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Technical Papers

Quality Documentation & Records

- K.Matthews, Managing Field and Laboratory Records for Environmental Investigations - 3:00 PM
- T.Hughes, Virtual TSA of Research QA and Records Management Systems - 3:30 PM
- D.Weingart Webb, QA Documentation and Information Quality: The Common Thread that Binds - 4:00 PM

TECHNICAL SESSION: Quality Documentation & Records

Managing Field and Laboratory Records for Environmental Investigations

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The purpose of this presentation is to describe the general practices employed by the U.S. EPA National Enforcement Investigations Center (NEIC) for managing field and laboratory records and to highlight specific forensic documentation techniques approaches.

Field and laboratory records generated during environmental investigations must be able to withstand legal and scientific scrutiny. The recordkeeping practices employed by the NEIC are designed to support not only technical quality requirements but to withstand forensic challenges, as well. Since NEIC investigative records serve as objective evidence of actions taken or observations made, they must contain documentation that demonstrates proper identification, accountability, permanence, legibility, and timeliness. In addition, an approach to error correction must provide clear and concise evidence of any change to the record. The following recordkeeping practices are designed to withstand forensic challenges to authenticity, completeness, and traceability that can arise in an enforcement action.

Identification

NEIC must ensure that records are traceable to the investigation by using a unique identifier on each page. At NEIC, the unique identifier is a project code. Annotate The records are also annotated in a way that shows the date the work was performed and the identity of the responsible person.

Legibility

Investigative records must be legible. Abbreviations are acceptable only if they are readily comprehensible to a reviewer.

Permanence

Unless prohibited by weather, NEIC personnel are expected to use pens with waterproof, non-erasable ink to record data and observations. When weather conditions do not make it feasible to use waterproof ink, make entries can be made using a non-smear lead pencil (e.g., 2H or 3H). Pencil (including color) may be appropriate for diagrams or tracings.

Timeliness

Ensure that Observations and calculations are expected to be clearly and permanently recorded at the time they are made and are be identifiable to a specific task. A record is expected to show when each element of the work was performed [e.g., relevant date(s) and where appropriate, time(s)] and who performed it.

Physical Accountability

Paginate Records are paginated using a page numbering system which indicates the total number of pages. This may be achieved in a number of ways including documenting the number of pages at the beginning of the package or numbering each page. AlsoFor bound logbooks, record the page number of the final entry is recorded in the front of the logbook.

Alternative Records

Where appropriate, preserve observations or test results in photographs or as photocopies. Where helpful, use diagrams are used in addition to narratives to record observations.

Procedural Departures

Document Departures from existing written methods and/or procedures are documented in the record. The record is expected to show the date and parties involved in the decision and the nature of the departure.

Physical Security

At NEIC, Hold investigative records are held secure and in confidenceand in confidence. Maintain Records are maintained in a secure environment to prevent damage, deterioration, or loss, and promote customer confidentiality. Ensure Records that are stored electronically have back-ups and are protected from unauthorized access or amendment. Lock up Offices and common use areas containing investigative records are locked during non-business hours. Secure Records that are kept in non-lockable offices or common-use areas are secured in lockable containers during non-business hours.

If records must be taken offsite, personnel are advised to ensure that the information is not disclosed to anyone except those who are authorized access to the information. They are advised to store records in a locked briefcase or other secure container when not in use, and take appropriate administrative, technological, and physical safeguards to ensure the security and confidentiality of the records in their care.

Error Corrections

Properly document Error corrections in investigative records must be able to withstand scientific and legal scrutiny. In general, the approach includes:

- Explaining changes in the record clearly and concisely to communicate the reason for the change. Recording the actual date of the error correction as well as the signature or initial of the person making the correction. Do Not obliterate or erasing anything in the record.

In particular, the approach to correcting errors in investigative records is dependent upon when the error is identified. For example:

Contemporaneous Errors – Authors line out, initial, and date errors made contemporaneously with the creation of a record. Brief, factual explanations for clarification are included if needed.

