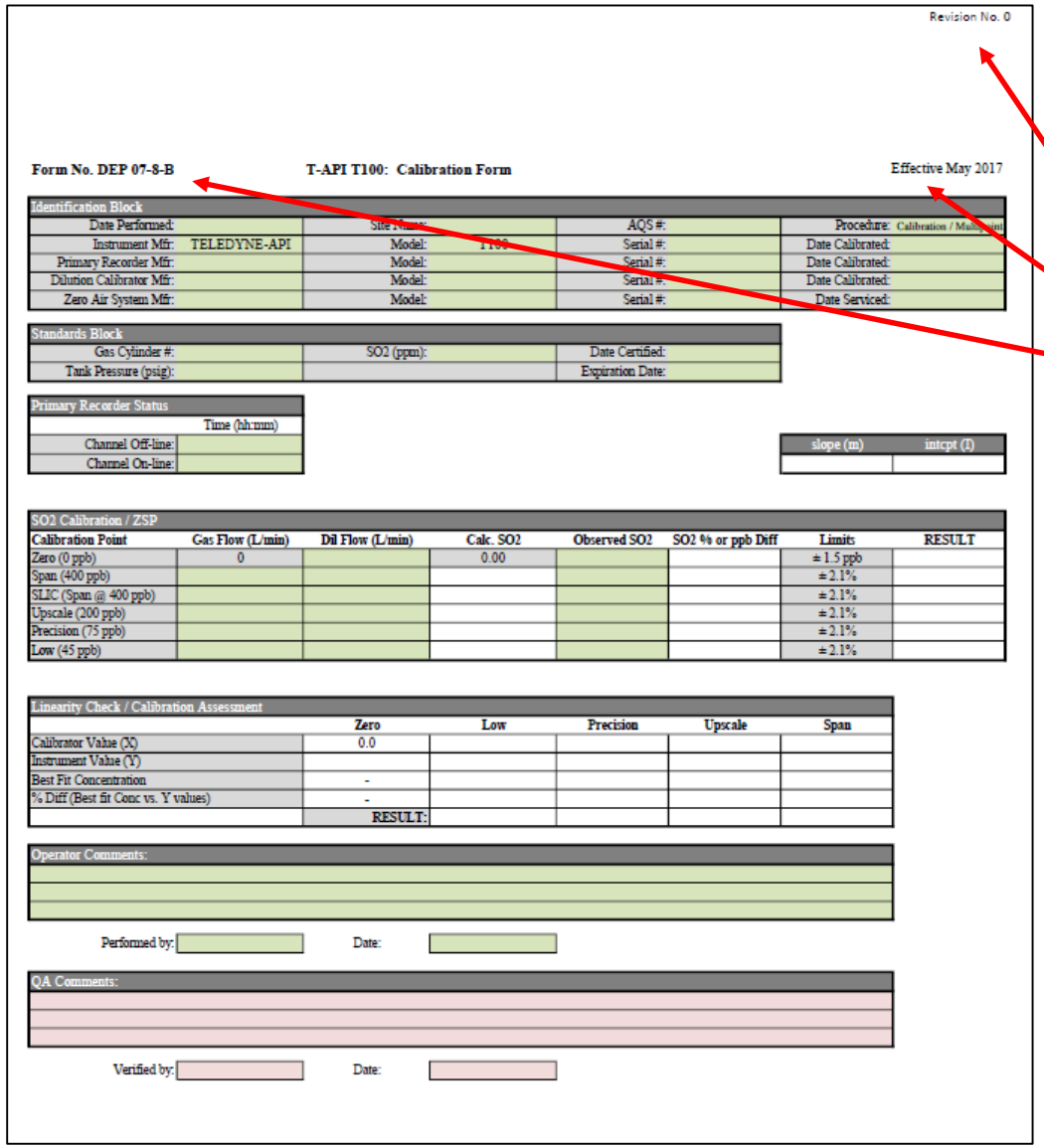


Manual 23
CO Monitoring Using the Thermo 48i-TLE
Revision No. 0.1
June 2016
Page 2 of 59

Table of Contents

EXAMPLE INDEX (SOP)

Assigned Document #	Manual 23
Title	CO Monitoring…
Document Version →	Revision 0.1
Date	June 2016
Page X of Y	Page 2 of 59



Revision No. 0

Form No. DEP 07-8-B T-API T100: Calibration Form Effective May 2017

Identification Block					
Date Performed:		Site Name:		AQS #:	Procedure: Calibration / Maintenance
Instrument Mfr:	TELEDYNE-API	Model:	T100	Serial #:	Date Calibrated:
Primary Recorder Mfr:		Model:		Serial #:	Date Calibrated:
Dilution Calibrator Mfr:		Model:		Serial #:	Date Calibrated:
Zero Air System Mfr:		Model:		Serial #:	Date Serviced:

Standards Block		
Gas Cylinder #:	SO2 (ppm):	Date Certified:
Tank Pressure (psig):		Expiration Date:

Primary Recorder Status	Time (hh:mm)
Channel Off-line:	
Channel On-line:	

slope (m)	intcpt (I)

SO2 Calibration / ZSP							
Calibration Point	Gas Flow (L/min)	Dil Flow (L/min)	Calc. SO2	Observed SO2	SO2 % or ppb Diff	Limits	RESULT
Zero (0 ppb)	0		0.00			± 1.5 ppb	
Span (400 ppb)						± 2.1%	
SLIC (Span @ 400 ppb)						± 2.1%	
Upscale (200 ppb)						± 2.1%	
Precision (75 ppb)						± 2.1%	
Low (45 ppb)						± 2.1%	

Linearity Check / Calibration Assessment					
	Zero	Low	Precision	Upscale	Span
Calibrator Value (X)	0.0				
Instrument Value (Y)					
Best Fit Concentration	-				
% Diff (Best fit Conc vs. Y values)	-				
	RESULT:				

Operator Comments:

Performed by: Date:

QA Comments:

Verified by: Date:

