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**PRODUCT TRACEABILITY AND QUALITY
AS APPLIED TO THE UNITED STATES TRANSURANIC AND
HIGH-LEVEL WASTE REPOSITORY PROGRAMS**

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RESUMÉ

Comme avec tout programme de dépôt, les prédictions sur la performance du site à très long terme rencontrent souvent le scepticisme du public et des décideurs, tels que les agences de contrôle et du gouvernement. L'expérience de la Waste Isolation Pilot Plant (WIPP) et du Yucca Mountain Project (YMP) indique qu'il est essentiel de démontrer que les données, les modèles conceptuels, les codes informatiques, et les analyses numériques soient défendables. Cinq grands principes généraux se sont avérés être à la base de tout dépôt acceptable à la fois aux yeux du public et sur le plan technique. Les principes sont la capacité de dépistage, la transparence, la reproductibilité, la capacité de récupération, et les rapports.

- La capacité de dépistage permet de comprendre la source et de justifier les données et les autres actions produisant des conclusions.
- La transparence permet de suivre la logique, les calculs, et les autres opérations produisant des résultats.
- La reproductibilité permet de reconstruire les résultats sans recourir à l'auteur de l'information.
- La capacité de récupération permet de récupérer la documentation qui démontre ces grands principes généraux.
- Les rapports garantissent que le travail soit acceptable techniquement, complet, et exact.

Cet article traite de ces principes dans leur application à la WIPP et au YMP. En établissant des contrôles de gestion et de l'assurance de qualité (par ex., les procédures, les audits, les rapports de pairs), ces principes sont mis en application. Sans le succès dans l'application de ces principes, la WIPP ne serait pas allée de la recherche à la maturité industrielle. Le YMP s'assure que ceux-ci soient mis en application pour les activités prévoyant la délivrance de permis. Tout programme de dépôt se sentant concerné de démontrer qu'il est défendable aux yeux du public et

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des régulateurs feraient bien d'incorporer la capacité de dépistage, la transparence, la reproductibilité, la capacité de récupération, et les rapports au sein de leur programme

SUMMARY

As with any repository program, predictions of the performance of a site over very long time frames may often meet with skepticism from the public and decision-makers, such as regulatory and governmental agencies. Experience at the Waste Isolation Pilot Plant (WIPP) and the Yucca Mountain Project (YMP) indicates that demonstrating the defensibility of data, conceptual models, computer codes, and numerical analyses is critical. Five overarching principles have been found to be the basis of a technically and publicly acceptable repository. The principles are traceability, transparency, reproducibility, retrievability, and reviews.

- Traceability allows one to understand the source and justification of data and other input that generate conclusions.
- Transparency allows one to follow the logic, calculations, and other operations that produce results.
- Reproducibility allows one to reconstruct the results without recourse to the originator of the information.
- Retrievability allows one to retrieve documentation that demonstrate these overarching principles.
- Reviews ensure that the work is technically acceptable, complete, and accurate.

This paper discusses how these principles are applied to the WIPP and the YMP. By setting up quality assurance and management controls (e.g., procedures, audits, peer reviews) these principles are implemented. Without successfully applying these principles the WIPP would not have gone from research to industrial maturity. The YMP is ensuring that these are implemented for activities that support licensing. Any repository program concerned with demonstrating defensibility to the public and regulators would do well by incorporating traceability, transparency, reproducibility, retrievability, and reviews into their program.

INTRODUCTION

Repository programs throughout the world have developed quality assurance standards and guidelines to manage site characterization, performance assessment, design, and construction of disposal facilities. Notable examples are the International Organization for Standardization's Quality Systems, the American Society of Mechanical Engineers' Quality Assurance Requirements for Nuclear Facility Applications (NQA-1), and the International Atomic Energy Agency's Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations. The content of these guidelines is similar. They address such activities as training, design, software, procurement, calibrations, records, assessments, and corrective action.

Most quality assurance programs in the United States nuclear energy and weapons programs follow NQA-1. The authors' experience on the Waste Isolation Pilot Plant and the Yucca Mountain Project has led them to discover five overarching principles that can be implemented under NQA-1, but are not explicitly called out in the standard as guiding principles.

These principles are traceability, transparency, reproducibility, retrievability, and reviews (T^2R^3).

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IMPORTANCE OF T^2R^3

Repository science is not well understood by the general public. The results of predictive modeling may be met by skepticism and distrust, and are often challenged. Repository programs typically span many decades. Many personnel may work on a project and most tasks will be completed by successive teams and individuals. Given the long times involved, rarely will a single team or individual be able to work on a repository from initial concepts through operations.