Errors Identified During Review - Errors found during the review process are brought to the attention of the author. Authors line-out, initial, and date the entry. Brief, factual explanations for clarification are included if needed.

Errors Identified In Inactive Investigations or After Release Outside of NEIC - Original records are not changed if an error is found after the record has been transmitted outside of the organization or if the investigation is closed.

If there are no legal proceedings in progress, a separate entry or memo for the investigative file is prepared with a brief, factual explanation. The report is amended if the error impacts the information presented in the final report.

If legal proceedings have commenced, legal counsel is consulted immediately to ensure that any corrections are communicated to all recipients of the record. Documentation is prepared for the investigative file of the resolution of the error that was identified.

For over 30 years, NEIC has provided environmental forensic support for state, tribal, local, and federal environmental enforcement and compliance assurance programs. Our continuing goal is to generate scientifically sound and legally defensible information for successful environmental actions. In recent years to support this goal, NEIC maintains accreditation in the areas of field measurements/monitoring testing, field sampling, and laboratory analysis. This accreditation meets the requirements of ISO/IEC 17025, ANSI/ASQ E4, and the International Laboratory Accreditation Cooperation (ILAC) Guide 19 (G19) Guidelines for Forensic Science Laboratories.

A VIRTUAL TECHNICAL SYSTEMS AUDIT OF RESEARCH QUALITY ASSURANCE AND RECORD MANAGEMENT SYSTEMS IN ORD, U.S EPA

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NHEERL conducts technical systems audits (TSAs) on its research projects. The findings are reported by the QA Manager (QAM) to the Director of QA (DQA) as Exemplary Findings (things the QA Team liked); Corrective Actions (things that must be corrected immediately); and Areas for Improvement (things that should be corrected as recommended unless there is a reason why they should not be corrected or can be handled in another way). We thought it might be interesting to have a QA and Records Manager and the DQA in NHEERL conduct a virtual TSA on quality assurance (QA) and record management (RM) systems for research data in ORD. Here are the findings of such a virtual TSA.

A. Exemplary Findings

1. The meetings and QA training by EPA's Quality Staff are exceptional.
2. TSAs are a comprehensive and flexible means of auditing research studies, especially when combined with data audits and in-life surveillances.
3. The QA Community in ORD has an excellent communications system for collaboration and interacting on large inter/intralaboratory studies (e.g., National Coastal Assessment, World Trade Center, wadeable streams, disinfection by-products in drinking water).
4. The ORD SOPs presently being developed are excellent standards for inter/intralaboratory research studies.
5. ORD Division and Laboratory management are generally very supportive of QA and RM initiatives for research studies.

B. Corrective Actions

1. ORD needs a Quality Management Plan (QMP), especially with the recent development of ORD SOPs and large ORD interlaboratory studies.
2. The records management system in ORD consists largely of paper records (notebooks) and diverse electronic files. ORD needs a uniform E-records policy and monetary support for a comprehensive electronic system to maintain research records. Such an E-records system for scientific records is especially important for highly visible and regulatory research studies

C. Areas for Improvement

1. The QA, Records, and IT Staff need an effective way to talk and interact with each other. Presently, each of these entities meets separately several times a year.
2. ORD should consider a yearly meeting of QA, RM and IT Staff (i.e., the ORD QRIT meeting), possibly held in DC. This meeting could be held in conjunction with the EPA Science Forum held each year.
3. Electronic records training needs to be available to QA, Records, and IT Managers. This E-training could be given at the yearly ORD QRIT Meeting.

This is an abstract for presentation which has been reviewed by the U.S. EPA; views expressed do not necessarily represent EPA policy.

