QUALITY ASSURANCE RECORDS SYSTEM FOR RESEARCH AND DEVELOPMENT ACTIVITIES IN SUPPORT OF GEOLOGIC REPOSITORY PROGRAMS

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ABSTRACT

The Pacific Northwest Laboratory (PNL), which is operated by Battelle Memorial Institute for the Department of Energy, is conducting various studies associated with the high-level waste repository site selection process. In conjunction with this effort, PNL has developed a quality assurance (QA) program that is applicable to all organizations that are performing research and development (R&D) activities in support of the repository programs. This QA program meets the basic and supplemental requirements of ANSI/ASME NQA-1-1983 and the Nuclear Regulatory Commission (NRC) Review Plan for QA Programs for Site Characterization of High Level Nuclear Waste Repositories (1). A key part of this program is the handling of QA records that may ultimately support the licensing process for the repository. This paper describes a QA records system that is flexible enough to accommodate several types of research, such as paper studies, test method development, site characterization studies, software development, and hardware design. In addition, the QA records system is acceptable to a variety of clients who have licensing concerns. The QA procedures and their relation to the requirements are described. Most important is the discussion on the approaches used to assure that the records are organized such that the user can readily recreate or defend data, conclusions, and recommendations resulting from the research.

INTRODUCTION

Recent events in the nuclear industry have made it very clear how important records can be in supporting critical licensing and operating decisions. In 1981, problems associated with QA records contributed to the Nuclear Regulatory Commission's (NRC's) denial of an operating license to the Zimmer nuclear power plant near Cincinnati, Ohio (2). Since 1979, PNL researchers have been participating in R&D activities associated with the design, selection and operation of a suitable high-level nuclear waste repository. Because of the political sensitivity of this issue, PNL has taken steps to minimize the potential for future problems as a result of records that are inadequate and/or difficult to retrieve.

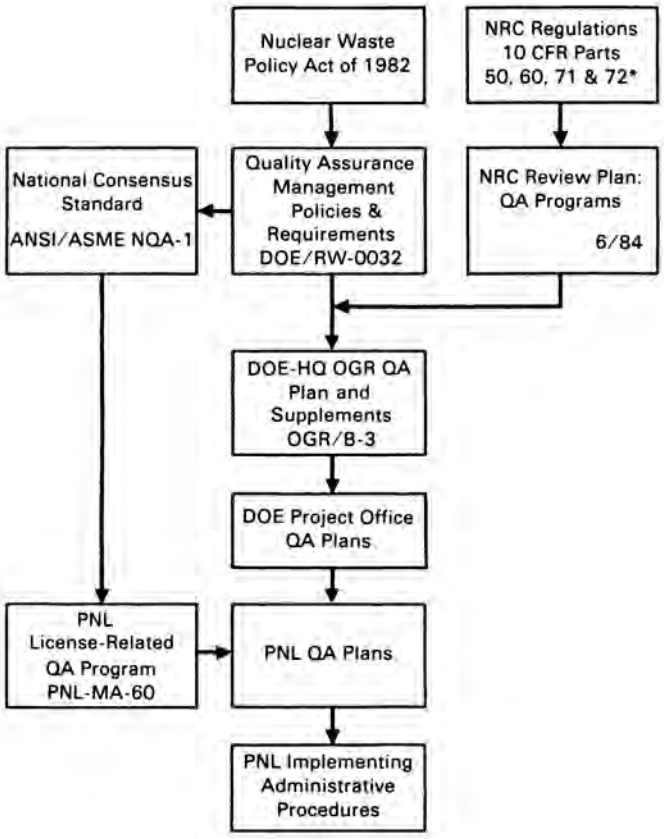
For the past several years, PNL researchers have performed various studies associated with the repository site selection process and the four candidate geologies (salt, basalt, tuff, and crystalline rock). The initial development of the QA records system proved difficult because each of the site-specific projects (e.g., the Basalt Waste Isolation Project) had different interpretations of the basic records system requirements necessary for their site. Consequently, though PNL was compelled to respond to different requirements from each of the site-specific projects, the effort has resulted in a QA records system that is responsive to a full spectrum of interpretations.

Discussions beginning in 1984 led to the establishment of a QA records system adequate for use in the license-related research at PNL. The first administrative procedures implementing the system were distributed for use in March of 1985. Since that time the procedures have been consolidated, condensed, and further improved.

