Electronic Recordkeeping: Best Practices

Region 4 Quality Assurance Training
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Topics to Discuss

- General Records Information
- Electronic Records’ Management Considerations
- Electronic Record Documentation
- Considerations for Common Electronic Record Repositories
- Evaluations of Electronic Record Logbook Systems
- Final Points
Whether in the office... or in the laboratory... in the field...

good recordkeeping practices are critical to the success of your program!
Each data point is influenced by numerous people and processes. **Thorough documentation** of each step in the data flow is needed to ensure accurate data validation.
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Electronic Records

- Air monitoring agencies have used electronic records for years.
- In recent years, some agencies have gone totally paperless.
- Important considerations with such a transition.

"Where we’re going, we don’t need hardcopy records!"
Things to Ponder...

- Air monitoring electronic records should:
  - Be date- and time-stamped with the person creating the record identified
  - Be well-organized and easily retrievable
  - Provide the same level of detail as hardcopy records
  - Be documented consistently and completely
  - Be retained (and backed-up) in a secure manner to ensure the preservation of original records for defensibility
  - Provide a means in which revisions can be tracked and made in a transparent manner
Electronic Logbook

- Offer several benefits over hardcopy logbooks
  - If backed-up on a routine basis, data are not easily destroyed
  - Accessible remotely
  - If set-up appropriately, timestamps of data entry are not easily falsified
  - Requires less storage space for archiving (and saves paper!)
Electronic Logbook

- EPA Technical Note– *Use of Electronic Logbooks for Ambient Air Monitoring* (April 20, 2016)

- Minimum components to consider:
  - **National Archives and Records Administration (NARA)** – Requirements that pertain to e-logbooks
  - **Your records’ policies**
  - **Americans with Disability Act (ADA) compliance**
  - **Relevant information should be documented/referenced in the QMP/QAPP(s)**
Minimum components to consider (continued):

- **Integrity** – Minimize risk of unauthorized alteration/erasure
- **Metadata/Identity** – Sufficient record identification to enable authorized retrieval, protection, and disposition
- **Backup** – Protect against information loss (both in terms of frequency and storage location)
- **Organization/Delegations** – Identify roles/responsibilities
Electronic Logbook

- Minimum components to consider (continued):
  - **Accessibility** – Process for various personnel to access information, including levels of access restriction or permissions
  - **Retrievability** – System for easy and efficient information retrieval
  - **Migration** – Allow records to be moved to ensure minimum retention and information are not lost
  - **Auditability** – Developed and documented to allow internal/external QA and IT testing or auditing
Minimum components to consider (continued):

- **E-Signatures/Legal Signatures** – Accepted and encouraged practice; must be considered for use
- **Information Security/Locking** – Data must be secured as an official record upon transmission
- **Data Entry/Data Revision/Correction** – Revisions may not overwrite original records
- **Version Control** – Maintain control of electronic logbook software version

For more information, please review the following:

- [http://www.epa.gov/records/tools/erks.htm](http://www.epa.gov/records/tools/erks.htm)
• Protecting the integrity of data/documentation is critical to the success of the monitoring program

• The Quality Assurance (QA) Manager or QA staff should verify e-logbooks can successfully meet these specifications (more on this later)

• The use of e-logbooks, and their adherence to these specifications, will be assessed by EPA during Technical Systems Audits (TSAs)
The EPA technical note applies to other electronic records, as well (not just electronic logbooks)!

HEADS UP!
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Electronic Logbooks

- Electronic logbooks should be documented with the data validation team in mind.
- If data were impacted by a local event, the data validation team should be provided that information.
- Also consider documenting equipment status (e.g., Is the pump failing?)
- Provide minimum documentation items and detail in SOPs.

Detailed documentation may enhance quality data capture!
Remember the 5 W’s of Documentation!

Who?
What?
When?
Where?
Why?
Electronic Strip Charts

- An electronic strip chart is used in conjunction with continuous analyzers to record their outputs.
- How do you document your electronic strip charts with pertinent information?
  - Electronic memos?
  - No notations on the chart? Then where is information recorded?
Troubleshooting, malfunctions, and anomalies should be documented!

Is data after 17:00 valid?