QA DOCUMENTATION AND THE COMMON THREAD OF INFORMATION QUALITY

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Abstract - Inspired by the 2004 USEPA Quality Systems Conference keynote address by Dr. Richard Wang of the MIT IQ Program, Canaan Valley Institute (CVI) staff became convinced that a mutually beneficial connection between information quality and quality assurance existed. Staff promoted QA IQ as a “state of mind”. This “QA IQ state of mind” has since become a dedicated theme within the CVI QA Program.

“Document engineering”, a new frontier in the computer science field, “that investigates systems for documents in any form and in all media”, provides the framework upon which this paper and our project are built. Since “...document engineering is concerned with principles, tools and processes that improve our ability to create, manage, and maintain documents”¹ it is a natural fit with the USEPA QA System.

*Hence, we propose to use the principles of document engineering for the development of an integrated relational database specific to QA documentation at CVI. This relational database will assist with both **project-specific QA** document development, QA reporting, as well as overall **organizational QA** integration for QMP reporting, auditing, accountability and tracking.*

This is expected to take significant strides to reduce document redundancy, expedite required documentation processes and facilitate QA activities throughout the QAPP lifecycle – even improving and enhancing how QA is applied during project management. This critical link, then, incorporates information quality at every level of the QA process.

Our project complements, and expands on, the usability of USEPA’s Quality System requirements and is appropriate for USEPA’s “graded approach”.

A belief in and a commitment to furthering this method is the reason for this paper.

Introduction

During development of the USEPA Quality System, the designers adopted major components of the American National Standards Institute/American Standards for Quality Control (ANSI/ASQC) and the International Standards Organization 9000 standards for quality assurance processes. According to the USEPA Quality System, this is designed “to document appropriate controls for quality-related documents and records determined to be important to the mission of the organization.”². Documentation required under the USEPA Quality System includes; a Quality Management Plan (QMP); a Quality Assurance Project Plan (QAPP), and Standard Operating Procedures (SOPs).

Under this system, projects funded under USEPA programs require multiple documents to address project-specific elements for quality assurance. Currently, there are twenty-one (21) USEPA Quality Systems guidance documents to assist in the development of QA documentation. Organizations may use any or all of these guidance documents in the development process.

When projects that contain environmental data receive formal approval, a QAPP, including all supporting documentation, is developed specific to the project activities. Using USEPA’s graded approach toward QA, a QAPP may be a simple baseline sampling and analysis plan or as complex as a multi-year research study. Our project is able to accommodate QA along any point of the “graded approach”.

The Current Documentation Process and Its Limitations

QA documents used by both USEPA and non-USEPA organizations are usually created using word processing software and may include customized templates depending on organizational preferences.

During the project lifetime, these documents are routinely referenced for project QA management and oversight. These reviews typically include the data quality objectives process, performance measures, sampling controls, etc., specific to the project. Indeed, the QAPP and its supporting document may be thought of as the “user guide” to project data activities. Once the specified QA/QC is completed on these tasks, new QA document layers are added to the project file.

Original QAPP documents using word processing software may be thought of as being “static”. In effect, these QA/QC documents are one-dimensional records that have neither the ability nor transferability to support audit trails, summaries, or tracking – all crucial components of effective project management.

Additionally, word processing programs limit the capacity to quantify and track the status of QA/QC within both the QMP and QAPP frameworks. They lack the structure to efficiently move QA through the normal process flow.

For new QA/QC documents created with word processing software staff must re-key project information and/or reference QAPP-specific tasks. New records, once again, lack

the ability to be tracked, summarized, or sorted, thus using crucial staff time toward the documentation process instead of toward furthering scientific method and analysis.

In summary, QA/QC activities under the current framework require extensive staff time to manually review, organize, and key and re-key QA activities at multiple points in the QAPP process. A decade ago, word processing documents were the standard for this document type. With advances in document engineering, that is no longer the case.

The Documentation Challenge

All twenty-one (21) USEPA quality guidance documents have been released within the past six years - with the most recent release occurring in March 2006. They are relatively new to users, and have a significant learning curve. They do, however, “connect the dots” for all users of the USEPA Quality System and are considered by many to be the standard by which other programs are measured.

