

Recordkeeping Requirements for Electronic Research and Development Notebooks

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What Is An Electronic Notebook?

An electronic Research and Development (R&D) Notebook is the electronic equivalent of a paper research notebook. Instead of recording information on paper, electronic notebook “pages” record the sketches, text, equations, images, graphs, signatures, and other data. These data can be read and navigated just like in a paper notebook. Instead of writing with a pen and taping in images and graphs, reading and adding to an electronic notebook is done through a computer and can involve input from keyboard, sketchpads, mouse, image files, microphone, and directly from scientific instruments. Electronic notebook software varies in how much it “looks and feels” like a paper notebook, but all the basic functions of a paper notebook are present. In addition, electronic notebooks allow easier input of scientific data and the ability for collaborators in different geographic locations to share the record of ideas, data and events of the joint experiments and research programs.

Is My Notebook Record Copy (The “Official” Copy)?

There are a number of regulations that R&D notebooks must meet (both paper and electronic) in order for them to be considered record copy. Notebooks can be useful scientific tools even if these regulations are not followed, but they cannot be considered as the record copy. Based on these regulations, several factors will determine whether an electronic notebook will be the ORNL record copy:

- Is the research project based at ORNL, is the principal researcher based at ORNL, or did the project team decide that the record copy would be retained at ORNL?
- Does the notebook meet the definition of a record?

Definition: Records include all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law, or in connection with the transaction of public business, and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the Government, or because of the informational value of the data in them.

What Are My Responsibilities In Maintaining My Record Copy Notebook?

The principal researcher must ensure:

- Authentication

Definition: Authentication is a confirmation that the record is accurate, complete, and appropriate to the actions taken.

- Alteration or amplification of previous entry **MUST** be made as new entries with the current date, and cross-referenced to the previous entry.
- Each entry must be signed and dated by the person who made the entry, and also by any others who contributed to the content thereof. If an invention is recorded, the true inventors thereof must write **INVENTED BY** before their name. The notebook should be periodically reviewed by at least **TWO** witnesses -- persons not directly involved with the work -- and be signed and dated by them with a statement that they have **READ** and **UNDERSTOOD** the entries (ORNL Office of General Patent Counsel, Requirements and Instructions for Research and Development Notebooks).

- Retrievability

A notebook should be retrievable during its life cycle. There should be a method for all authorized users of the notebook to retrieve desired documents, such as an indexing system or text search system. Electronic records should be uniquely identifiable and properly indexed, based on key fields, to ensure accurate retrieval.

- Usability

Appropriate media and systems for storing the notebook should retain records in a usable format until final disposition/destruction occurs.

- Security

A security plan should be in place that ensures:

- Only authorized persons have access
- Provides for backup and recovery
- Minimizes the risk of unauthorized alterations or erasures

How Long Do I Need To Retain My Notebook?

Record copy at ORNL must have a records retention and disposition schedule.

Definition: A records retention and disposition schedule states the retention and disposition of a Record Series, e.g., system, related documents.

- Records Policy & Management applies schedules based upon the use of the record and needs of the creators. The researcher provides this information. Every ORNL project requires an approved schedule. Decisions must reflect requirements from the National Archives and Records Administration (NARA) and the DOE.

http://home.ornl.gov/divisions/computing_information_networking/records/services-desc.shtml - scheduling

- Retention of a notebook can range from ten (10) years to permanent, depending on several factors:
 - Funding source: Work For Others (WFO), Cooperative Research and Development Agreement (CRADA), or DOE
 - Value of research

[NOTE: See Appendix for detail on records retention requirements.]

Records Policy & Management will provide a records retention schedule for your project including the electronic (or paper) notebook. An approved records disposition schedule is required for storage or destruction of any record copy.

How And Where Should I Store The Record Copy?

A paper notebook must be registered by Records Policy & Management and returned to Records Policy & Management (Laboratory Records) upon termination of the assignee's employment or of the program or project, or when it ceases to be of reference value.

Electronic R&D notebooks (record copy) may be stored on an electronic system approved by the Computing, Information, and Networking Division (CIND). An approved electronic system is designed to create and capture reliable and authentic records and to secure the integrity of the electronic record. Electronic notebooks may be archived in the Central Publications and Presentations Registry (CPPR). Call Records Policy & Management for transfer instructions.

