

CERTIFYING THE WASTE ISOLATION PILOT PLANT: LESSONS LEARNED FROM THE WIPP EXPERIENCE

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ABSTRACT

In May 1998, the United States Environmental Protection Agency (EPA) certified the United States Department of Energy's (DOE) Waste Isolation Pilot Plant (WIPP) as being in compliance with applicable long-term regulations governing the permanent disposal of spent nuclear fuel, high-level, and transuranic radioactive wastes. The WIPP is the first deep geologic repository in the United States to have successfully demonstrated regulatory compliance with long-term radioactive waste disposal requirements. The first disposal of TRU waste at WIPP occurred on March 26, 1999.

Many of the lessons learned during the WIPP Project's transition from site characterization and experimental research to the preparation of a successful application may be of general interest to other repository programs. During a four-year period (1992 to 1996), the WIPP team [including the DOE Carlsbad Area Office (CAO), the science advisor to CAO, Sandia National Laboratories (SNL), and the management and operating contractor of the WIPP site, Westinghouse Electric Corporation (WID)] met its aggressive schedule for submitting the application without compromising the integrity of the scientific basis for the long-term safety of the repository. Strong leadership of the CAO - SNL - WID team was essential. Within SNL, a mature and robust performance assessment (PA) allowed prioritization of remaining scientific activities with respect to their impact on regulatory compliance. Early and frequent dialog with EPA staff expedited the review process after the application was submitted.

Questions that faced SNL are familiar to geoscientists working in site evaluation projects. What data should be gathered during site characterization? How can we know when data are sufficient? How can we know when our understanding of the disposal system is sufficient to support our conceptual models? What constitutes adequate "validation" of conceptual models for processes that act over geologic time? How should we use peer review and expert judgement?

Other lessons learned by SNL and the WIPP team are more specific to the regulatory context of the project and the demands imposed by pervasive review by the regulator and other external organizations. How should we document the relationship between site data and the parameter values used in computer models? How can we manage software configuration and use it to support the regulatory requirement that analyses be traceable and reproducible? Can we institute a quality assurance (QA) program that will meet the regulatory requirements and enhance the process without unreasonable budget and schedule impacts? How can we resolve technical disputes, both within the project and with external critics? How should we involve regulators and stakeholders in the compliance process?

The WIPP team's answers to these questions, and others like them, were, in many cases, pragmatic solutions based on the needs of the program at the time. Some problems encountered and their solutions may be of limited interest. However, that it is possible to license a geologic repository in a regulatory proceeding while incorporating meaningful public review and criticism is a lesson of general interest to all radioactive waste management programs.

INTRODUCTION

The WIPP, located in semi-arid desert in southeastern New Mexico, is mined in bedded salt 650 meters below ground surface (Figures 1 and 2). The repository is designed to dispose of approximately 175,000 cubic meters of transuranic waste (waste containing α -emitting radionuclides with an atomic number greater than 92 and half-lives greater than 20 years at concentrations greater than 100 nCi [3700 bq] per gram of waste) derived from defense-related activities of the United States government. Total activity of the waste (as of 1995) is estimated to be $7.4 \times$

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10^6 curies (2.7×10^{17} becquerels), with the largest component of this activity coming from approximately 12,900 kg of plutonium.