EXAMPLE INDEX (QC Form)

Assigned Document #	→	Form No. DEP 07-8-B
Title		T100 Calibration
Document Version		Revision 0
Date		May 2017

The QAM or QA staff is usually responsible for control of the organization's quality system documents, such as QAPPs and SOPs

May also be responsible for control of blank QA/QC forms

Document Review Cycle

- Documents should be reviewed on a pre-determined frequency (e.g., annually)
- The date of the review and the name of the reviewer should be recorded
  - If revisions are needed, they should be completed following the review – with a summary of the changes documented (i.e., Revision History)
  - If no revisions are needed, the review itself should still be documented
  - If no revisions are needed, project staff should be notified of the completed review and that no changes are necessary

Document Review Cycle

A mechanism should be in place to **track** the review of each document

Examples could include a:

- Master list of QAPPs/SOPs maintained by the QAM
- Spreadsheet listing QAPPs/SOPs, with conditional formatting to highlight review status
- Database with all documents listed that can be quickly queried and report on review status

DEP 07-8
Revision No. 0
May 2017

DOCUMENT HISTORY

Revision No.	Date	Responsible Person	Description of Change
0	May 2017	John Doe	Initial Release

Revision History

Example for New Document (Revision 0)

REVISION	DATE	CHANGES TO SOP
16	06/21	Removed: 5.4.1.11 Correct the transfer standard zero readout to net zero by subtracting the value from itself. Subtract the zero transfer standard readout from each subsequent audit standard value to obtain a net transfer standard response.
16	3/10	The backup data logger system was removed and the site computer, using digitrend software, will now backup the primary data logger.
16	3/10	Changed audit points to 40, 80, 120, 220 ppb
16	3/10	Removed A/B check from audit
16	2/11	Changed calibration points to 0, 400, 200, 100, 50 ppb
16	2/11	Added automatic calibration
16	8/11	Changed audit frequency in section 5.8 from "Audits are to be performed quarterly at a frequency <90 days apart." "Each ozone site is to be audited once per year and 25% of sites are to be audited quarterly."
17	2/12	Changed L3TS certification to be performed annually
17	2/12	Changed L2TS certification calculation to only use current year's slope and intercept. Does not average last 6 slopes and intercepts.
18	04/02/12	Added Figure 3 to 401X audit section.
19	05/02/13	Added sample line integrity check.
20	04/08/14	Added Specification Table

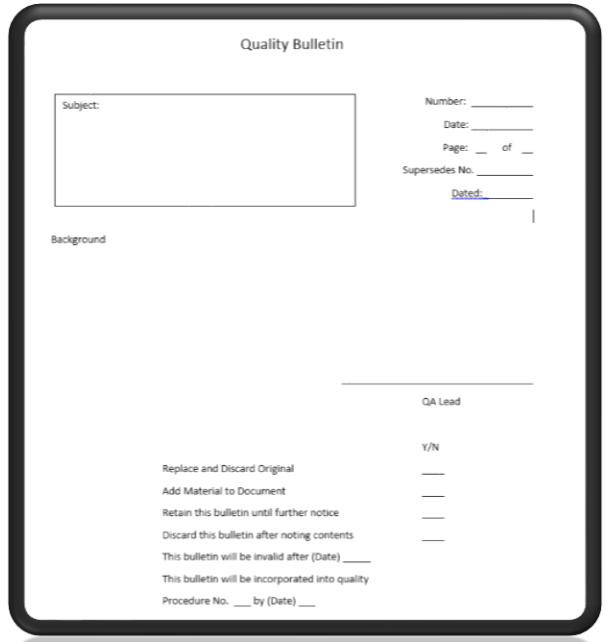
Revision History

Example with numerous revisions

Distribution

A mechanism should be in place to ensure all staff receive the updated versions of new documents. Examples include:

- Quality Bulletin (change notification)
- Hardcopy distribution of document with routing sheet requiring signatures
- Email distribution of new document, with instructions to destroy older versions
- A combination of these


Quality Bulletin

Subject:

