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"Traceability and Retrievability: Documentation, The Bridge from Science to Compliance"

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In this day of regulatory compliance, the fact that good science was practiced and documented is, in and of itself, not enough to assure a successful licensing or permitting result. Today the scientific community of the Department of Energy is facing the same reality that hit the real estate land title industry in the early 1980's.

Your word, your reputation, or your handshake does not substantiate your position.

A new level of documentation, that clearly walks a non-project reviewer through the traceability of all activities and decisions is required for successful acceptance of scientific results. Compliance reviewers (whether the Nuclear Regulatory Commission (NRC), Environmental Protection Agency (EPA), etc.) expect to verify the results of the scientific and program activities without the physical presence of the person or persons that conducted the activity. Traceability of activities and associated decisions through the retrieval of all associated records is a must.

This presentation is based on lessons learned from the various quality assurance (QA) audits and program reviews of Sandia National Laboratories, Nuclear Waste Management Programs Center, scientific and programmatic documentation.

We will build a bridge from science to compliance from lessons learned. Here now is a somewhat fictional rendition of actual scientific testing and compliance support activities.

SCIENCE

Utilizing Figure 1 Heater Test: time = 100 years, I will provide the basis of a compliance record traceability and retrieval scenario.

Figure 1 provides a visual picture of the comparison of temperatures and gas pore velocities in the rock fractures of an underground nuclear waste repository at 100 years using the Equivalent Continuum Model (ECM) and Dual Permeability Model (DKM). This scientific information has been generated through the recently initiated Large Block Heater Test for site characterization. The test looks at the effects of heat generated by the placement of nuclear waste into the repository on the adjoining rock. The block of rock being tested is 10-feet wide (3 meters). Insulation and vapor barriers were placed on the sides of the rock to create conditions similar to those in the underground repository. As the rock is heated, moisture will move away from the heaters towards the block's boundaries. Data will be collected during the heating and cool-down phases.

A series of tests like this will help scientists predict and observe the behavior of rock and moisture as it is heated from waste implantation in an underground repository. Scientists are studying four physical processes during the tests: thermal, mechanical, hydrologic, and chemical. During these thermal tests, scientists will study the flow of heat in the rock and the effect of an increase in temperature as waste is added to the repository. The mechanical studies examine the movement within the rock and changes in rock stress as a result of heat. The hydrologic tests study the movement of water in the rock as it is heated. The chemical tests look at changes in the chemical composition of the rock and the chemical changes of moisture in the rock as it is mobilized from the rock pores by the heat. These processes are interrelated and scientists are studying the relationships.

These relationships may become the basis for the Performance Assessment or Viability Assessment of a repository.

Design of a computer model which will indicate the predictability of a repository's operation under various given conditions is the basis of Performance Assessment or Viability Assessment. To build such a model, software codes must be designed to initiate the calculations for assessment model operation. To operate the model under various conditions, "parameters" must be established from all of the scientific data. In Figure 1, two parameters might be (1) the heat load is 83 kW/acre and (2) average infiltration of water is 0.3 mm/year.

The stage has now been set to move from science to compliance. The technical determination that these parameters are important to the assessment must now be substantiated through detailed and traceable documentation.

Regulator reviewers must be able to trace each activity and decision that is made along the life of the individual parameter(i.e.,(1) the heat load is 83 kW/acre and (2) average infiltration of water is 0.3 mm/year).

The program records must be identified and retrieved to support these parameters.

COMPLIANCE

Documentation is prepared to demonstrate compliance with regulator established criteria which are outlined in the governing compliance document (i.e., certification application, permit, license). Compliance for licensing or permitting is more programmatically inclusive than a QA audit. QA audits normally review small program segments but do not review the full traceability of complete activities. A QA audit may review that reviews and comments were properly prepared for a published report but they seldom review each data item that is reported and the full pedigree of that data. In a compliance review every decision is questioned and must be substantiated through detailed and traceable documentation. This will also include documentation to prove full implementation of a quality assurance program.

What might the regulators look for?

The compliance or license application must be written in a manner to ensure that every regulator required point is clearly addresses with technical responses to describe the work conducted or decisions made. Examples of poor application responses which are too vague to technically support the CFR specific requirements are: "studies were done", decisions were made", "after much discussion".

Licensing or permitting of a repository can only be approved by the regulator if technical points of the requirement document have been met. Data and model results must be fully substantiated. The pedigree of every piece of information must be verified, or all information may be considered suspect. The review process often is conducted independent of personal interface with the technical staff which allows the reviewer to assess the completeness of the documentation.

