DOE Legal and Compliance Issues for Electronic Notebooks

Al Geist
Computer Science and Mathematics Division
Oak Ridge National Laboratory
www.csm.ornl.gov/~geist

Research sponsored by Mathematics, Information and Computational Sciences Office
U.S. Department of Energy

DOE eNotebooks Used in Production

The DOE 2000 Electronic notebook project has a goal of making prototype implementations available to:

- General research community
- Academia
- Industry

Hundreds of electronic notebooks have been set up across the DOE Labs in:

- Collaborative projects
- Beamline and instrument logs
- Research groups

So I get the dreaded phone call

Motivation

Records Management departments feel out of the loop.

- Users download notebook software from the Web and set up multiple notebooks for their projects – no tracking, no provisions for long term archiving.

Paper Notebook compliance has dropped dramatically in the past few years.

- Recent survey inside ORNL showed less than 30% of paper notebooks met compliance requirements.

Storage space required to archive paper notebooks is growing too large.

- Space efficiency of electronic storage media is required.
- The results from one simulation on our Terascale computers would fill a stack of Patentpads that would reach half way to the moon – glimpse of your future!

Goals of this records management effort

Develop a compliance document for the use of electronic notebooks within the DOE labs.

- Begin with the compliance requirements for paper notebooks and extend this for the new paradigm.

Define a records management process that increases the lab-wide notebook compliance through the use of electronic notebooks.

- Deployment of electronic notebooks through records management departments benefit both the user and records management. Reduce user procedures.

DOE “Record Copy” Compliance

Entries must be in chronological order

Each entry must be signed and dated by author
and any other contributors to the page

Notebook should be periodically witnessed
by two experts who can read and understand it

Notebooks should be uniquely ID and indexed
to facilitate accurate retrieval until disposition

Each Notebook requires:
- a security plan to prevent unauthorized access or tampering
- a records retention and disposition schedule (10, 25, forever)
- a disaster plan both preventive (backups) and recovery steps
- to be turned into records management when *“done”*

Compliance Issues

Witnessing

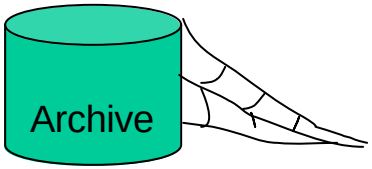
Getting two witnesses – can't be automated like notarization
Annotation feature provides the technical need

Time Stamp

Valid timestamps can't be done locally
Requires a trusted time stamp server

Long-term Storage

Department of Energy requirements require that laboratory notebooks be kept for 10 years, 25 years, or forever based on content and owner



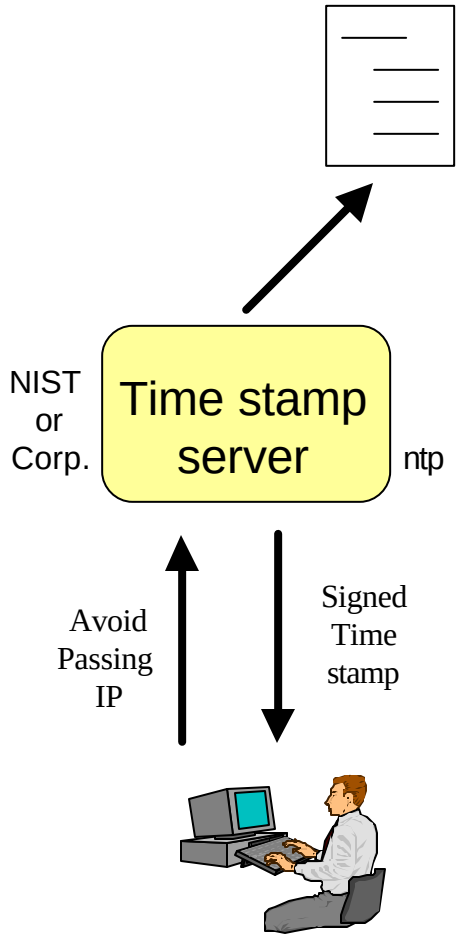
Aside: Notarization and Time Stamps

Electronic Time Stamping is very similar to the process we call notarization

You can't just stick a time stamp in your ELN even if you get it from a trusted source.

It needs to include the signature of the source and what is being time stamped including the author's signature.

Time stamping server needs to store some "information" in a non-electronic form to guarantee audit trail. (Typically published)



Compliance Raises Basic Design Issues

- Long term storage of computer media
  - computer technology and interfaces will be much different
  - long term storage - format readable 25 years in future
  - transfer of notebook entries as machines upgrade (eg. 64 bit)

- Patent Claims may require

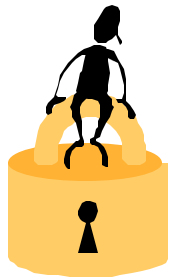
  Authentication - digital signatures used to verify author

  Tamper-proof entires

  entries can be verified as not changed since notarization

Tamper-proof Entries

An important point is that no notebook (paper or electronic) is tamper-proof. But techniques exist to detect tampering.



- Authentication
  - digital signatures (recently legalized)
    used to verify author
- Notarization
  - third party notary
    If electronic then also needs non-electronic verification
  - time stamp to verify time of entry must be based on trusted source
- Secure Storage
  - entries can be verified as not changed since notarization
    cryptographic methods like MD5 provide the means

ORNL approach to long-term storage

PDF too limiting

Proprietary standard, not editable, unable to save information in its native format for later use, rapid version changes

XML doesn't handle data types

Excellent for formatting, but it is a markup language not a storage format

Multi-part MIME (ORNL storage format choice)

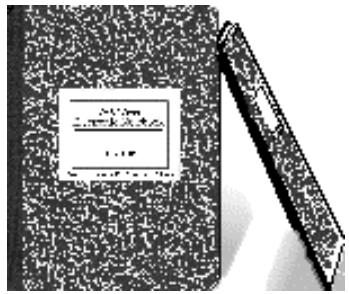
A widely used standard, self-defining format, tools exist to decode even if notebook software not available, strong handling of data types, large number of MIME types are already predefined

Note this is our standard notebook object (Nob)

Records Management Guidelines

csm

Computer Science and Mathematics



"Mandatory instructions for use of technical notebooks" handout

- Distributed with every notebook ID user obtains

Official DOE "record copy" compliance document

- Modified to cover both paper and electronic records
- Available online with links to relevant government regulations

Both of these are included in your conference material

ornl

Records Management ELN Process

RM advertises and maintains ELN server
- Researchers simply request an electronic notebook and are given a URL and access password.

ELN are given serial numbers when set up
- Notebook software can be configured to request a serial number from the RM server when first installed.

When ELN is finished, data is in the hands if RM
- RM does not have to hope notebook is turned in for archiving.

Benefits both user and RM personnel
- Compliance plans, backup schedules, and long-term archiving done automatically for user. RM department gets much higher level of compliance.

Process relieves researchers of many procedures. JOY! They are more likely to want to use ELN.

People here asking what's next?

Yes, we have some cool stuff in the pipe

time stamp & notarize servers

Version 2.0 redesign
based completely in Java 2 and servlets

Java plugins provide easier customization

Multipart MIME page storage

Technology transfer from DOE to private industry

authentication

Enote server

clients

browsers
instruments
publish tools
…

XML
client interface
page layout

For Further Information

DOE 2000 Electronic Notebook Website

http://www.csm.ornl.gov/enote/

For Commercialization opportunities:
Contact ORNL Technology Transfer
Grady Vanderhoofven
Phone: **(865) 241-2354**
Email:vanderhoofgs@ornl.gov

Also see:
Compliance documents in your conference material