Number: _____
Date: _____
Page: __ of __
Supersedes No. _____
Dated: _____

Background

QA Lead

Y/N

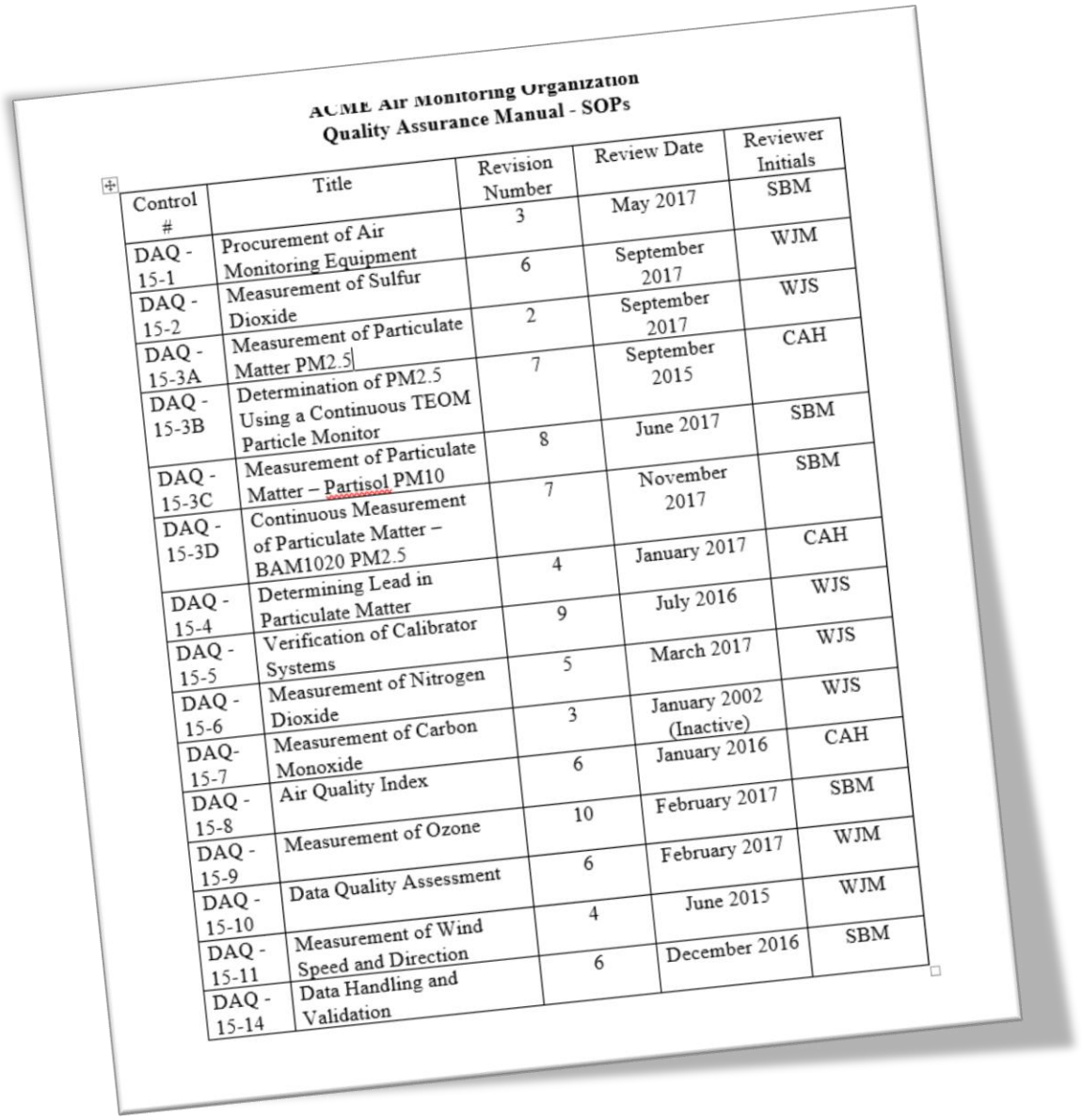
Replace and Discard Original ___
Add Material to Document ___
Retain this bulletin until further notice ___
Discard this bulletin after noting contents ___
This bulletin will be invalid after (Date) ____
This bulletin will be incorporated into quality
Procedure No. ___ by (Date) ___

Document Repository

A centralized, designated location within the organization where all current, controlled documents are filed

Could include:

- File cabinet in the QAM's office for hardcopy / original, signed copies
- Designated folder on the Local Area Network (LAN), with restricted access so only an approved administrator (e.g., the QAM) can add, modify, or delete documents
- An agency website
- A combination of these



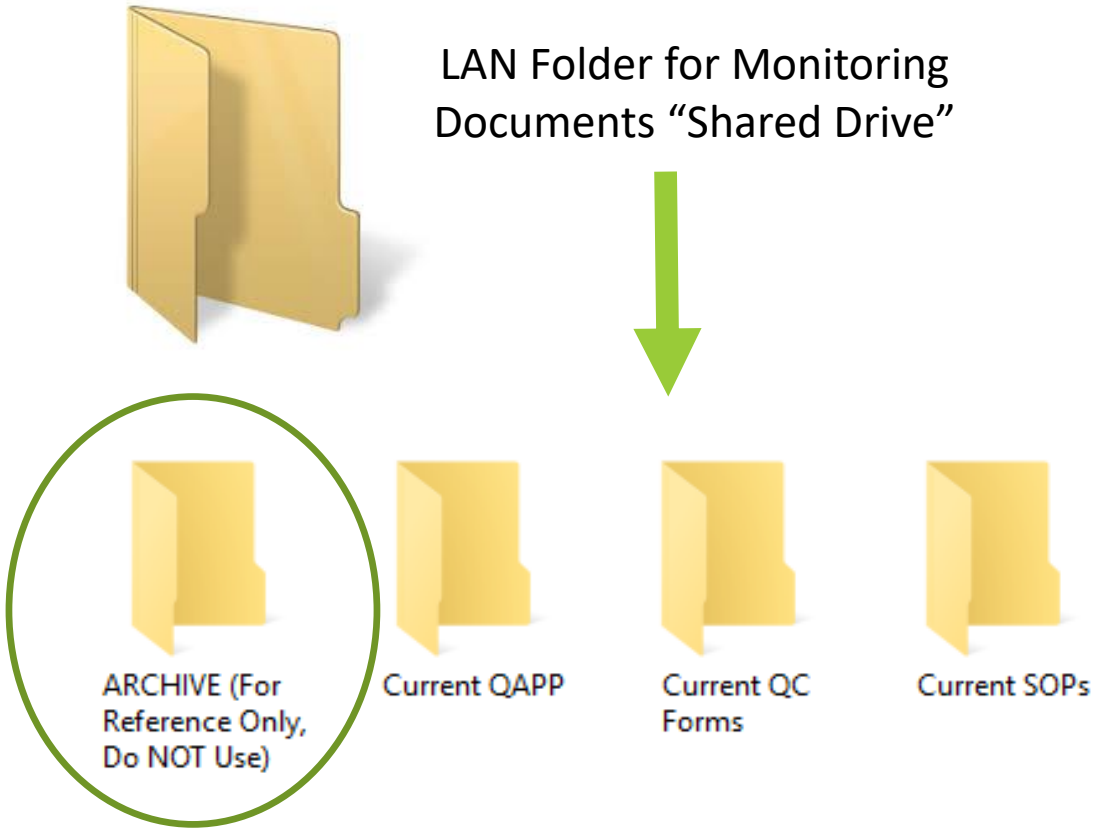
ACME Air Monitoring Organization
Quality Assurance Manual - SOPs