Let's look at a sample process of moving from an idea to a completed repository performance or viability assessment activity. Utilizing Figure 2 Traceability Flow Chart we will begin with the end of the compliance process, a repository compliance/license application or permit request. What will the regulators review to establish the pedigree of the final assessment?

The regulator issued compliance requirements are usually well defined. These requirements might be issued in the Code of Federal Regulations (CFR). The application or permit request must provide very specific information to answer every technical point required by the requirements document.

Upon receiving the application, the regulator will most likely assemble teams of reviewers who will verify every response to a requirement by the applicant.

Remember, regulators have the role of protecting the health and safety of the nation. Their ultimate decision to grant a permit, application, or license carries a tremendous public weight. The specific regulator must base their decision on documented fact, not personal impression or speculation.

SCIENCE TO COMPLIANCE

Referring back to my introductory statements, the NRC, EPA or other regulator and/or John Q public will require proof that the average infiltration of water is 0.3 mm/year (return to Figure 1).

A performance or viability assessment is an activity unto itself, however it can not function without the input of many other activities. Many times it is the culminating activity for all previous scientific research. As an example, a recent performance assessment (PA) activity identified over 3,500 parameters. In this fictional example, 0.3 mm/year would be just one of those parameters. Each parameter required the following documentation: references as to its origination or source, signatures of approval, reference to independent technical review results, reference to generating or controlling quality assurance procedures, change controls for all corrections or changes to dates/signatures/technical content, test plans, qualification and training records of the scientist, chain-of-custody for samples, audit records, etc.

The pedigree of each parameter must be defensible. The rationale and justification for selection of the parameters must be clearly documented and retrievable. Traceability of each decision or activity is imperative. However, this traceability must be meaningful and should clearly indicate the decision process that was implemented over the life of the activity. This documentation should include meeting results: issues discussed, decisions made, action items issued, and a list of attendees This traceability information should assist a researcher in retrieving the documentation which supports the activities or decisions.

How must you do that? I will walk you through a small sample of the detailed documentation and traceability that is required.

Figure 1 was generated from a published report. Technical data which supported the number 0.3 mm/year was referenced. A parameter records package may have been created which identified the details of how data was collected and how 0.3 mm/year was established and verified.

At this point in the traceability and retrieval process, knowing that this parameter records package is a starting point for research is of great benefit. Now you can go one of two directions to conduct the traceability.. From this package you can review all of the software codes that utilized the specific parameter. The documentation of each software code development process for modeling design and mathematical calculation will be reviewed to assure that quality assurance was fully implemented throughout all activities. Or you can go toward the final report document with all of the reviews and approvals. The following are regulator reviewer questions that you most likely will need to provide documentation for each parameter.

Who were the individuals conducting the mathematical calculation?
How were they qualified to conduct this activity?
What quality assurance procedures were they trained to?
What equations did they use?
Why did they select that equation?
How was the software qualified?
Was their work subjected to audits?
What were the audit findings and how were they resolved?
Was there any impact to the code when a process in the calculation was changed?
Did they cite a reference?
If the reference was data, how was it qualified?
Who approved the data? Show me where in the scientific notebook the approval signature resides.
What was the managers qualification to conduct the approval?

Traceability and retrieval through record indexing or optical character recognition (OCR) most likely will not assure that the links necessary to answer all of these questions can be provided without human interface. It becomes even more difficult when the regulator expects to be able to conduct all verification of documentation and traceability of activities and decisions without the assistance of the information source(s). Many of our DOE activities were initiated at least ten years ago. At that time we had no idea what information would be specifically necessary to support compliance requirements, nor did we have a real idea as to how the regulator would conduct their verification. Therefore, creation of new documentation may be necessary to fill gaps.

RECOMMENDED SOLUTION

My recommended solution to the dilemma of proving that scientific study is traceable and retrievable is based on the implementation of "process documentation." A new form of documentation necessary to build into the planning of every DOE activity that may be subject to a compliance licensing or permitting process.

"Process documentation" should be provided for each parameter that is being utilized in any performance or viability assessment. It most likely will need to be created "after the fact". It should begin with the parameter and end with the very first IDEA or planning activity (i.e., study plan, test plan) and trace the activity steps and decisions. References should be clearly identified to existing documents with associated identifiers. This will document the life cycle of an activity.

It may be necessary to prepare this documentation at various levels to include or build on a variety of other activities. This documentation may be likened to a Decision History or a Roadmap. A single document would be prepared during or after a specific activity that traces the activities which were conducted and the decisions which were made.

