

# Electronic Record Keeping and the Ambient Monitoring QA Program

Catherine Brown, EPA Region 9  
EPA's Quality Management Conference  
Austin April 26, 2006



# Topics (1 of 2)

- Overview of federal record keeping
- Trend toward electronic records
- EPA's regulatory response
- Status of CROMERR
- Electronic record keeping in ambient monitoring

# Topics (2 of 2)

- E-recordkeeping Implementation Guidelines
- E-recordkeeping example systems
- Questions/discussion

# Overview of Federal record keeping

- Federal agencies publish rules which specify implementation requirements for the laws they enforce.
  - For EPA Air Program: 40 CFR
- The number of federal records required, including associated QA, continues to increase.

# Trend toward E-record keeping

- Reinventing Government Policy 1995
- Reinventing Environmental Information Report 1996
  - Reduce burden of compliance & regulatory reporting
- Government Paperwork Reduction Act 1998
  - Mandated the substituting of e-information by Oct 2003
- OMB 'E-Government Initiative'
- In general, advances in tools and technologies for transferring and managing data have increased productivity in government and business

# EPA's response

- In 2001, Cross Media Electronic Reporting and Records Rule (CROMERRR) proposed for 40 CFR
- Response to proposed rule strong
- 2005 re-proposed minus 'records' or 'record keeping'

# Electronic Reporting

- “Electronic reporting is sharing information by submitting or accepting compliance reports, lab data, permits or other transactions from regulated facilities, states, tribes or other stakeholders by other than paper means.”

# Electronic Recordkeeping

- “Electronic recordkeeping is the storing, maintaining and retrieving of documents and records while ensuring their authenticity and integrity.”

# Final CROMERR

- Published October 13, 2005
- Effective January 11, 2006
- To be codified as Part 3 of Title 40 of the Code of Federal Regulations (CFR)

# What Final Rule Does

- Removes all regulatory obstacles to e-reporting under EPA and EPA-authorized programs;
- Sets requirements for electronic reporting to EPA;
- Requires EPA approval of modifications or revisions to authorized programs that allow or wish to allow e-reporting;
- Creates a special, optional process for obtaining EPA approval of program modifications or revisions related to e-reporting;
- Sets mandatory standards for e-reporting systems operated by authorized programs.

# New Part 3 Regulation

- Subpart A – General Provisions
  - Definitions in section 3.3.
- Subpart B – Electronic Reporting to EPA.
- Subpart C – Reserved.
- Subpart D – E-Reporting under EPA-Authorized Programs
  - Section 3.1000 - revising/modifying authorized programs.
  - Section 3.2000 – requirements for authorized program electronic reporting systems.

# Final rule does not...

- Set requirements for e-record-keeping;
- Make e-reporting mandatory;
- Prohibit mandatory e-reporting under other federal, state, tribe or local law;
- Initiate e-reporting for specific programs – EPA must publish a *Federal Register* notice to “turn on” e-reporting for specific programs.

# Final rule applies to:

- Persons or entities that submit reports or documents to EPA to satisfy other parts of Title 40 –
  - regulated entities
  - states, tribes or local governments in a few cases
- States, tribes and local governments that administer authorized programs under Title 40, when they receive reports or documents under those authorized programs.

# Final rule does not apply to:

- Documents submitted via fax or magnetic or optical media;
- Data transfers between EPA and states, tribes or local governments –
  - as part of their authorized programs, or
  - as a part of administrative arrangements with EPA;
- Submissions to EPA not under Title 40;
- Submissions to states, tribes or local governments not under their authorized programs.

# E-reporting System Processes

- Registration – signature provisions
- Signature Process – signature provisions
- Submission Process – general and signature provisions
- Signature Validation – signature provisions
- Copy of Record – general and signature provisions

# E-record keeping in ambient monitoring

- Signature log
- Chain-of-custody procedures
- Maintenance logs
- Station activity logs
- Measurement records (often a proprietary database)
- Backup strip chart records
- Calibration data
- Standards certification

# E-record keeping: Implementation Guidelines

- From OAQPS in 6/05
  - Reliability of system and procedures
  - Backup
  - Authentication
  - Integrity of electronic research records
  - Corroboration
  - Recommendations

# E-record keeping: Example Systems

- FDA: selected commercial vendor (Documentum)
- NHEERL selected based (in part) on FDA choice (NuGenesis/Documentum)
- Superfund/OEI developed: Enterprise Content Management System (ECMS) prototype development (Documentum)
- EPA/ORD-LV: 'Quality of Information Management & Technology; Computer Operations Checklist'

# Conclusion

- CROMERR does not apply to e-record keeping or data reporting
- Other agencies have moved ahead; we can learn from their experiences
- There is an outline of Implementation Guidelines from OAQPS
- Share information on how data is secured electronically in monitoring programs

# Acknowledgements

- David Swartz, OEI
- Anna Kelly
- Mike Papp
- Mark Shanis
- Joel Craig, San Luis Obispo County APCD
- Mark Stoelting, Bay Area AQMD
- G. Brilis, EPA/ORD-LV

# Contact Info

David Schwarz

[Schwarz.david@epa.gov](mailto:Schwarz.david@epa.gov); (202) 566-1704

Evi Huffer

[Huffer.evi@epa.gov](mailto:Huffer.evi@epa.gov); (202) 566-1697

[www.epa.gov/exchangenetwork](http://www.epa.gov/exchangenetwork)