Control #	Title	Revision Number	Review Date	Reviewer Initials
DAQ - 15-1	Procurement of Air Monitoring Equipment	3	May 2017	SBM
DAQ - 15-2	Measurement of Sulfur Dioxide	6	September 2017	WJM
DAQ - 15-3A	Measurement of Particulate Matter PM2.5	2	September 2017	WJS
DAQ - 15-3B	Determination of PM2.5 Using a Continuous TEOM Particle Monitor	7	September 2015	CAH
DAQ - 15-3C	Measurement of Particulate Matter – Partisol PM10	8	June 2017	SBM
DAQ - 15-3D	Continuous Measurement of Particulate Matter – BAM1020 PM2.5	7	November 2017	SBM
DAQ - 15-4	Determining Lead in Particulate Matter	4	January 2017	CAH
DAQ - 15-5	Verification of Calibrator Systems	9	July 2016	WJS
DAQ - 15-6	Measurement of Nitrogen Dioxide	5	March 2017	WJS
DAQ- 15-7	Measurement of Carbon Monoxide	3	January 2002 (Inactive)	WJS
DAQ - 15-8	Air Quality Index	6	January 2016	CAH
DAQ - 15-9	Measurement of Ozone	10	February 2017	SBM
DAQ - 15-10	Data Quality Assessment	6	February 2017	WJM
DAQ - 15-11	Measurement of Wind Speed and Direction	4	June 2015	WJM
DAQ - 15-14	Data Handling and Validation	6	December 2016	SBM

The Document Repository should contain a posting that lists all current documents for quick reference

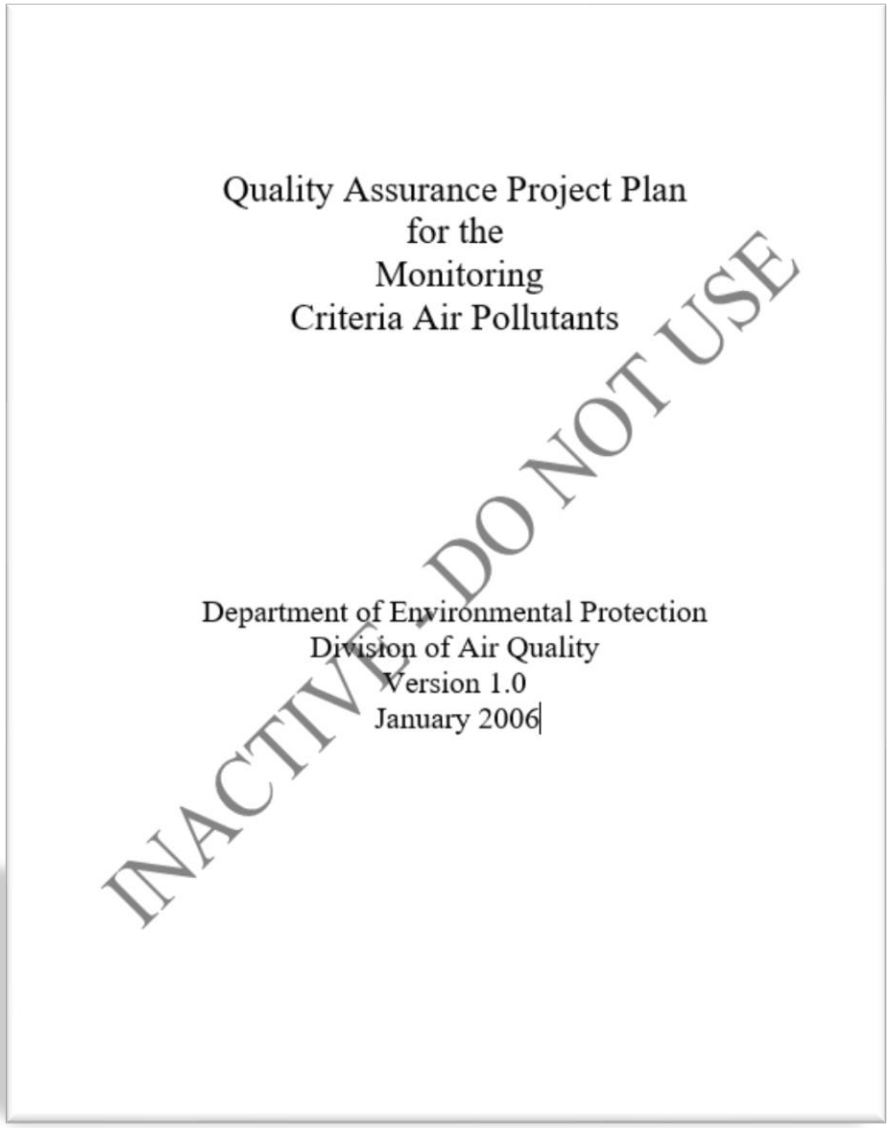
Project staff can use this list to cross-check their documents and ensure they have current versions

Document Archive



Older versions of documents should be retained, but moved to a secure location that is clearly labeled “archive”

Can be a hardcopy archival system, electronic, or both



As a best practice, archived versions of documents should be labeled in a manner that shows they are outdated or discontinued

Records and Documentation

Whether in the office, in the field, or in the laboratory, good recordkeeping practices are critical to the success of your program!

What is the difference between a document and a record?

