

University of California



YUCCA MOUNTAIN PROJECT Technical Implementation Plan

No.: TIP-YM-12

Revision: 0

Change Notice: TIP-YM-12-0-1

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Subject:

ELECTRONIC RECORD KEEPING

AUTHOR:

J. Blink

Training Required: Yes No

Comments: Training required for personnel implementing this procedure.

REVISION HISTORY

Rev. No.	CN No.	Effective Date	Description of Revision/CN
0		05/27/92	Initial Issue.
0	TIP-YM-12-0-1	03/09/95	Changes in Responsibility. Addition of Revision History. Affects Title Page and page 3 of 3.

APPROVALS:

W. L. Clarke 3/8/95
 W.L. Clarke, Project Leader Date

R. E. Monks 3/8/95
 R.E. Monks, Quality Assurance Manager Date

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1.0 PURPOSE

This procedure established controls for electronic records maintained in lieu of paper records such as scientific notebooks or software configuration management systems.

2.0 SCOPE

This procedure applies to electronic records that substitute for paper records that document a chronology; examples include scientific notebooks and software configuration management systems. Documents not requiring a chronological record are not subject to this procedure; examples include drafts of technical reports or software lifecycle documents (such as software requirements specifications).

3. CONTEXT

The availability of computer hardware and software permits generation of records that may be updated, corrected, or revised to be consistent with the evolving knowledge of the record source. However, the requirements for traceability, review, and authentication apply, and electronic records must be subject to controls to assure that such requirements are met. This procedure establishes those controls.

4.0 RESPONSIBILITIES

Technical Area Leaders (or LLNL-YMP supervisors of personnel not within a Technical Area) are responsible to assure that records subject to this procedure comply with applicable requirements.

5.0 DEFINITIONS

An Electronic Record is any electronic file or set of files established to document information traditionally documented in established paper records such as scientific notebooks or software configuration management systems. Data or information produced electronically, such as instrument readings or modeling input/output files, are not subject to this procedure.

6.0 PROCEDURE

6.1 Format

Format Electronic Record systems that meet the intent of procedures established to control paper records need not meet non-applicable requirements of those procedures. For example, electronic scientific notebooks need not be bound, and electronic software configuration management systems need not use the filing system of TIP-YM-11 if the documentation requirements are met.

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6.2 Revision Number

Revision Number records document the chronology of information, in addition to the final result. When paper records are corrected, the evolution of the record is documented; electronic records must meet the same requirement. If an entry completed on an earlier date is to be altered, the existing record must first be printed. The altered record is assigned a new revision number to prevent confusion with the earlier version. The revision number, page number, and record identification shall be a part of the electronic record and be included on each page of all printouts of the record.

6.3 Author Authentication

Each entry in an electronic record must include the date and the name of the author. It is recommended that the software automatically record the date and author by using information available from the computer's clock and the log-in procedure. The author's signature when the record is eventually submitted to the LRC authenticates all previous entries (including those by co-authors).

6.4 Reviewer Authentication

The reviewer must authenticate reviews. Two options are available:

- 6.4.1 The record can be printed and the reviewer can sign and date the printout to indicate the review.
- 6.4.2 The reviewer's name and review date can be entered in the electronic record. However, when the record printout is submitted to the LRC, the reviewer must sign the record or provide a signed memo to be attached to the record.

6.5 Submission to the LRC

The author shall maintain a backup copy of all electronic records until the record is printed and forwarded to the LRC. A backup shall be produced within one week of an entry (weekly backups).

At least quarterly, the record must be printed (preferably on 8-1/2 x 11 inch paper) and submitted to the LRC as a completed record. The revision number must be incremented at this time.

At any other time an electronic record's revision number is changed, the previous version must be printed and submitted to the LRC as a record segment or a completed record. After a version is accepted by the LRC, the electronic file of that version need not be retained.

7.0 RECORDS PRINTOUTS

Records Printouts of electronic records will be treated as quality records. When the record is complete, the LRC will assemble all record segments into a record package. The record source must sign the record transmittal form of the assembled record package. If a record segment includes repetition of an earlier record segment previously submitted under the same revision number, the previous record segment may be destroyed.