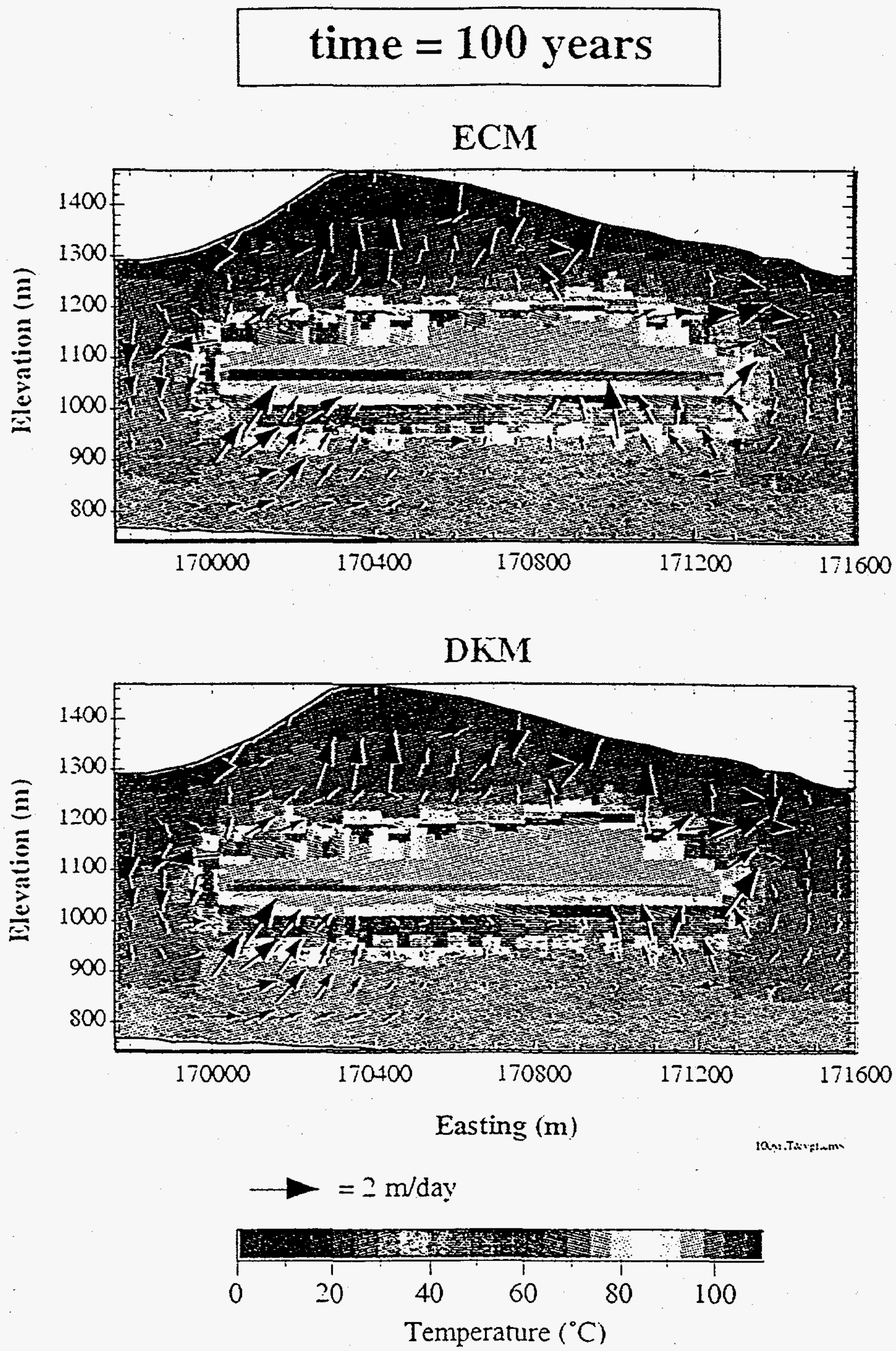
An example would be preparation of a "Repository Assessment Roadmap" for each parameter that would answer the following questions and those that were identified earlier in the presentation:

What activity or requirement initiated the repository assessment?
Identification of the work-breakdown- structure number(s).
Identification of the lead scientific investigator.
List of all persons that worked on the project.
List each QA procedure that was implemented.
Reference meeting minutes or other approved means documenting the decisions that were made, who made them and who was in attendance.
Indicate the source of the data whether technical activities or professional judgment.