DOCUMENT

Content file that has information in a structured or unstructured format

Created by **planning**

Is an **editable** file (i.e., can be revised or changed)

Is not final – meaning, has the possibility of being modified

Can be stored hardcopy or digitally

RECORD

Historical / final file that provides "proof of existence"

Is created **when something is done**

Is **not** editable

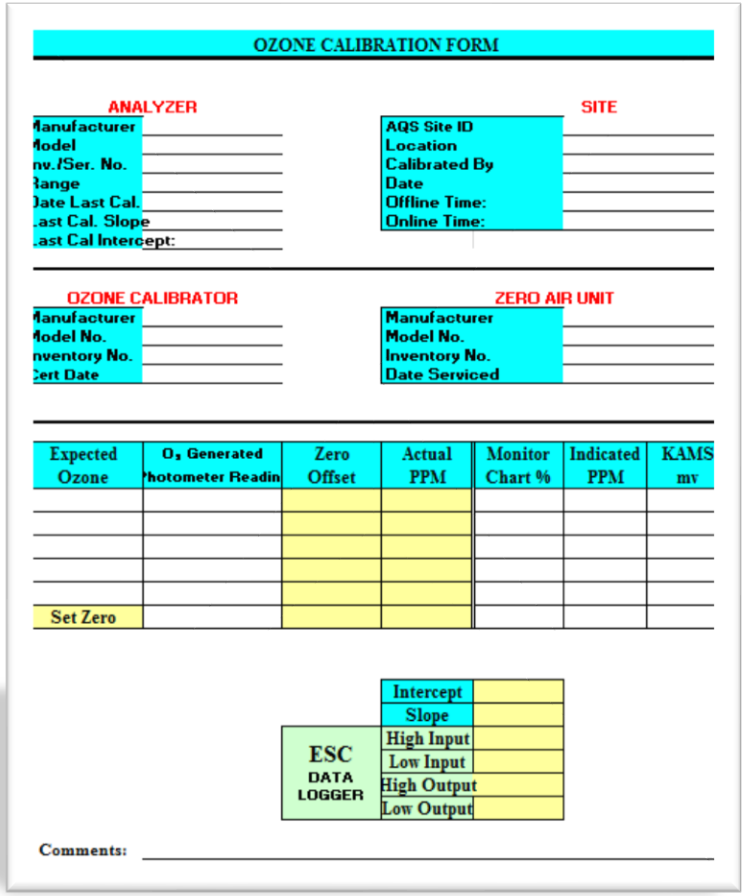
Cannot be recreated

Media does not impact its classification (i.e., it can be paper, microfilm, digital, etc)

Has a retention schedule

Many records start out as documents, but become records when finalized

DOCUMENT:
EMPTY
CALIBRATION FORM



OZONE CALIBRATION FORM

ANALYZER

Manufacturer	
Model	
Inv./Ser. No.	
Range	
Date Last Cal.	
Last Cal. Slope	
Last Cal Intercept:	

SITE

AQS Site ID	
Location	
Calibrated By	
Date	
Offline Time:	
Online Time:	

OZONE CALIBRATOR

Manufacturer	
Model No.	
Inventory No.	
Cert Date	

ZERO AIR UNIT

Manufacturer	
Model No.	
Inventory No.	
Date Serviced	

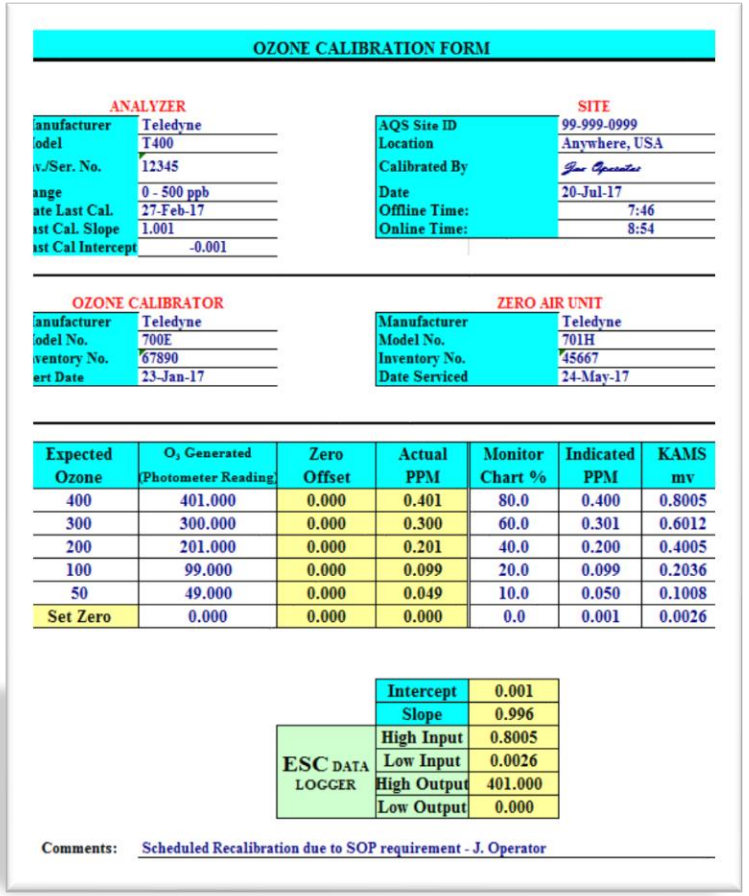
Expected Ozone	O_3 Generated Photometer Readin	Zero Offset	Actual PPM	Monitor Chart %	Indicated PPM	KAMS mv
Set Zero						

ESC DATA LOGGER

Intercept	
Slope	
High Input	
Low Input	
High Output	
Low Output	

Comments: _____

RECORD:
COMPLETED
CALIBRATION FORM



OZONE CALIBRATION FORM

ANALYZER

Manufacturer	Teledyne
Model	T400
Inv./Ser. No.	12345
Range	0 - 500 ppb
Date Last Cal.	27-Feb-17
Last Cal. Slope	1.001
Last Cal Intercept	-0.001

SITE

AQS Site ID	99-999-0999
Location	Anywhere, USA
Calibrated By	Joe Operator
Date	20-Jul-17
Offline Time:	7:46
Online Time:	8:54

OZONE CALIBRATOR

Manufacturer	Teledyne
Model No.	700E
Inventory No.	67890
Cert Date	23-Jan-17

ZERO AIR UNIT

Manufacturer	Teledyne
Model No.	701H
Inventory No.	45667
Date Serviced	24-May-17

Expected Ozone	O_3 Generated (Photometer Reading)	Zero Offset	Actual PPM	Monitor Chart %	Indicated PPM	KAMS mv
400	401.000	0.000	0.401	80.0	0.400	0.8005
300	300.000	0.000	0.300	60.0	0.301	0.6012
200	201.000	0.000	0.201	40.0	0.200	0.4005
100	99.000	0.000	0.099	20.0	0.099	0.2036
50	49.000	0.000	0.049	10.0	0.050	0.1008
Set Zero	0.000	0.000	0.000	0.0	0.001	0.0026