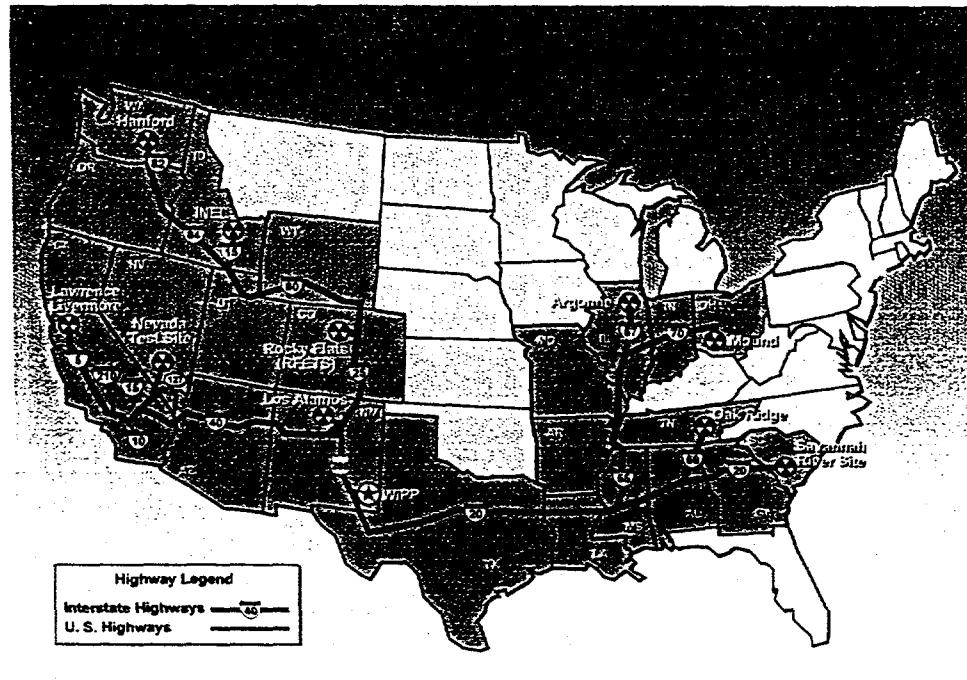


Fig. 1. Location of WIPP in southeastern New Mexico, with current TRU waste storage sites and transportation routes to WIPP shown.

Evaluations of the suitability of the site for disposal of radioactive waste began in 1974, and extensive site characterization activities continued throughout the late 1970s and the 1980s. Although excavation of the underground facilities began in 1981, the process of regulatory certification by an independent agency did not begin until 1992, when the United States Congress established the EPA as the regulator for the WIPP [1]. Following a series of iterative PAs in the early 1990s and the subsequent refocusing of scientific programs to support specific compliance-related needs, the DOE submitted a Compliance Certification Application (CCA) to the EPA in October 1996 [2]. The EPA issued a draft certification ruling for public comment in October 1997, and issued the final certification in May 1998 [3]. Disposal operations for non-hazardous TRU waste began on March 26, 1999. Disposal operations for hazardous TRU waste (i.e., waste that is also contaminated with regulated, hazardous non-radioactive materials such as volatile organic compounds and heavy metals) are currently scheduled to begin in late 1999, pending receipt of an operating permit from the State of New Mexico.

KEY DEVELOPMENTS IN CERTIFYING WIPP

Several key elements played a role in the successful compliance certification of the WIPP. These included strong leadership, prioritization of activities, implementation of a QA program, maturation of the regulatory structure, and frequent dialogue with the regulator.

Strong Leadership

In its 1992 Land Withdrawal Act [1], Congress set forth the responsibilities of the DOE as the manager of WIPP and of the EPA as the independent regulator responsible for developing disposal regulations and criteria for evaluating and certifying the long-term safety of WIPP. The DOE's CAO led a team of organizations to the successful certification of WIPP on a Congressionally-mandated, aggressive schedule. As the scientific advisor on this team,

SNL implemented a compliance-focused program by prioritizing technical research and development activities according to their expected impact, by creating a compliance-focused QA program, and by coordinating its technical contributions to the CCA closely with the CAO and WID.