RECORDS REQUIREMENTS

The QA program applicable to the selection and operation of a high-level nuclear waste repository must be based on the 18 criteria of NRC Regulation 10 CFR 50, Appendix B (3). The Office of Civilian Radioactive Waste Management has established the national consensus standard ANSI/ASME NQA-1 (NQA-1) as the basic QA requirements standard for the overall geologic repository program (4). Figure 1 shows a simplified relationship between the governing documents and the administrative procedures used by PNL in response to these requirements. NQA-1, Basic Requirement 17, Quality Assurance Records, provides the basic requirements for the handling, storage, and control of QA records. NQA-1 Supplement 17S-1 expands the Basic Requirement and adds additional detail, especially in the area of retention and storage requirements. The Office of Geologic Repositories (OGR) QA Plan, Supplement 4, further amplifies the requirements for the control of QA records and specifically addresses requirements for identification, as well as providing a list of typical records (5). As a subcontractor to the project offices, PNL receives and must respond to specific QA requirements from each of the offices. The system described herein incorporates the appropriate guidelines of these governing documents.

The governing standards address three major items associated with the control of QA records: generation, traceability, and storage and handling. These three items comprise the crux of the QA records system; deficiencies in any of these aspects will hinder the proper and efficient operation of the system.



*Reference Appendix B, 10 CFR 50 for QA Requirements

Fig. 1. Governing Document Hierarchy.

The PNL records system is embodied in two separate administrative procedures.(a) The first and most critical procedure covers the generation and identification of the records, and lays the foundation for the records retrieval methods. This is the only procedure necessary for the R&D staff to understand and implement. The other procedure is written for staff who are responsible for operating a central records storage facility. This procedure, which covers receipt, access, and transmittal of records to the client, will not be discussed in this paper.

RECORDS GENERATION

When defining a QA records system, the first item that must be addressed is that of records generation. The inherent problem is that of dealing with the documents once they have become records (a document becomes a record only after it has been validated). The focus should not be on the actual generation of the documents to be filed, but rather on the potential end use of the QA records both as unique items and as a collection.

The PNL records system is initiated by having each research project generate a research Project Records List (PRL, Fig. 2). The PRL serves primarily as a method by which PNL and the client can review the records intended to be generated and assure that records appropriate for defending the work being conducted will be maintained by PNL. The PRL should be considered a planning document and is not a part of the data traceability link to be discussed later. The PRL also establishes other items, such as frequency of records turnover to the client and retention classifications.

After approval of the PRL, the project is required to prepare a Project File Index (PFI, Fig. 3)--the key to successful implementation of the PNL records system. The project manager uses the following steps to create the PFI.

1. Determine and list all of the end-products that will be delivered to the client. In many cases, this is simply a list of project milestones but may be different if several milestones are associated with one product. For example, if one end-product of the project is a report on the interaction of waste isolation materials, there may be interim milestones associated with procurement of test equipment, development and issuance of test procedures, and acquisition of samples. In developing the end-product list, the project manager would not consider each of the interim milestones as a separate product.

2. Review a list of potential project-specific records provided in the records management administrative procedure and identify all of those records that will be generated in support of each end-product. The potential project-specific records list is very broad; it includes records applicable to literature searches, laboratory investigations, and software and hardware design. At this stage of the process, the project manager selects only those records applicable to a specific end-product. If more than one end-product exists, a corresponding list of records must be developed for each one (Ref. T1 through T4 of Fig. 3).

3. Review the list of potential project-specific records again, this time considering only those records that are generic to the project. For example, training records for individuals on the project would be considered project-generic records.

4. Classify the selected records in accordance with a file classification guide also found in the 1986 records management administrative procedure.(a) The purpose of the classification guide is to group records in a consistent manner, thereby making it easy for individuals to work on different projects or end-products without the need to relearn a different classification system.

5. Compile the result of these efforts into a PFI. Sub-indices may be appropriate to organize the records into two primary categories: those that are generic to the project and those that are in direct support of a specific end-product.

The ultimate objective of the above exercise is to assure that all of the records for a specific end-product are filed and stored together. This will substantially improve the client's ability to recreate and defend that end-product.

(a) PACIFIC NORTHWEST LABORATORY (PNL), "Research Records System," PAP-1701 (1986).
PACIFIC NORTHWEST LABORATORY (PNL), "Storage and Management of Completed Research Records," RCP-1701 (1986).

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PROJECT RECORDS LIST

L2D4P PRL
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PRL Revision 0

Project Title: Waste Product Qualification Sponsor: Site-Specific Resources

Project Manager P. T. Hill Project No.: 99999 Date 1/1/87

Retention Classification (Records are classified Lifetime unless specified otherwise by the sponsor.)

(X) Lifetime ( ) Nonpermanent ( ) Long term ( ) Short term

Dual Storage Required?

( ) Yes (X) No

Frequence of Turnover to Sponsor?