Bubbles indicate annotations
Remember, other data users may ask to look at your charts!

- Charts and other records should be documented in a manner such that any outside data user can make sense of the notations!
- Additionally, notations should be such that they could “stand alone” in a court of law, and help the witness recreate events many years down the road...
Using Excel Spreadsheets

A great tool for documenting precision checks, calibrations, maintenance, and QA audits.
But... Excel Spreadsheets are easily corrupted

- Lock cells to preserve formulas
- Password-protect forms
- Do not create individual forms
  - Use only agency-approved (controlled) documents
- Forms should have control numbers and/or revision dates
But... Excel Spreadsheets are easily corrupted

- Do not reuse forms completed for previous events (e.g., QC checks)
  - It’s tempting! But the original templated spreadsheet should be used in case a particular form becomes corrupted
- Double check computations manually (formulas occasionally corrupt)
- Routine review of Excel spreadsheets should be completed by QA staff and be included in the QAPP and SOPs (QA Handbook)
“... can secure your templated spreadsheets!”
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Agency Network Drives

- Is there a shared network drive for important files?
- Is it secure?
- Are official files write-protected, so they cannot be modified after upload without permission?
- Is the network drive backed-up? At what frequency?
Each folder on a shared network drive should:

- Be assigned a specific recordkeeping function (e.g., working documents, original QC/QA records)
- Have access restrictions applied to certain staff as appropriate
  - For example, “read” and “write” access for field staff, but “overwrite” access for a designated system administrator (e.g., QAM)
- Be backed-up on a routine frequency
Mention of commercial products in this presentation does not constitute endorsement or recommendation for use.
SharePoint

- SharePoint is becoming more commonly used by air monitoring agencies

**Benefits:**
- Customizable library structure
- Metadata for information sorting and queries
- Different views available
- Supports collaborative work
- Options to easily export information
Access Database
Other Commercial Logbook Systems

- Other systems provide benefits such as the following:
  - Near real-time availability of air monitoring information from the field
  - Calendar for scheduling certain activities
  - Electronic forms and reports with drop-down menus for documenting information
  - Control charts of certain information
  - Equipment inventory tracking
Words of Caution

- Records could be edited or deleted without proper permissions and alert settings.
- Should be a designated system administrator to set access restrictions.
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Evaluating an Electronic Logging System

- Should be a regular function of the agency’s QAM or QA staff
- Should be completed on a routine frequency (e.g., annually)
- Will be completed by those pesky EPA auditors...
Specific Questions to Ask Yourself...

- Are electronic records **organized**?
- If asked to retrieve an electronic record several years down the road, could you easily find it? Would it have enough detail?
  - *If multiple staff have to converse in an attempt to remember what happened, there is not enough documentation!*
- Are electronic records adequately **protected** and **preserved**?
Common TSA Findings

- Unsecured record repositories
  - Witnessed records moved or deleted without staff knowledge
- Edits are not tracked with a proper audit trail
  - Original records are not secured as such
- Records don’t include enough detail to stand alone in recreating an event
- Spreadsheet cells are not locked
If it’s not documented, it did not happen!
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A Few Last Pointers...

- Document in the “now”
  - Avoid documenting days or weeks after events have occurred
- Only the facts, please! Be cognizant of the third-party users who may read your entries
- Mistakes happen! Be transparent when documenting corrections
- Be thorough & detailed so that future employees can explain what happened, if asked
A Few Last Pointers...

- Electronic records are needed to demonstrate data traceability and defensibility
  - Data validation staff should have sufficient detail in electronic records to make data quality decisions
  - Electronic records must be retained in accordance with the agency’s QAPP(s)
    - The electronic records management structure should be documented in the QAPP(s)
  - Any other hardcopy records created in association with electronic records (e.g., QC/QA forms completed by hand) must also be retained in accordance with the QAPP(s)
A Few Last Pointers...

- Electronic records are needed to demonstrate data traceability and defensibility
  - Electronic records must be adequately protected to preserve their contents
  - Repositories (e.g., network drives, web-based systems) should be configured to restrict levels of access to certain personnel as appropriate
Remember, there is never too much documentation!
Questions?

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