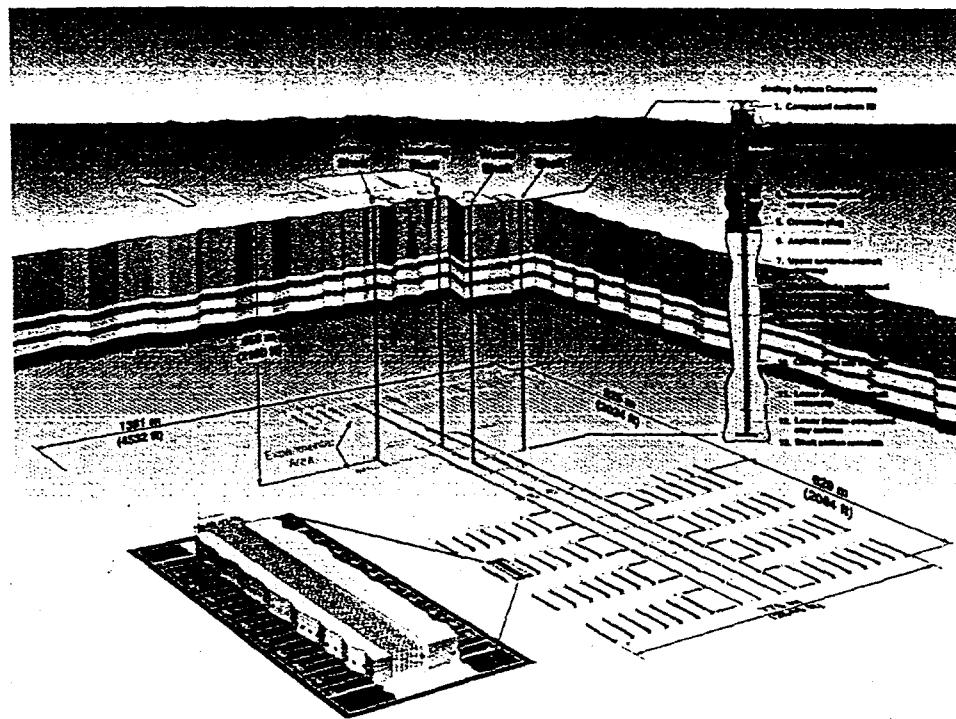


Fig. 2. Schematic diagram of the WIPP repository, illustrating the surface facilities, shaft seal design, and layout of disposal rooms. Disposal rooms are 91.44 m long, nearly the length of an American football field.

Prioritization of Activities

Following nearly two decades of general scientific investigations and model development, in 1994 scientific resources were focused on specific problems determined to be important to compliance with EPA regulations. Mainly, these few focused programs collected key data or developed improved models for key processes. This prioritization of technical programs demonstrated commitment of the scientific advisor to the compliance program. The prioritization process evaluated the effects of plausible, proposed technical activities on project budget, schedule, and compliance with radioactive waste disposal regulations. A baseline model was developed in part through stakeholder interactions. This baseline model was considered defensible due to its very conservative nature, but was unable to demonstrate compliance with the radioactive waste disposal regulations. Plausible technical activities aimed at making the baseline model more realistic were proposed by scientists and engineers, and judgements of the impact of collecting data or developing new models on uncertainty were elicited from them. A set of probabilistic PA calculations predicted the improvements to total system performance resulting from plausible combinations of alternative technical activities.

Data collection and model development programs were initiated in the topics of colloids and waste spill during drilling intrusion. Some ongoing programs were continued but were refocused on reducing specific uncertainties. For example, the groundwater flow and transport research program was focused on unambiguously characterizing matrix diffusion and sorption in the most likely flow path. The shaft seal program was focused on design changes and characterization for demonstrating permeability lower than 10^{-16} m^2 . Some areas of research were cancelled when the uncertainties they addressed were determined to be acceptable without further data.

Implementing a Quality Assurance Program

In 1996, EPA's 40 CFR Part 194 [4] imposed a formal QA standard on the WIPP Project, but for many years prior SNL had applied QA to its work as part of good business and scientific practice. The SNL WIPP project QA program ensures that technical work maintains the essential quality characteristics of traceability, transparency, reviews, reproducibility, and retrievability. Traceability is the clear identification of data sources and decision rationales. Transparency is clarity of logic and decisions. Reviews are independent and documented.

Reproducibility is whether a qualified peer could reconstruct the experiment or thought process based on the documentation provided. Retrievability is whether records (objective evidence of work performed and the controls applied to it) can be rapidly and reliably obtained, for example through the use of an indexed records center. These five essential quality characteristics, referred to as T^2R^3 , are consistent with the scientific method. Since 1993, SNL's QA program has conformed to the standards of NQA-1 [5], NQA-2a [6], NQA-3 [7], and DOE Order 5700.6C [8]. A least-work principle is used to help balance the demands of strict QA procedures with the interests of budget and schedule competitiveness.