(X) Annually ( ) Every 2 years ( ) Other

QAD Representative Concurrence Date Project Manager Approval Date

Record Types

Technical Program Plan
QA Plan
Technical and Topical Reports
Technical Procedures
Software Development, Testing, Verification & Application Records
Audit Reports and Corrective Action
Surveillance Reports and Corrective Action
Incident & Unusual Occurrence Reports
Nonconformance and Deficiency Reports and Corrective Action
Measuring & Test Equipment Operation Instructions & Calibration Records
Inspection Reports
Purchase Order and Contract Documentation
Design Criteria
Laboratory Record Books
Test Plans
Data Reduction Records
QA Transmittal Records
Training Records
Engineering Drawings
Independent Technical Review & Peer Review Records

Fig. 2. Typical Project Records List.

TRACEABILITY

Record traceability encompasses both the identification of each specific record and its retrievability. The requirements contained in the records standards that address identification and retrievability are particularly difficult to interpret for an R&D environment. NQA-1, Supplement 17S-1, Section 2.6 attempts to clarify the interpretation of "identifiable" by stating that sufficient information shall be provided to permit identification between the record and the item(s) or activity(ies) to which it applies. This requirement can be complied with in varying degrees, especially when one considers the ambiguous definition of item or activity. Supplement 4 of the OGR QA Plan adds further detail to this area by requiring each record to be identified by a unique number or other designation that is directly traceable to controlling programmatic information (e.g. project number, contract number, etc.). However, even the use of identifying numbers does not guarantee traceability to the end-product, because more than one end-product may be produced on each project. Therefore, this supplement further requires that all final reports contain a list that enables prompt retrieval of all records used to compile or evaluate the report. The existence of this list is helpful; however, unless the files are structured as described previously, the time required to retrieve the records may still be unacceptable.

To address the identification requirements, PNL labels each record with the PNL project QA plan number and revision, a PFI identification number, and the file classification. The QA Plan number is unique within PNL, whereas the PFI identification number is not always unique but nonetheless required if more than one index per project exists. The file classification is generic by design. The sum of this information enables the record to be removed from the file and returned to its proper location at any time.

The primary method of documenting research is a written report. Once delivered to the client, the data may be used in site characterization, performance assessment, operation, or licensing activities. Activities associated with the site selection process have been delayed by opposition from state and local governments, Indian tribes, and other interested parties. Challenges to the siting process involve issues that have been at least partially investigated by project office subcontractors such as PNL. Future opposition will undoubtedly focus on the reports generated by the subcontractors that contain the recommendations, data, or analyses in question. Therefore, it is critical that all records supporting any particular report are complete and accurate (valid), and equally important, that they can be retrieved with a minimum effort.

The goal of easy and complete retrieval can be achieved if the preparation of the PFI is completed as

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PROJECT FILE INDEX

DATE 1-1-87
REV. 0

Project Title (from statement of work)		Document No.
REPOSITORY RELATED PROJECT		N/A
Name of Sponsor	Project No. (Acctg or W.P.)	QA Plan No.
Site-Specific Resources	99999	WTC-007

Functional Classifications	Custodian	Location
A ADMINISTRATION	A. J. Clerk	3763/4/300A
A1 Policy and Management		
A1.1 Project Plan & Contract		
A1.2 Change Control		
A2 Organization		
A2.1 Project Organization Chart		
A2.2 Delegations of Authority		
O OTHER SERVICES	A. J. Clerk	3763/4/300A
O1 Records Management		
O1.1 Project File Index		
O1.2 Records Transmittals/Receipts		
O2 Document Control		
P PERSONNEL (Training Records, Resumes, etc. to be filed alphabetically)	A. J. Clerk	3763/4/300A
Q QUALITY ASSURANCE	A. J. Clerk	3763/4/300A
Q1 QA Program		
Q1.1 QA Plan		
Q2 Quality Assurance Audits & Responses		
Q2.1 Internal/External Audits		
Q2.2 Internal/External Surveillances		
Q3 Nonconformances and Corrective Action		
T TECHNICAL		
T1 Waste Canister Analyses	K. E. Known	324/118/300A
T1.1 Technical Report on Canister Design (Milestone A)		
T1.2 Design Criteria		
T1.3 Design Calculations/Analyses		
T1.4 Statements of Work to Supporting Organizations		
T2 Waste Canister Impact Tests	K. E. Known	324/118/300A
T2.1 Technical Report on Impact Tests (Milestone B)		
T2.2 Canister Procurement & Receiving		
T2.3 Test Documentation		
T2.3.1 Test Plan		
T2.3.2 Technical Procedures		
T2.4 Basic Data		
T2.5 Laboratory Record Book		
T2.6 Measuring and Test Equipment		
T2.6.1 M&TE List		
T2.6.2 Calibration Records		
T2.7 Statements of Work to Supporting Organizations		
T3 Waste Performance Model	O. T. Code	Sigma I/3000A
T3.1 Technical Report on Performance Computer Model (Milestone C)		
T3.2 Laboratory Record Book		
T3.3 Calculations		
T3.4 Software Documentation		
T3.4.1 Software Requirements Form		
T3.4.2 Final Internal Review		
T3.4.3 Verification/Validation Plan		
T3.4.4 Configuration Management		
T3.4.5 Application Control		
T3.5 Sponsor Technical Input		
T4 Groundwater/Waste Interactions	L. C. Nostle	205/18/300A
T4.1 Technical Report on Groundwater/Waste Interactions (Milestone D)		
T4.2 Groundwater Sampling Information		
T4.3 Reference Waste Composition		
T4.4 Technical Procedures		
T4.5 Measuring and Test Equipment		
T4.5.1 M&TE List		
T4.5.2 Calibration Records		
T4.6 Laboratory Record Book		