With this system, USEPA’s Quality staff have provided the ideal platform from which to build an automated system. Their guidance documents, in totality, are a final “blueprint” to an automated, integrated future.

Therefore, we have the responsibility to respond to this challenge by developing tools utilizing the new generation of information technologies that employ document engineering principles. By taking this to a higher level of document engineering, we are able to present QA information in multiple formats that continue to meet programmatic or regulatory requirements, but offer a wider range of capabilities.

To do this, we must envision a QA environment that integrates required QA documentation in a relational database environment. The benefits of this approach are many, and include; a reduction in the documentation burden on staff; the creation of Reports and Forms preloaded with project information and QA elements; and organizational level summaries and reports - all ensuring information quality is maintained throughout the life of the project. If “collect once, use many” is the standard for USEPA environmental data, then “enter once, use many” should be the standard for USEPA information.

A Review of the Technology

Available technologies were reviewed for applicability and usefulness. While not exhaustive, this search considered a number of important elements, including, costs, expandability, and the overall usefulness of the programs. These considerations indicate that designing a MS Access program specific to the USEPA quality system would benefit the most users and have the greatest uniformity across the QA landscape.

While a MS Access database is only one option, it is one of the most widely available database programs and offers the greatest programmability for its value. Specifically, small to mid-size environmental organizations would likely receive the

greatest benefit overall. It is also probable that scientists themselves would find substantial benefit from the reduction of documentary tasks. This allows more time to be devoted to scientific research and processes – the “heart” of all environmental research projects.

Also, MS Access database information is easily imported into SQL formats currently in use by many organizations for data warehousing and project management activities.

Integrated Solutions

Using USEPA’s own QA Systems model as a guide, the database would be populated from the top down. Initially, data entry would include all relevant QMP documentation requirements on a QMP data entry e-form. A modified version of USEPA QAARWP elements provides data fields for this portion of the database. These would show timetables and content requirements for annual reports; information on QA/QC courses provided and taken; innovative practices; QMP revisions; technical assessments; technical assistance; QA guidance developed; publications and presentations; awards and recognition; semi-annual reports with project details, and other notable items. This allows an easy reference for auditing, tracking and reporting purposes on an organizational level. Using a relational database, original data is entered and verified once. Then, when data is needed, applied, or referenced, customized QA forms pull it from the database into new forms and reports. Information will not “morph” into slightly different iterations as QA progresses.

It is important to stress that the database should be under a document control regime so that approved project components are not changed or modified without the proper authority and revision approvals.

Next, QA and project staff would insert QAPP information on another data entry e-form. Every QAPP would reference back to the QMP that is its “umbrella” document. The user would select the EPA funding source from a drop down menu, or similar tool. All previously entered information for that funding source, as noted in the foregoing paragraph, would automatically populate the QAPP and move forward as a permanent part of this record.

QAPP elements provide the framework for integration of required documentation elements. Suggested integration includes;

- QAPP datasheets populated by QAPP sampling, measurement, analysis and QA methods. Datasheets in e-form are programmed to include all relevant project information, including sample or measurement sites, number of samples, sample or measurement protocols, data analysis methodology, etc.
- QAPP QA history log that will allow staff to update the e-QAPP with notations of site visits, field notes, meeting notes, equipment issues, etc. A quick glance at the QA history log could provide the user with the current status of activities.

- QAPP QA e-forms populated by QAPP QA checks for field samples or measurements showing the QA QC method, frequency and reporting format. It will also allow for data deviations to be noted and processed according to pre-established protocols.
- And much, much more.

In Conclusion

In the long term, a solution that allows documentation to be an administrative science in its own right better serves the science it seeks to document.

¹*University of Wisconsin-Milwaukee, Symposium of Document Engineering website, March 24, 2006.*

²*EPA QA/R-2, March 2001, pg 13*