Engaging the Regulator

Once the EPA was designated as the regulator of long-term performance of the WIPP, the WIPP team began a program of educational technical exchange and training with EPA staff. Beginning in 1994, a series of EPA-Stakeholder Technical Exchange meetings oriented EPA technical staff on the status and history of data collection and model development on the WIPP project. PA model training sessions began about the same time, during which EPA staff became familiar with WIPP PA methods and models. This provided opportunities for exposing technical questions and concerns early, resulting in improvements in the technical quality of the compliance application. Of particular importance during the PA training was familiarization with the WIPP use of feature, event, and process (FEP) screening as a method in issue resolution. EPA QA staff were invited to audit relevant procedures, and corrective action requests from the audit resulted in significant improvement in the implementation of the WIPP QA program.

LESSONS LEARNED

The successful licensing of a deep geologic repository required demonstrating the adequacy of the technical basis for compliance to a diligent and responsible regulator and concerned stakeholders. In this process documentation and verification by audits and tests were the basis for decision-making. All assertions of fact and assumptions required documentation. All model calculations required traceability and reproducibility. All modeling assumptions such as governing equations, boundary conditions, and input parameters required traceability to underlying data or evidence supporting their selection. All data required traceability to methods of collection, calibrations of measuring instruments, and personnel and their qualifications. This level of documentation is not customary in geoscience projects. Overcoming the reticence of scientists to declare data and models as adequate added to the challenge. Some of the practical lessons learned along the way are discussed in this section.

Deciding What Data to Collect

Collecting data for characterization of the natural and engineered environment is integral in siting nuclear waste repositories. Essential management questions are: What data should we collect at different stages of the project? What data will be needed to support licensing? How do we know when we have enough data?

The focus of data collection steadily narrows during the evolution of a siting project. Most repository programs approach waste disposal in deliberate steps, recognizing that attractive sites could have unknown qualities that make siting a repository infeasible. The stages of WIPP leading to waste disposal operations can be called feasibility, viability, and licensing.

The feasibility stage of site selection confirms the absence of unacceptable features. In feasibility studies, the scope of data collection is broad. Little is known about the disposal system, and something needs to be known about almost everything to support the feasibility analysis. Literature studies are used to build preliminary conceptual models and identify uncertainties that warrant direct experimental study. PAs begin (at least qualitatively) with the first system-level conceptual models, and guide system characterization toward uncertainties that matter. QA is built-in from the start to ensure T^2R^3 documentation and to meet any regulatory requirements. Data collection during

the feasibility stage focuses on any data specifically called out by regulation or agreements, on literature data, and on sufficient experimental and field information, to confirm the absence of unacceptable features, and to characterize uncertainty in conceptual models of site performance.

The viability stage provides evidence that total system performance satisfies applicable safety standards. As system understanding matures, site-specific data are sufficient to support preliminary quantitative estimates of uncertainty in overall performance. Conceptual models allow assessing relative importance of specific FEPs. A formal FEP screening process is developed to identify those FEPs that are sufficiently unlikely or inconsequential to be set aside with no further data collection. Data collection in a maturing project focuses on data specifically called out by regulation or agreement, data to improve realism and reduce uncertainty in areas where overall performance predictions will improve as a result, data that support significant simplifications in the technical basis for the license application, data that support specific FEP screening decisions, and data to resolve specific stakeholder concerns. By the end of the viability stage, data collection is focused on conceptual and data uncertainties that matter, with a focus on increasing realism in model depictions. Throughout the viability stage, PAs are conducted iteratively with feedback from characterization programs to identify areas where data uncertainties have the potential to impact licensing.

The licensing phase confirms the acceptable performance of the disposal system in documented evidence that is independently confirmed by the regulator through auditing and testing. In the final period before a license application is submitted, data collection focuses intensively on those areas needed either to support the PA or required explicitly by other regulatory drivers. As the license application is submitted, data collection in support of the license application should be complete to the satisfaction of the applicant. Data collection may continue for performance confirmation or in response to requests from the regulator for resolution of external issues. Data collection activities will be narrowly focused on well-defined topics defined by the regulator or through dispute resolution. Intensive emphasis will be placed on the QA of the data used to support a license application. Data collection activities include any data specifically called out by regulation, data specifically requested by the regulator, data required to support parts of the license application determined to be incomplete or inadequate, and data required for operations-phase monitoring or confirmation activities.