Fig. 3. Typical Project File Index.

described earlier. As mentioned, each end-product has its own PFI or a subsection of a PFI structured specifically for that work. Then, as records are generated and filed, traceability is enhanced simply by nature of the file structure. Here the key benefit of the filing method becomes apparent. Because all records for a specific end-product are filed together, it could be considered unnecessary to cross reference or add other information on each record to provide the ability of recreating the complete set of records.

This benefit becomes even more apparent when the PNL records system is compared to other systems that are keyed only to the generic topic of the record. For instance, all procurement records generated on a project would be filed together irrespective of the end-product they support. Retrieving the procurement records associated with one specific end-product would require a significant amount of time even if the records were easily identifiable. This situation is eliminated in the PNL filing system.

If generic records are required to defend results, they too can be easily retrieved. For example, if the qualifications of an individual contributing to a specific end-product are in question, then the generic training file for the project would contain the appropriate records for that individual. Calibration records are another type of documentation that could be placed in generic files. It is not uncommon for a piece of measuring and test equipment to be used in generating data for more than one end-product. Instead of duplicating all of the calibration records and filing them according to the end-product, a generic file for the calibration records could be maintained.

STORAGE AND HANDLING

Upon completion of the PFI during the initial stages of the project, a copy is provided to the central records storage facility. Then on a monthly basis, copies of completed records are transmitted from the individual research projects to the storage facility where they are filed in accordance with the appropriate PFI. The result of this process is the creation of a duplicate file that serves two purposes:

1. It allows PNL to meet the optional dual facility storage requirements contained in Supplement 17S-1 of NQA-1 and permitted by Supplement 4 of the OGR QA Plan. (At PNL, this was the most cost effective method of complying with the requirements, because a single storage facility that met the requirements of Supplement 17S-1 was not available.)

2. The duplicate file and the central records storage facility provide a clearing house for transmittal of the records to the client. Usually annually, all of the records accumulated during the previous year are assimilated into a records turnover package and transmitted to the client. Included in this turnover package is a Detailed File Classification Log. This log is updated by the central records facility personnel on a continual basis as the records are received at the facility. In addition to the QA Plan number, the PFI identification and the file classification, the log contains a brief description, the number of pages, and a date for each record contained in the file. This log is organized in the same manner as the PFI and as such provides a list of supporting documentation for each end-product. The log also provides the client with an easy method of determining the completeness of the records turnover package.

CONCLUSION

PNL has developed a QA records system that is responsive to the requirements associated with the selection of a high-level nuclear waste repository. The system can accommodate records generated in a variety of R&D disciplines. An important feature of the system is its ability to enhance the traceability of individual records to the end-product that they support. It is expected that interveners will challenge the repository siting process by questioning complicated technical issues discussed in written reports. Consequently, complete and rapid retrieval of the supporting documentation will be vital to a successful defense of the work.

REFERENCES

1. NUCLEAR REGULATORY COMMISSION (NRC), "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories" (1984).

2. *Nuclear News*, 25, 1 (1982).

3. NUCLEAR REGULATORY COMMISSION (NRC), Code of Federal Regulations, Title 10, Part 60, Subpart G.

4. DEPARTMENT OF ENERGY (DOE), "Quality Assurance Management Policies and Requirements," DOE/RW-0032 (1985).

5. DEPARTMENT OF ENERGY (DOE), "Office of Geologic Repositories Quality Assurance Plan for High-Level Radioactive Waste Repositories," OGR/B-3, Draft #3 (1986).