If you retain the notebook for its life cycle, you should ensure that it is:

- Easily retrievable in a timely fashion
- Retained in a usable format
- If notebook is scheduled as permanent, requirements are more detailed

- See 36 Code of Federal Regulations (CFR) 1234.30(4)

http://www.access.gpo.gov/nara/cfr/waisidx_98/36cfr1234_98.html

http://home.ornl.gov/divisions/computing_information_networking/records/services-desc.shtml#scheduling

- Whatever storage media is used, information should be periodically reviewed and migrated to ensure its preservation. Proper selection of software, media, and file formats to be used to store electronic records will help ensure that records can be adequately read, retrieved, and duplicated until they are no longer required. Instructions for retrieval and/or preservation must be documented in a manner to ensure long-term readability. This might include physical and technical characteristics of the records, hardware and software platforms required to read the records, a description of the form of the data, and any other technical information needed to read or process the records.

What Else Do I Need To Do To Take Care Of My Notebook?

Disaster Plan. If you are maintaining electronic record copy, you should have a disaster plan that considers:

- Types of potential hazards
- Preventive measures
- Steps to be followed in the event of a disaster

Preventing disaster could be as easy as creating a backup copy of your notebook and transmitting or taking it out of the same physical location for storage.

Destruction. Record copy can be destroyed only in accordance with an ORNL records retention and disposition schedule.

<http://eshtrain.ct.ornl.gov/sbms/SBMSearch/ORNLProc/io003.htm>

Who Can Help Me With Requirements In This Guide?

Records Policy & Management is responsible for administering the ORNL records management and document control program. Contact RP&M at 576-5061, stewartjg@ornl.gov. For records retention schedules, call 574-6767, or e-mail swensonem@ornl.gov.

APPENDIX

RECORDS RETENTION REQUIREMENTS

Two DOE record schedules relate to Research and Development records created at ORNL. They are (1) Work for Others (WFO), Cooperative Research and Development Agreements (CRADAs) and Cost-Sharing Agreements (DOE N1-434-95-5), and (2) Research and Development Records (DOE N1-434-96-9).

I. WFO, CRADAs and Cost-Sharing Agreements

A. WFO. There is other supporting documentation included in this schedule, but the retention requirements for Project Deliverable Records are:

1. All information created during the life of the project (1.f).
 - a. All information and/or technical data arising from work performed for another government agency, unless provided otherwise by DOE.
 - b. All information and/or technical data arising from work performed under contract for State agencies, local agencies, or domestic/private corporations.

Retention: Transfer one set of the case file to the agency for which the work was conducted. Retain record set of the case file for legal and financial purposes for 10 years, following approval by DOE and the respective government agency, then destroy.

B. CRADAs and Cost-Sharing Agreements. Project Files (2.b) (2.f.2)

1. Records documenting CRADA projects from initiation to completion or termination. Records include, but are not limited to, proposals; project planning justification records; start-up reports and correspondence; budgetary documentation; monthly, quarterly and yearly status reports; technical data and studies; partnership meeting minutes; implementation policies and procedures; non-disclosure agreements; presentation materials; and all other related records.

Retention: Transfer one records set to corporate partner following project completion and/or termination, as set forth in the initial CRADA Agreement. Retain one records set for 10 years after project completion or termination, then destroy.

II. Research and Development Records. There is other supporting documentation included in this schedule, but retention requirements for the Research and Development Records are:

A. Level I: Projects which receive national or international awards of distinction; active participation of nationally or internationally prominent investigators; research which resulted in a significant improvement in public health, safety, or other vital national interests; scientific endeavors which were the subject of widespread national or international media attention and/or extensive congressional, DOE or other government agency investigation; show the development of new and nationally or internationally significant techniques which are critical for future scientific endeavors; or made a significant impact on the development of national or international scientific, political, economic, or social priorities.

Retention: Permanent. Transfer to the National Archives and Records Administration (NARA) 30 years after termination of project/program.

B. Level II: Research that leads to the development of a “first of a kind” process or product; improved an existing process, product or application; or has implications for future research.

Retention: Destroy 25 years after termination of project/program.

C. Level III: Research projects/programs that do not fall into Levels I or II.

Retention: Destroy 10 years after termination of project/program.

REFERENCE DOCUMENTS

44 United States Code

DOE Electronic Records Guide, 1996

ORNL Office of the General Patent Counsel, Instructions for Research and Development Notebooks

ORNL-IO-003, Records Management and Document Control

DOE Work for Others and Cooperative Research and Development Agreement Records Schedule, DOE N1-434-95-5

DOE Research and Development Records Schedule, DOE N1-343-96-9