The key lesson learned is that as a project matures, it is not the perspective of experimental scientists, but rather the total-system PA methods (FEP analysis and screening, uncertainty analysis, modeling, and sensitivity analysis) that provide the context for evaluating the need for additional data.

Understanding Physical Processes Adequately

Three key points are relevant to being sure that physical processes that will or may occur are understood adequately. First, recognize that support of decision-making rather than science is the purpose of characterization: focus on uncertainties that matter, and document the process and rationale used to choose areas of investigation. Second, use the scientific method and the principle of T^2R^3 for programs that are conducted, emphasizing consideration of uncertainty and alternatives, documentation of decisions and rationale, and external publication and peer review. Third, satisfy any additional requirements in the current QA program.

Understanding is related to uncertainty as it affects the decision to be made. Focus in the characterization program comes from reducing the magnitude of the problem and in using data to rule out inconsistent hypotheses. Only a few uncertainties need to be reduced through characterization. Most uncertainties are unimportant to the decision. Models or screening calculations can be used to test the potential impact of uncertainty on the decision. For many uncertainties work focuses on documenting the basis for the assessed range of uncertainty and the rationale or process whereby the uncertainty was determined to be unimportant to the decision.

For those few uncertainties that matter, data collection activities are conducted for the purpose of eliminating conceptual models (i.e., identifying and validating a preferred conceptual model, or testing to discriminate between conceptual models) or reducing the range of possible values of a parameter. It is important to realize that collecting data to better define the middle of a distribution may have little effect on predictions of total system performance. Documentation following the principles of T^2R^3 is essential for defending the management decisions about which

scientific investigations to pursue. Documentation is used to convince skeptics that available data and screening calculations demonstrate an adequate level of understanding (acceptable levels of uncertainty).

Impartial project reviewers are likely to challenge claims of adequate understanding first, if decisions and rationale are not documented or the documentation is not readily retrievable; second, if decisions and rationale deviate from normal scientific or engineering practice; and third, if reasonable alternatives consistent with the data have not been evaluated. T²R³ documentation and frequent peer review provide the solution to these problems. A WIPP lesson learned for adequate understanding is that most critics are *willing to be convinced* that a program has acquired adequate understanding, if provided with T²R³ documentation and evidence of consistency with standard practices and consideration of reasonable alternatives.

Developing Model Input Parameters

In large, mature projects, seldom are the scientists and engineers who collect data also responsible for the development and application of system-level PA calculations. In projects anticipating thorough external review, agreement between model developers and experimental scientists is critical and cannot be left to chance. Therefore, a managed process is the key to developing defensible model input parameters. The steps in SNL's process for developing WIPP CCA PA parameter distributions are:

- Site characterization specialists document available data, interpretation of data, and propose ranges of parameter values
- Site characterization specialists, PA analysts, and data/uncertainty specialists meet to jointly evaluate the proposed range of parameter values
- Parameter range and probability distribution are decided and documented
- Internal review for consistency and completeness is conducted
- Meetings continue until disputes encountered in internal review are resolved.

The meetings between site characterization specialists, PA analysts, and the data/uncertainty specialist provide an opportunity and obligation to address concerns often encountered in applying experimental data to system-level models, such as model scale, data relevance, limitations of experimental procedures, intended uses of the data, and data analysis techniques. A key step in this process is providing T²R³ documentation of these meetings and their results.

Managing Software Configuration and Use

Configuration management is the meticulous identification, storage, and ongoing tracking of computer codes from a baseline version through all subsequent versions, along with all relevant inputs, outputs, compilation options, library linkages, and any other information needed to faithfully reproduce any calculation for which a code has been used. Run management is the automated execution of a suite of codes by those granted the necessary access, including retrieval of all the needed codes and inputs from within configuration management, and appropriate disposition of outputs, as well as the distribution of the computational load across appropriate and/or available resources. The WIPP project controls configuration and run management in its Configuration Management System (CMS). Configuration and run management provide retrievability of any result, input, or output for review; traceability of any result through all codes and inputs and the individuals involved at each step; exact reproducibility of any result; reliability through logical grouping of components of a calculation for easy audits; efficiency by reduction of manual interaction for record-keeping; and scalability by automatic execution of any number of replicate calculations.