These principles, abbreviated as T^2R^3 , will ensure that adequate, sufficiently detailed information is available to fully describe all of the actions and logic that led to the selection of a repository.

IMPLEMENTATION

T^2R^3 are not always addressed by name in Quality Assurance (QA) requirements documents and standards, but when taken as a system, these standards address the goals of the T^2R^3 principles. The implementation of T^2R^3 is achieved through procedures, parts, and people.

Procedures

“Procedures” include the plans, instructions, and drawings that control the activities used to license a repository. Procedures should be in place at the earliest stage possible to reduce costs by reducing errors, duplication, and re-work. Using multi-discipline teams to develop the procedures and including the staff that will be affected by the procedures will ensure that the procedures are adequate, correct, and do not interfere with work processes. These documents are the first step towards T^2R^3 . They document work-as-planned and direct the documentation of work-as-completed, thus leaving a record for a third-party, such as the public, to clearly understand what was done and why (traceability and transparency).

The concept of “grading” should be considered when developing or implementing repository QA. Grading a program means applying the minimum, but adequate, level of control to activities. Doing more than is necessary makes implementation difficult, frustrates staff, and increases costs. Doing less than is necessary puts the defensibility of the activity at risk. Successful grading matches important activities with greater QA controls and less important activities with lesser QA controls. The basis for a graded QA program must be documented and reviewed.

As an example, grading QA requirements can be applied to software/computer codes. Codes used to make screening calculations are not as complex and have less health and safety impact than codes that are used to calculate dose to a population. While both are important, based on how their results will be used, they do not require the same level of control. For example:

- Codes used in screening calculations could require documentation (paper or electronic) of the code's name and version, platform, functionality, review to confirm results are reasonable, test cases, and acceptance criteria.
- Codes used in dose calculations could require full life-cycle methodology (requirements, design, implementation, validation, installation and checkout, maintenance, and retirement.)

Parts

Hardware, software, records, and instrumentation are examples of "parts". For repository programs the application of T²R³ is especially critical for data, software (computer codes), and conceptual models.

To achieve T²R³, the source of data used in making the safety case for a repository must be identified and justified. If data sets are not used, their exclusion must also be discussed (Traceability). The experiments used to collect data must be documented, reviewed, and placed in a secure records system (Reproducibility, Reviews, Retrievability).

The use of software and computer codes must be carefully managed as the results may be part of the basis for site acceptance or rejection. Codes must be adequately tested. For each calculation, the selection of the code and input should be documented and justified (Traceability). Input files, executable or source code, and output files should be archived (Reproducibility and Retrievability).

The acceptability of conceptual models is enhanced through T²R³. What the model represents, how it was developed, and validated by data, why it was selected, and why other reasonable models were rejected should be well documented (Traceability, Transparency, Reproducibility). Model validation for repository programs is very difficult. External, peer review can greatly increase the defensibility of the set of conceptual models used to represent a repository system (Reviews).

People

Successful incorporation of T²R³ may require a significant change in the attitudes and work approaches, or culture, within an organization. This may be the most difficult task related to initiating a T2R3 program. The importance of T²R³ should be clearly and repeatedly stated in terms that management and staff can understand. Management should provide clear communication on what is expected, establish priorities, and set clear goals.

In a repository program, T²R³ may be required by the public, regulatory officials, or customers; is fundamentally the same as the scientific method; ensures accuracy and completeness; and is critical to demonstrate the safety of a repository site in a legal and political arena. If possible, the implementation of T²R³ should be included in the performance appraisals of staff and management. What is measured and rewarded will be repeated. Management must commit to

T^2R^3 and lead the effort. Assigning an expert in T^2R^3 to assist work groups will speed implementation. This person can serve as a resource for the technical staff.

Program improvement

Most QA standards require audits to check compliance with requirements and initiate actions to improve the program. The same holds true for T^2R^3 . As the repository program evolves, the methods to achieve T^2R^3 should be re-examined to ensure that they are still adequate or to look for opportunities to simplify the program. Opportunities to improve always should be sought.

Implementing T^2R^3 may require changing the way an organization works. Properly done, it can increase the confidence the public has towards a repository program. It can help an organization defend a position when challenged by the public. It can provide continuity as a repository project evolves over time. It is a never-ending journey, but can contribute directly to a project's success.

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