QUALITY ASSURANCE OFFICE YUCCA MOUNTAIN PROJECT

Memorandum

Mail Station: L-204
Ext: 2-3916

February 16, 1995
QA:95/026

TO: L. Lewis, S. Lundeen, C. Wilgus, and T. Wolery
FROM: R.E. Hamati *R. Hamati*
SUBJECT: Electronic Documentation Within the LLNL-YMP

This memo serves two purposes:

1. To summarize the discussions and decisions that transcribed from the meeting held by the Electronic Documentation Committee on February 10, 1995.
2. To describe the background and the events that preceded the meeting and which resulted in the formation of the committee.

During the audit of LLNL-YMP by the DOE (Audit YMP-94-10) during the week of September 19-23, 1994, Mr. Bruce Mabrito, an NRC Observer had a "Question/Concern" (Log No. 0003) associated with the integrity of electronic records. The issue concerns scientific notebook entries as well as source code for software. The question was discussed during the audit and a commitment was made to provide within the next six months a more exact response about the subject. This issue has since been investigated individually by some of the LLNL-YMP people involved in software activities and recently the Electronic Documentation Committee was formed to formalize the process, discuss all suggestions and recommend an approach that would be feasible, credible, and acceptable to the NRC. The committee is composed of T. Wolery, C. Wilgus, S. Lundeen, L. Lewis, and R. Hamati, and the first meeting took place on February 10, 1995.

The broad outline of what transcribed from the meeting can be summarized as follows:

- The problem is complex in nature because of the many users involved and the different servers and software codes used.
- The problem is certainly not unique to LLNL-YMP. Electronic notebooks and specially the tempering with such notebooks is being looked into in many industries and the progress has not been as fast as one would expect.
- LLNL-YMP uses many servers and as a consequence, one solution may not be practical in resolving all the issues associated with electronic record keeping on all servers.

- Currently, most systems that require configuration management use well-established tools such as the UNIX utility SCCS to maintain software. Features of SCCS do record the time of entry of software updates as well as the author of the update. The system allows a description of the entry for record/version-updates, and does satisfy the issue raised in the "Question/Concern" for software.
- The electronic documentation system associated with requests for changes to the databases supporting geological studies, CNGBOCHS, allows a user to electronically enter a request and alter the entry up to the time the request is satisfied. At the time the correction/request is satisfied, the record becomes permanent. Since no entries can be altered after the request is closed, the CNGBOCHS system appears to satisfy the issue raised in the "Question/Concern" for databases supporting geological studies.
- For electronic documentation for scientific notebooks, research into systems available to satisfy the SN entries has been conducted. Systems described in articles such as "Electronic Laboratory Notebooks May Revolutionize Research Record Keeping" C&EN, May 23, 1994, and the Deftrack system at LLNL have been considered. Problems associated with these systems, such as cost, special equipment, additional (large) software costs for licensing database tools, etc. have been noted and are substantial. In order to address the requirement for an electronic documentation system and develop a solution, a plan described in the next bullet was suggested.
- The UNIX mail system will be the tool to begin development of the LLNL-YMP electronic documentation system. The suggestion is that a postmaster be created to receive documents in electronic form. The documents will be "attached" to the mail message. This will allow any file (Framemaker, MacProject, Word, Word Perfect, binary, ASCII, etc.) to be sent to the postmaster. The mail tool does time stamp the message and identifies the sender. The postmaster will copy or move the file to a file recording area and set privileges so that no one can change the entry. Special utilities will then be developed to develop databases for reporting and any additional YMP requirement.

Our meeting scheduled for February 24, 1995, at 9:30 a.m., should initiate a project plan to develop a prototype for this system. We need to define user requirements and develop a prototype. TIP-YM-12, Rev. 0, will be officially revised when a prototype is adopted. At that time, it will include the details of how the system is to operate. To assist in addressing and resolving this problem, please bring your comments/suggestions in written form to the meeting.

cc: J. Blink
B. Clarke
R. Monks

QUALITY ASSURANCE OFFICE YUCCA MOUNTAIN PROJECT

Memorandum

Mail Station: L-204
Ext: 2-3916

February 27, 1995
QA:95/036

TO: L. Lewis, S. Lundeen, C. Wilgus, and T. Wolery
FROM: R.E. Hamati
SUBJECT: Electronic Documentation Within the LLNL-YMP

The following is a summary of the discussions held during the meeting of the LLNL-YMP Electronic Document Committee on February 24, 1995.