Once the parameter input values and codes for the CCA PA were identified and prepared, two people in five months conducted 4.2 CPU-years of computation using 200,000 files and generating 95 Gigabytes of digital information for permanent storage in the CMS. During its review of the CCA, the EPA conducted calculations to investigate about 150 performance-assessment parameters for sensitivity, creating more than 7,500 plots and 4,000 other files in CMS, in 3.5 months by three individuals. Defense and review of the CCA PA calculations would not have been possible without an almost fully-automated CMS.

Resolving Disputes

Disputes over technical matters can be expected internally and externally. Although consensus is desirable, the goal of dispute resolution is to convince independent regulators or oversight groups that treatment of an issue is reasonable and sufficient, rather than to find consensus or to convince all parties. Disputes based on claims of omission or misrepresentation can be largely foreclosed through intelligent development of project positions. For example, a comprehensive FEP screening process forecloses assertions of omission, and documents the project's treatment of the issue, allowing the regulator or independent oversight group to make an informed decision. Internal disputes over the manner in which models are used to represent processes in system-level PAs can be reduced by the involvement of site characterization specialists in the development and application of PA models.

In dispute resolution, focus should be placed on activities that could convince the regulator or independent oversight group, rather than the individual critic. Committed opponents are unlikely to be convinced. Just as in site characterization activities, documentation of technical work (data gathering and modeling) should be T^2R^3 , as well as satisfy any additional QA program requirements. Furthermore, attitude counts – be honest and candid with the critic, stakeholder, and regulator.

When disputes occur, efficient resolution may rest on identifying a specific activity to test the disputed issue. Arguments over differences of opinion or perception of facts that don't matter are not worth pursuing. If providing the project's treatment of the disputed issue in T^2R^3 documentation does not work, focus on activities that can be conducted to document an issue's lack of importance. Modeling for model comparison or sensitivity analyses can explore the importance of uncertainty. Data gathering can be used to confirm ranges of uncertainty or conservative assumptions used. When a dispute over an important issue occurs, again focus on identifying activities that can resolve the issue; if that cannot be achieved, either modify the project position or use T^2R^3 documentation to convince the regulator or independent oversight group of the reasonable nature of the activities conducted by the project to characterize the issue.

Internal disputes can be foreclosed in many areas by involvement of site characterization specialists and PA specialists in the processes of decision-making and performance predictions. Disputed points can be included as alternative models, or expressed in the values chosen for parameter distributions. If models and sensitivity analyses are unable to resolve disputes, specific experimental tests may be conducted to resolve the disputes. Where agreement is not reached through participation, modeling, or experimentation, resolution by management action is required. Good documentation following the principles of T^2R^3 forecloses future arguments about whether or not the issue has been heard, and provides objective evidence of the merits of the disputants' cases and manner of resolution, so outside reviewers can examine the merits of the various cases, the manner of resolution, and the justification for the final decision.

Using Peer Review

Peer review is an essential part of sound science and engineering. All work should be reviewed by technical peers, and documentation of peer review following the concepts of T^2R^3 should be standard practice. Peer review may be internal or external, and may be conducted by individuals or panels. There are two basic types of peer review panels: Expert Review Panels and Formal Expert Elicitation Panels. Expert review is the use of personal or team knowledge and experience to design, execute, and interpret experiments or build models. Expert elicitation is the use of external knowledge or experience to supplement information gathered internally by scientific investigations.

Expert review panels are used to confirm the appropriate use of expert judgement in designing, executing, and interpreting experiments or models. Expert review panels may be convened to evaluate experimental objectives and design; relevance of information and data; importance of information or data; conclusions drawn from information or data; conceptual, mathematical, and computer models; and alternative explanations. Expert review panels may be useful for qualifying data or information for applications other than those for which the data were obtained. Expert review panels are implemented procedurally, using the following general steps:

- candidate members are identified based on their expert knowledge and experience;
- a charter is developed and panel members are hired;

- meetings are conducted by project scientists;
- meetings are held occasionally during project life; and,
- the expert panel documents its meetings and conclusions with reports or letters of recommendations.