ESC DATA LOGGER

Intercept	0.001
Slope	0.996
High Input	0.8005
Low Input	0.0026
High Output	401.000
Low Output	0.000

Comments: Scheduled Recalibration due to SOP requirement - J. Operator

Types of Air Monitoring Records

- Training Records / Certificates
- Equipment / Standards Certifications
- Electronic/Hardcopy Logbooks (Instrument, Site, Lab, Shop)
- Electronic/Paper Strip Charts
- QA/QC Forms (calibrations, maintenance, precision checks, etc)
- Chain-of-Custody
- Spreadsheets / Databases

Hardcopy Logbooks

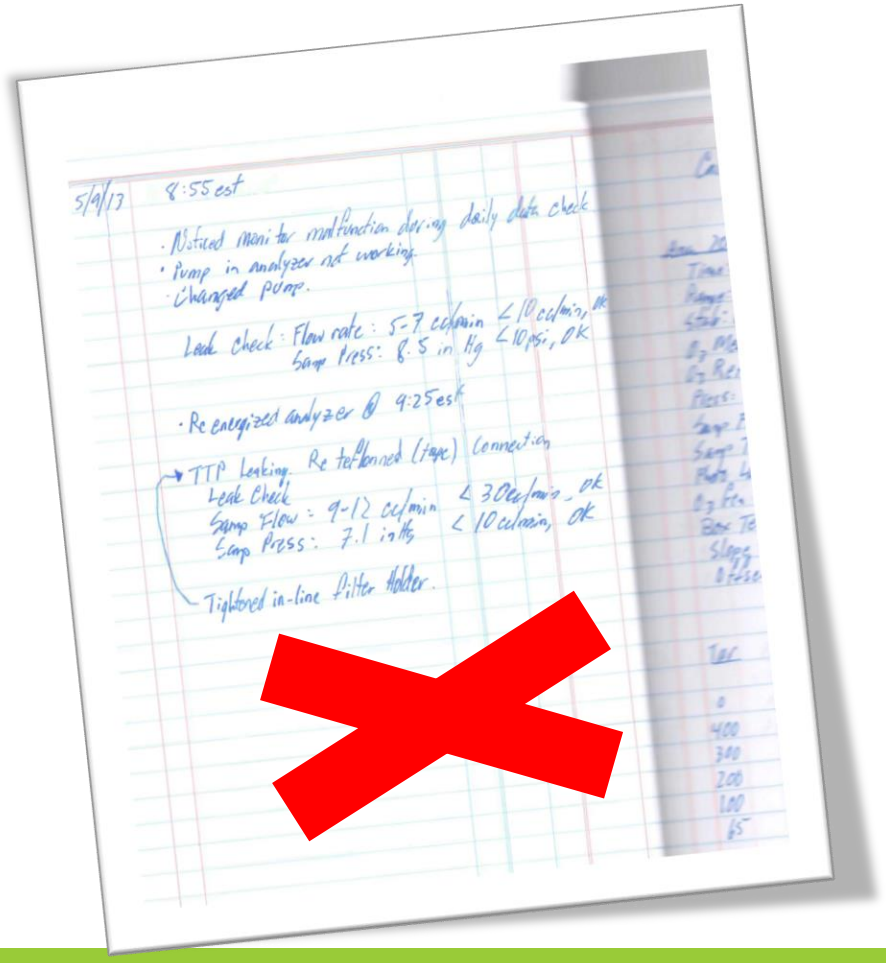
- Bound
- Page-numbered

Logbook Best Practices

- Write in indelible ink
- No pencil!
- Avoid use of liquid correction fluid, such as Wite-Out®
- Corrections should be made with a single line through the incorrect entry, the author's initials, and the date of the correction
- Write the corrected information next to the incorrect entry, if it can be done legibly, or use the next space

Logbook Best Practices

- Do not leave large spaces in logbooks, which can give the appearance of backfilling
- Mark through any unused space with an "X"
- If you leave out important information, you can enter it later – but be transparent when doing so!
  - Example: "*Omitted information from last Friday's entry. While on site Friday (12-8-17), I also cleaned the sampler inlet head and air screens. Jane Operator 12-11-17*"



Logbook Entries

- Document procedures involving the analyzers, samplers, and the site itself
- Each entry should have enough detail that it can "stand alone", and from it, you can recreate data and events
- Be specific!
- Avoid ambiguous phrases or words such as "etc", "misc"

