

Regulatory Compliance

Sandia National Laboratories' Defense Waste Management Programs has demonstrated expertise in working within a regulatory environment.

Description

The success of scientific work done in support of repository programs is ultimately judged in terms of regulatory compliance. Does the work meet regulatory expectations regarding traceability, transparency, and reproducibility? Is the scientific evaluation complete, and does it provide a sufficient basis for a regulatory decision? Finally, and greatest interest to many participants in the process, is the site in compliance with the quantitative regulatory standards?

Capabilities

SNL has demonstrated expertise in working within a regulatory environment (i.e., in compliance with applicable quality assurance procedures that ensure traceability, transparency, and reproducibility) in both the Waste Isolation Pilot Plant (WIPP) and Yucca Mountain projects. All technical work that will support the regulatory decision, from data collection to performance assessment analysis, is conducted under stringent quality assurance programs that ensure that the information will be suitable for its intended use.

SNL's expertise in regulatory compliance goes beyond

designing and implementing effective quality assurance programs, and includes analyzing and interpreting regulations to ensure that the technical products (e.g., performance assessments) are designed from the start to meet regulatory needs. For example, FEP screening work must be planned and executed consistent with regulatory guidance, and the scenarios selected for analysis must meet regulatory expectations with respect to completeness and representativeness. Models and data must be acceptable to technical staff advising the regulator, and computational analyses must be transparent and reproducible by the regulator as well as by the applicant. Sandia has been involved in the development of the regulatory framework for radioactive waste disposal since the early 1980s, first as an advisor to the NRC and more recently through its role in reviewing and commenting on proposed EPA and NRC regulations that apply to the WIPP and Yucca Mountain projects.

Accomplishments

Sandia played a key role in successfully preparing and submitting the Compliance Certification Application (CCA) to the EPA in 1996, providing



*WIPP Compliance
Certification Application*



the scientific basis for the application and conducting the performance assessment that demonstrated compliance with the EPA standard. Aspects of the regulatory interactions included:

- Commenting on proposed EPA regulations and advising the DOE during the EPA's rulemaking process,
- Support for DOE and EPA audits of data and models,
- Design and execution of the CCA PA consistent with regulatory requirements,
- Training of EPA technical staff in the use of PA models,
- Public technical exchanges with EPA and stakeholders on all aspects of the scientific program and PA,
- Participation in public hearings,
- Peer reviews,
- Preparing and documenting responses to all comments from the EPA and stakeholders regarding technical aspects of the PA and its scientific and regulatory basis, and
- Support for the EPA in conducting its own set of PA calculations using the Sandia models to verify the CCA results and to test sensitivity to alternative assumptions about models and parameters.

Since EPA's certification of the WIPP, Sandia continues to have a key role in the continued compliance activities supporting the WIPP certification. These activities include:

- Maintaining and updating a "compliance baseline," that accurately reflects the regulatory basis of the most recent current certification decision,
- Continually maintaining the ability to conduct a compliance-level PA at the request of the DOE or the EPA using the current compliance baseline,
- Preparation of numerous planned change notices and requests to the EPA that support DOE-initiated changes to the WIPP disposal program, and
- Developing recertification applications that comprehensively incorporate approved changes and any new data and information since the last certification decision.

For more information, please contact:

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