Expert review panels were conducted in support of compliance with EPA's 40 CFR Part 194.27 in the topic areas of conceptual models, natural barriers, engineered barriers, waste characterization, site markers (passive institutional controls), and qualification of existing data. The expert review panels convened to support compliance with EPA regulations were administered independently and their membership was developed using a process including nomination from external organizations.

The WIPP team convened expert review panels for many topics prior to the preparation of the CCA license application (more than sixteen external peer review panels are identified in the CCA). For example, since 1978, the National Research Council Committee on the Waste Isolation Pilot Plant has published at least 13 reports, providing broad oversight of policy and science issues on the WIPP. Expert review panels were convened for specific topics, for example: using geostatistics for aquifer characterization (WIPP Geostatistics Expert Group); developing models of hydrofracture in bedded evaporites (WIPP Fracture Expert Group); PA methods (WIPP PA Peer Review Panel); and conceptual model uncertainty (WIPP Conceptual Model Uncertainty Expert Group). Furthermore, in late 1996 a joint IAEA/NEA WIPP International Review Group was chartered to review the WIPP Compliance Certification Application.

The potential results of expert review are many. Over time, use of expert review for critique and program guidance builds confidence in acceptability and integrity of a science program. It helps identify, prioritize and defend potential activities within a science and engineering program. It familiarizes the scientific community with details of a science-intensive R&D program and its experiments and models. Furthermore, it provides improved documentation and communication techniques, and may satisfy specific regulatory requirements.

The WIPP experience with expert review finds that its format is superior to expert elicitation for discussions and interchange. Expert review is a superior procedure for developing practical knowledge on beliefs in a profession. Finally, expert review for high-consequence events such as regulatory proceedings requires a large commitment.

Expert elicitation is the use of an expert panel to acquire information rather than to review existing information. Expert elicitation may provide either an estimate of uncertainty in the likely state of a phenomenon if it could be observed or measured, or a distribution of belief about a phenomenon in the profession. In WIPP experience, regulatory constraints on the use of expert elicitation are profound: it may not be allowed if a phenomenon is observable; and it may be required if a phenomenon is unknowable. Although the general procedure for convening an expert elicitation panel is similar to that for an expert review panel, there are two significant differences under WIPP regulations. First, the panel must be administered independently from nominations to conclusions. Second, the panel must be carefully focused on a single problem, and must know in advance the desired format and use of the results.

WIPP experience in expert elicitation for regulatory purposes comprises an elicitation to develop information on the particle diameter of degraded waste. Prior to development of the CCA, expert elicitation was conducted to develop information to support data collection or design activities in the topics of inadvertent future human intrusion, site markers, radionuclide source term, and chemical retardation.

Lessons learned through SNL's WIPP experience are that information provided by expert elicitation is binding, however the information may not be useful if the elicited product does not conform to specifications. Thus, expert elicitation should be conducted only if required and no other option exists.

Balancing Quality Assurance with Technical Programs and Cost

SNL has applied a QA program to its WIPP work since the early 1980s, and currently a QA program is required for compliance with the EPA's 40 CFR Part 194. QA is based on preserving records of work performed and the controls applied to it; in some topic areas in the current program specific controls are mandated by the EPA. The

SNL WIPP QA program is developed using the principles of least-work, T^2R^3 , and satisfying mandates in the EPA's regulations. Key concepts to implement a sensible and manageable QA program are:

- address the upper-tier requirements directly, use matrices for traceability;
- develop QA procedures with the input of users (scientists and engineers);
- implement the QA program at the earliest time possible;
- identify the types of information that will be required by decision-makers early;
- provide adequate training to staff; and
- hold people, not organizations, accountable for QA compliance.

Furthermore, the principle of least work indicates that one program-level requirements document should be referenced for all QA procedures. Stand-alone procedures should be created to implement the program requirements. Forms should be managed wisely. Technology can be applied to reduce costs through the use of electronic distribution and standard electronic tools. Staff QA coordinators were established as points of contact for work groups in each technical area. These coordinators facilitate implementation of the QA program, but are not independent. Technical staff retain responsibility for QA implementation.