Utilizing a roadmap or decision history document, a regulator should be able to follow the full traceability and be able to retrieve each identified record. Finally, if you have never prepared such documentation trails, it will be necessary to work closely with your regulator to determine how they are planning to conduct their regulatory compliance verification. Only then can you concentrate on preparing these documents to support the information trail that will be utilized for a successful licensing or permitting process.

CITED REFERENCES

There are no cited references associated with this paper.



Comparison of temperatures and gas pore velocities in the fractures at 100 years using the ECM and DKM. Velocities larger than 2 m/day are not shown. The heat load is 83 kW/acre and the average infiltration is 0.3 mm/year.

Figure 1 Heater Test: time = 100 years

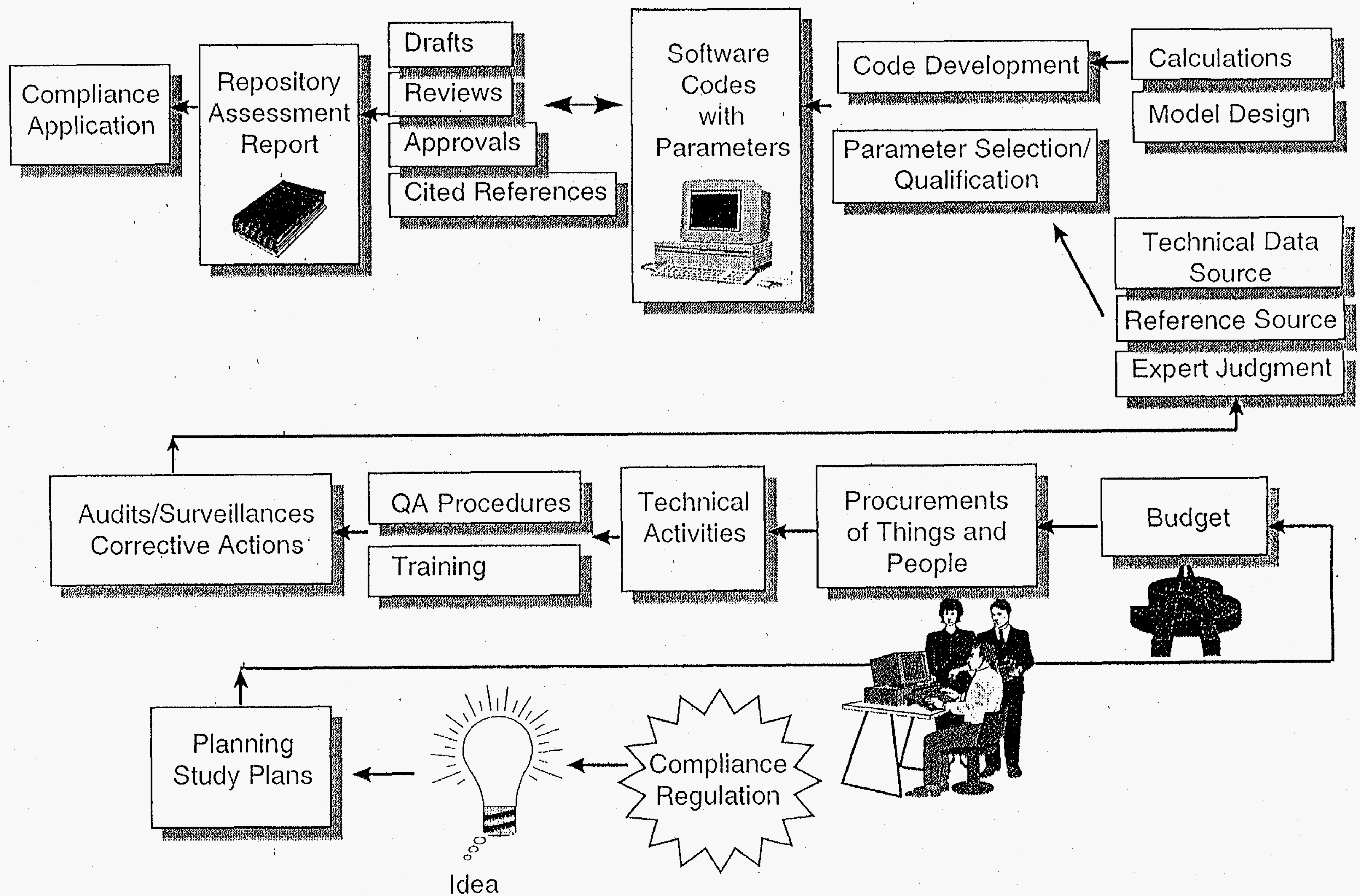


Figure 2. Traceability Flow Chart

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