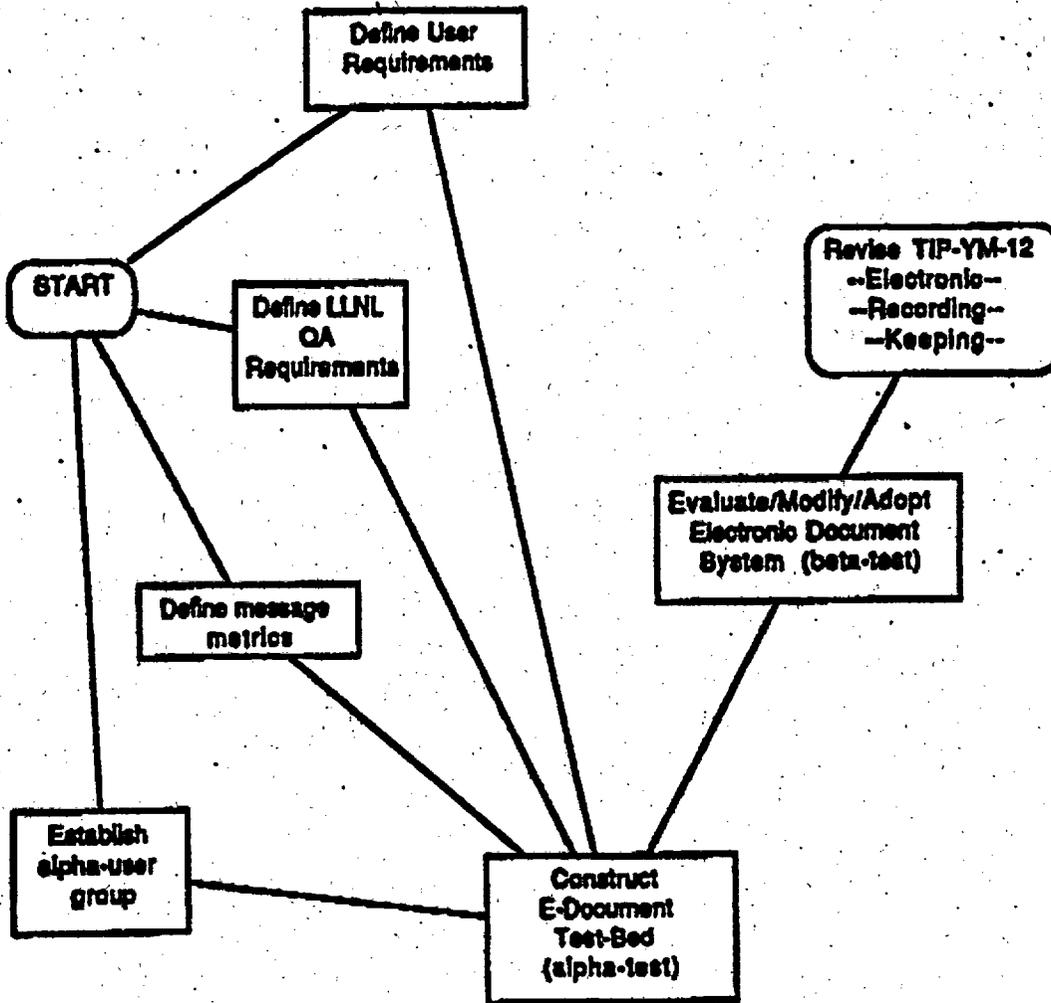
The options that were discussed included several commercially available products along with the development of a prototype electronic document system based on the UNIX mail utility.

With respect to the commercially available systems, Tom Wolery accepted the task of researching and evaluating advertised systems that have been brought to the attention of the Committee. Although all commercially advertised systems do not appear to meet the needs of the LLNL-YMP, their current status and performance will be evaluated.

With respect to an electronic document system based on the UNIX mail utility (task outline attached), substantial discussions were held focusing on user requirements. It was decided to postpone this discussion until additional information was collected. The additional information includes the evaluation of commercial systems and a better definition of the YMP QA requirements.

cc: J. Blink
B. Bryan
B. Clarke
R. Monks

Electronic_Document_System Task Outline



Ray Hamel
Lynn Lewis
Suzanna Lundeen
Conrad Wilgus
Tom Wolery

Revised 2/24/94