Key lessons learned for least-work in a QA program is to focus on the upper-tier requirements directly, and to focus on T^2R^3 early to ensure future usefulness of all data collected.

How to Qualify Data

Data collection for the WIPP project began in the 1970s in the basic areas of site characterization – geohydrology, rock mechanics, waste and disposal room interactions, and the repository sealing system. QA program requirements evolved significantly, culminating in the 1996 EPA 40 CFR Part 194 [4] requirement whereby only “qualified” data could be used for regulatory purposes. Qualified data are those data collected under a QA program conforming to the specifications of 40 CFR Part 194 or those data accepted as fact by the scientific community (handbook data). A data qualification program was implemented to qualify “existing” data. Existing data are those data collected prior to DOE’s certification of SNL’s quality-assurance program, or developed outside of the DOE WIPP program in other institutions.

SNL’s approach to qualifying existing data was to:

- identify all data;
- identify the subset of all data comprising “existing” data;
- determine the potential use of existing data;
- create record packages by topically grouping existing data;
- qualify existing data first by demonstrating that the data was collected under an equivalent QA program; and
- qualify remaining data record packages by peer review to establish technical credibility of the data itself.

Independent review teams (IRT) were used initially to qualify existing data records packages under the equivalent QA program provision. Two independent QA representatives and one to three technical representatives served on each IRT. Twenty-eight existing data records packages were qualified by IRT’s under the equivalent QA program provision.

Seven existing data records packages were qualified by peer review to establish the technical credibility of the data itself. The peer review panels comprised independent senior scientists with extensive and specific experience in the topic areas of interest. Some existing data were abandoned as being too difficult to qualify. The EPA observed the IRT and peer review sessions, participated in audits and surveillances of the processes, and accepted the process.

The primary lesson learned in data qualification is to develop all data according to the principles of T^2R^3 , which mitigates the impact of change in requirements through time. Other lessons learned in the WIPP experience pertinent to data qualification are to maintain independence by separating the contracts hiring IRT and peer review panel members from the organization that collected data, and to carefully hire recognized professionals on the panels. Documentation of standards and criteria, and consistent implementation across panels are important.

How to Qualify Software

The SNL software QA program addresses the development, acquisition, validation, and modification of software, software configuration management, access control, software retirement, and software problem reporting and evaluation. It is based on the life cycle methods found in such standards as NQA, ISO, and IEEE. For each code to be qualified, the program is implemented by a team comprised of a code sponsor and supporting staff, department manager, technical reviewer, and software configuration management coordinator, each with defined responsibilities during the software life cycle. Documentation is consistently developed for all qualified codes through the use of established, uniform requirements and formats. Key steps in the process are the design and execution of test cases and technical review in all development stages. Configuration management provides for uniform distribution of code versions and for efficient and prompt identification of users who may be affected as errors are identified, reported, and corrected.

The software qualification process relies heavily on review for confidence and integrity. A WIPP lesson learned is that it is critical to protect and preserve the integrity of the software review process by dedicating to it the appropriate resources and time.

SUMMARY AND CONCLUSIONS

The WIPP team's success in certifying the WIPP with EPA regulations can be attributed to several key developments and the dedication of organizations and their staff to overcoming many challenging problems while maintaining a commitment to quality work. Key developments to the successful demonstration of compliance were the emergence of strong leadership, prioritization of technical programs to serve compliance-specific needs, implementation of a credible QA program, and engaging the regulator in educational technical exchanges and practical training sessions. Pragmatic lessons were learned along the way in areas of data collection, parameter development, code configuration management and run management, software qualification, understanding physical processes, and dispute resolution. A cross-cutting lesson learned is that documentation through records is the basis of decision-making. Accordingly, work must be traceable, transparent, reviewed, reproducible, and easily retrievable. Fundamentally, credibility depends on documented and retrievable records of work, consistency with standard scientific and engineering practices, and consideration of reasonable alternatives. Finally, due to the size of projects and compartmentalization of expertise, the development of system-level models, parameters, and site characterization strategies must be carefully managed to provide credibility from the perspective of both site characterization specialists and PA analysts. It is hoped in sharing these lessons learned that other organizations pursuing deep geologic disposal will overcome tough challenges with less difficulty.

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