**Department of Energy**
Washington, DC 20585

IPI-IV-1-03

FEB 1 4 2003

Dickson Kehl, ALO
Robert Fisher, CH
Emily Schneider, OR
William Daubenspeck, LLNL
Gary Drew, OAK
Robert Southworth, RL
Lisa Jarr, NETL

# Electronic Laboratory Notebooks

## Summary

Electronic laboratory notebooks, which have essential qualities equivalent to those of bound paper notebooks will be acceptable to Department of Energy for recording subject inventions and supporting data at National Laboratories.

## Purpose of this Paper

The purpose of this paper is to provide guidance to DOE counsel in evaluating the use of electronic notebooks for recording subject inventions and supporting data.

Procedures for reporting subject inventions to DOE remain the same as provided for under 48 CFR 970.5227-11(c)(1); 48 CFR 970.5227-10(f)(5); and 48 CFR 970.5227-12(f)(3) appended to this paper.

## Bound Paper Notebooks

Bound paper notebooks are the standard for laboratory notebooks under 48 CFR 970.5227 for inventors to chronologically record their inventions and supporting laboratory data.

Bound paper notebooks used for this purpose have the following essential qualities:

- Pages permanently bound and consecutively numbered so that alteration of page or sequence is immediately detectable.
- Provision for signature and dating by an author, witnesses and notary.
- Entries, including signatures, made with permanent ink so that alteration is apparent.
- Paper, binding and ink of a quality suitable for long term integrity.
- Indexable.



Printed with soy ink on recycled paper

- Somewhat searchable.
- Secure during the author's use and during storage and retention by the owner.
- An identified custodial system.

Federal courts, state courts and the U.S. Patent Office have found bound paper notebooks satisfactory to accomplish three essential legal functions relating to inventions:

1. 37 CFR 1.131 Affidavit or Declaration of prior invention to overcome cited patent or publication.
2. 37 CFR 1.623(c) Interference - Preliminary statement, copy of first written description and drawing.
3. Establish ownership of the invention by conception and reduction to practice at an identified location on a date certain.

Electronic Laboratory Notebooks

Electronic laboratory notebooks are currently being developed for use as an alternative to bound paper laboratory notebooks. Besides recording inventions and supporting data, they will be used for the above identified three essential legal functions relating to inventions.

The sewn binding and paper and ink quality of a laboratory notebook do not absolutely prevent alteration. All pages are bound and numbered sequentially. Blank spaces, if any, are lined out. Each page is witnessed and perhaps notarized to corroborate the content and date of the information recorded on the page. These features cooperate to make apparent any alteration to the notebook or its contents. Alterations may include addition or deletion of contents, change in sequence, change in date and time and alteration of a signature.

Electronic notebooks are available which deter alteration. This is accomplished in one way or another by resisting modification of the record or by conspicuously displaying the date of last modification.

The Electronic Signatures in Global and National Commerce Act is codified under 21 CFR Part 11. The Act provides for electronic signatures including notary signatures. An authenticated electronic signature satisfies any legal requirement to notarize, acknowledge, verify or make oath. DOE may also set a standard for electronic signatures in the future.

Electronic notebooks must provide for long term retention and retrieval of information. Litigation may arise in connection with a patent during the twenty-year term of the patent or thereafter. Accordingly, electronic record must be retrievable without deterioration for time periods in excess of twenty years. One consideration is the data format. Backup or storage in Adobe© Portable Document Format (PDF) or the equivalent may be desirable so that it will be readable and printable on future equipment and software. Indexing of the archived electronic notebook should also be provided for future retrieval.

Security of electronic notebooks, both in-use and during store and retention, should be consistent with that for paper bound notebooks.

Potential Benefits of Electronic Laboratory Notebooks

Electronic laboratory notebooks provide advantages that include: capacity to capture large amounts of data, capacity for lengthy attachments, enhanced searchability, enhanced shareability, capacity for graphics and legibility of entries.

Conclusion

Electronic notebooks that have the essential qualities of paper bound notebooks are acceptable to the Department of Energy for recording subject inventions and supporting data. These essential qualities are as follows:

- Consecutively numbered pages or other accepted sequencing convention to provide continuity and to allow for making reference to the stored information, to facilitate indexing and for retrieval.
- The minimum standard for alteration deterrence is identification and dating of alterations in a clearly apparent manner.
- Authentication of signatures as provided by 21 CFR 11 or future DOE standard.
- Storage media configuration and quality to provide integrity and retrieval of the stored information.
- Provision for indexing and searching.
- Security from unpermitted access.
- A documented custodial system.

We may be required to update this conclusion after the use of electronic notebooks for the above identified three essential legal functions has been tested in state and federal court and with any future federal regulation.

Paul A. Gottlieb
Assistant General Counsel
for Technology Transfer
and Intellectual Property

## Appendix

Subject Invention Disclosures

48 CFR 970.5227-11(c)(1) *Contractor procedures for reporting subject inventions to Contractor personnel.* Subject inventions shall be reported to Contractor personnel responsible for patent matters within six (6) months of conception and/or first actual reduction to practice, whichever occurs first in the performance of work under this contract. Accordingly, the Contractor shall establish and maintain effective procedures for ensuring such prompt identification and timely disclosure of subject inventions to Contractor personnel responsible for patent matters, and the procedures shall include the maintenance of laboratory notebooks, or equivalent records, and other records that are reasonably necessary to document the conception and/or the first actual reduction to practice of subject inventions, and the maintenance of records demonstrating compliance with such procedures. The Contractor shall submit a written description of such procedures to the Contracting Officer, upon request, for evaluation of the effectiveness of such procedures by the Contracting Officer.

48 CFR 970.5227-10(f)(5) *Invention Identification* Procedures. The Contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a written description of such procedures to the Contracting Officer so that the Contracting Officer may evaluate and determine their effectiveness.

48 CFR 970.5227-12(f)(3) *Contractor procedures for reporting subject inventions to DOE.* The Contractor agrees to establish and maintain effective procedures for ensuring the prompt identification and timely disclosure of subject inventions to DOE. The Contractor shall submit a written description of such procedures to the Contracting Officer, upon request, for evaluation and approval of the effectiveness of such procedures by the Contracting Officer.