The 5 W's of Documentation

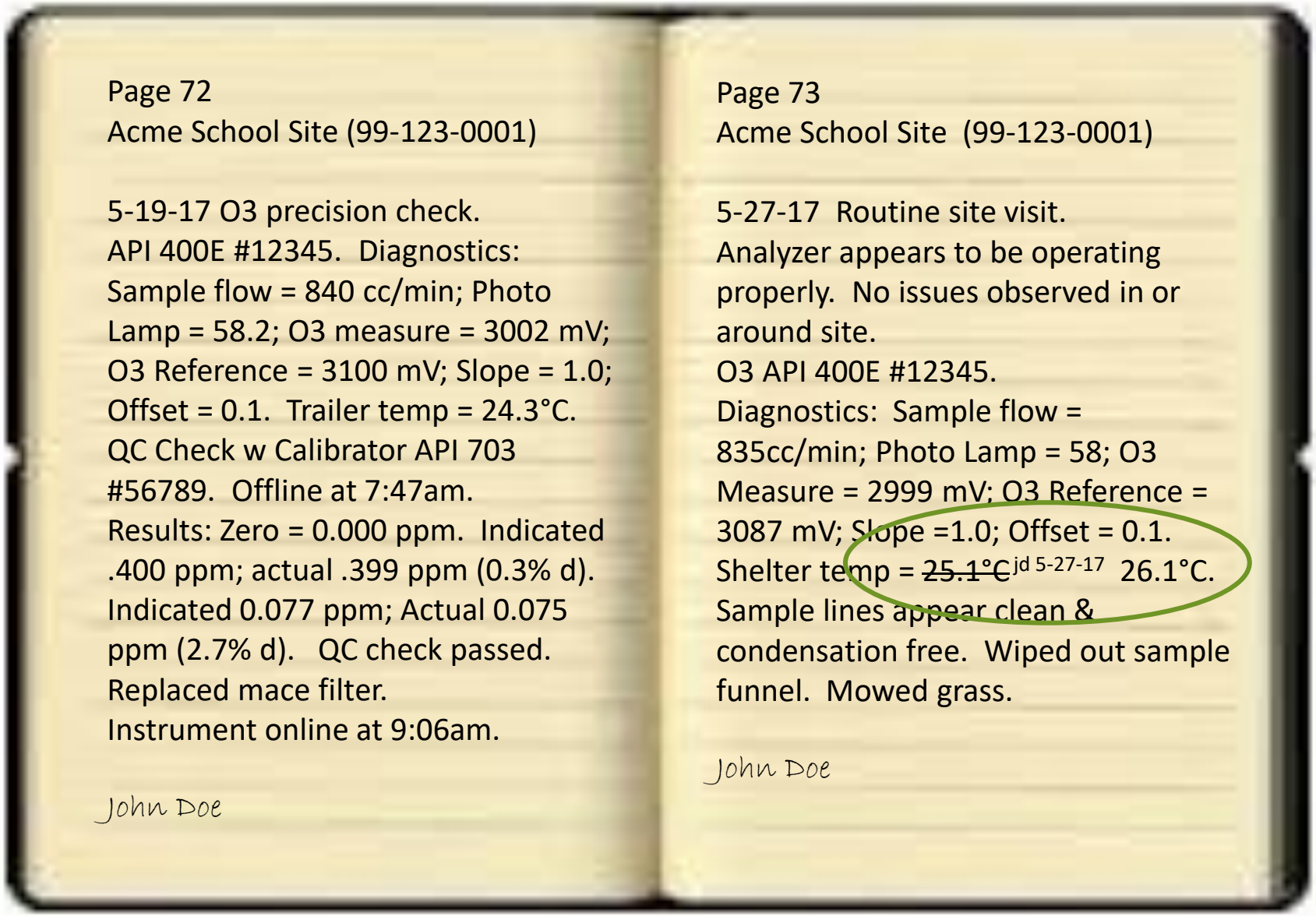
- **Who** is performing the work?
  - All data records should be signed and dated
- **What** pollutant, procedure, analyzer, calibrator?
  - Equipment IDs, makes & models (Traceability!)
- **When** is the activity occurring?
  - Time and date are critical!

The 5 W's of Documentation

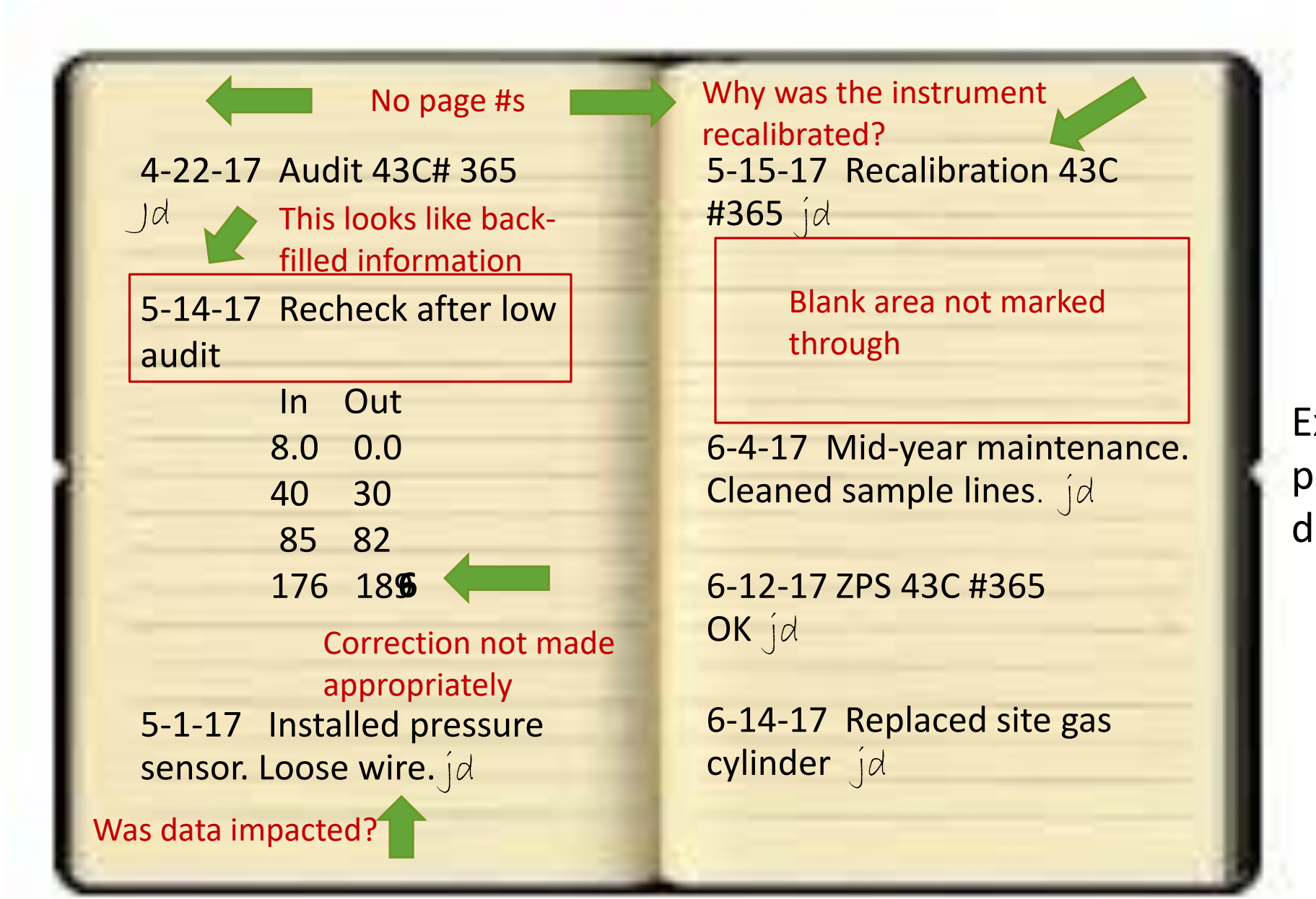
- **Where** is the data being collected?
  - Identify the location of the site/data acquisition
- **Why** is the activity needed?
  - Be specific!
  - For example: Is it time for an annual recalibration per the SOP, or has an instrument malfunctioned? **Explain.** If the latter, what was the **specific** malfunction?
  - Details are vital for successful data validation team

Logbook Entries

- Answer the 5 W's
- Provide detail with the organization's data validation team in mind
  - For example, if data were impacted by a local event, the data validation team will need to know that!
  - Include a statement such as: *"Prescribed burn in the area on sample run date"*
- Detailed documentation can enhance data capture!
- To ensure consistency across operators, as well as ensure a standardized minimum, SOPs should provide clear instruction regarding logbook documentation requirements



Example of good logbook documentation, including appropriate technique for corrections



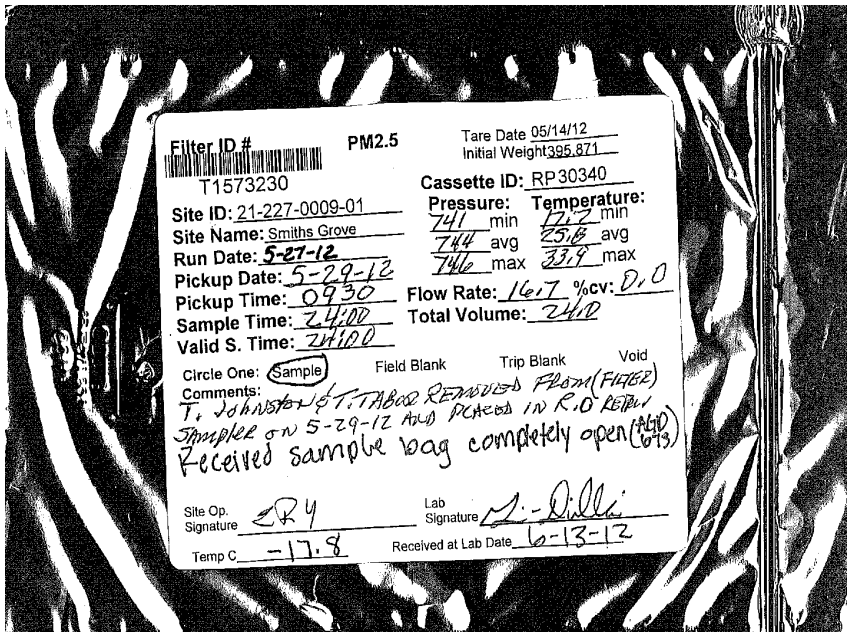
Example of poor logbook documentation

Electronic Logbooks

The same documentation techniques and strategies that apply to hardcopy logbooks apply to electronic logbooks.

E-logbooks and electronic recordkeeping best practices are discussed in the “Electronic Recordkeeping” presentation.

Chain-of-Custody (COC)



- Do not leave entries blank
- Document "N/A" if not applicable
- Add comments when needed
- Sign / date forms

Note: *All* individuals who have handled the sample should sign & date the COC

If it is not documented, it did not happen!

Records Management

Includes indexing, storing, securing, and archiving the numerous records generated during the monitoring project in a manner that keeps them safe and easily accessible to those who need them

QAM and/or QA staff are often responsible for filing and maintaining QA/QC records – such as audit reports, equipment certifications, and others

This activity may be handled by a records custodian or other designated staff

It should be detailed in the QAPP

Where are your records?

- General filing procedure should be in the QMP
- Air monitoring recordkeeping should be detailed in the QAPP
- Centralized repository recommended - hardcopy and/or electronic
- Hardcopy records should be filed in one primary location (e.g., “the file room”)
  - Do not store records in the offices of individual employees!
- If records are maintained at field sites, it should be temporary, with a mechanism in place to ensure documents are transferred safely to the main (centralized) repository

Important Questions to Ask

- Are the records **organized**?
- If asked to retrieve a record from several years ago, could you easily find it?
- Could someone **new** or from **outside** your agency easily find it?

If the answer to any of these questions is "no", the records management system may need improvement.

Are Your Records Secure?

- Recommend back-up of records in two systems / media
  - Hardcopy scanned to PDF
  - Electronic to external hard drive / CD
  - Second server off-site
- Back-up should occur frequently and routinely (e.g., nightly, weekly)
- Files should be write-protected, so they cannot be modified without permission after upload to an electronic repository

Record Preservation

- Hardcopy logbooks or handwritten QC forms should be scanned on a routine schedule (e.g., quarterly)
- Scanning preserves and protects the written information (in the event of a disaster, vandalism, etc)
- Especially important for intermittent samplers, where a large percentage of data is collected manually by staff

Records Retention

- See 2 CFR §200.333 and 2 CFR §1500.6 for requirements involving records generated as part of a federal grant / award
- Generally, most records must be kept at least 3 years, unless under litigation or audit (at which point they must be retained until final action has been taken)
- Some records may require a longer retention time, depending on the nature of the content
- Know your organization's specific requirements! Air monitoring organizations often have additional state/local recordkeeping requirements!

Questions?

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706-355-8657