QUALITY ASSURANCE PROGRAM
Cementitious Barriers Partnership

December 2008 • CBP-01

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CEMENTITIOUS BARRIERS PARTNERSHIP (CBP)

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December 2008
Report CBP 01

ACKNOWLEDGEMENTS

This report was prepared for the United States Department of Energy in part under Contract No. DE-AC09-08SR22470 and is an account of work performed in part under that contract. This report was prepared in support of the Savannah River Nuclear Solutions Cooperative Research Agreement (CRADA) CR-08-001. Reference herein to any specific commercial product, process, or service by trademark, name, manufacturer, or otherwise does not necessarily constitute or imply endorsement, recommendation, or favoring of same by Savannah River Nuclear Solutions or by the United States Government or any agency thereof. The views and opinions of the authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof.

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This report is based in part on work supported by the United States Department of Energy under Cooperative Agreement Number DE-FC01-06EW07053 entitled "The Consortium for Risk Evaluation with Stakeholder Participation III" awarded to Vanderbilt University. The opinions, findings, conclusions, or recommendations expressed herein are those of the author(s) and do not necessarily represent the views of the Department of Energy or Vanderbilt University.

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FOREWORD

The Cementitious Barriers Partnership (CBP) Project is a multi-disciplinary, multi-institutional collaboration supported by the United States Department of Energy (US DOE) Office of Waste Processing. The objective of the CBP project is to develop a set of tools to improve understanding and prediction of the long-term structural, hydraulic, and chemical performance of cementitious barriers used in nuclear applications.

A multi-disciplinary partnership of federal, academic, private sector, and international expertise has been formed to accomplish the project objective. In addition to the US DOE, the CBP partners are the United States Nuclear Regulatory Commission (NRC), the National Institute of Standards and Technology (NIST), the Savannah River National Laboratory (SRNL), Vanderbilt University (VU) / Consortium for Risk Evaluation with Stakeholder Participation (CRESP), Energy Research Center of the Netherlands (ECN), and SIMCO Technologies, Inc.

The periods of cementitious performance being evaluated are >100 years for operating facilities and > 1000 years for waste management. The set of simulation tools and data developed under this project will be used to evaluate and predict the behavior of cementitious barriers used in near-surface engineered waste disposal systems, e.g., waste forms, containment structures, entombments, and environmental remediation, including decontamination and decommissioning (D&D) activities. The simulation tools also will support analysis of structural concrete components of nuclear facilities (spent-fuel pools, dry spent-fuel storage units, and recycling facilities such as fuel fabrication, separations processes). Simulation parameters will be obtained from prior literature and will be experimentally measured under this project, as necessary, to demonstrate application of the simulation tools for three prototype applications (waste form in concrete vault, high-level waste tank grouting, and spent-fuel pool). Test methods and data needs to support use of the simulation tools for future applications will be defined.

The CBP project is a five-year effort focused on reducing the uncertainties of current methodologies for assessing cementitious barrier performance and increasing the consistency and transparency of the assessment process. The results of this project will enable improved risk-informed, performance-based decision-making and support several of the strategic initiatives in the DOE Office of Environmental Management Engineering & Technology Roadmap. Those strategic initiatives include 1) enhanced tank closure processes; 2) enhanced stabilization technologies; 3) advanced predictive capabilities; 4) enhanced remediation methods; 5) adapted technologies for site-specific and complex-wide D&D applications; 6) improved SNF storage, stabilization and disposal preparation; 7) enhanced storage, monitoring and stabilization systems; and 8) enhanced long-term performance evaluation and monitoring.

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ABBREVIATIONS AND ACRONYMS

ANSI/ASME	American National Standards Institute/American Society of Mechanical Engineers
CBP	Cementitious Barriers Partnership
CRADA	Cooperative Research and Development Agreement
CRESP	Consortium for Risk Evaluation with Stakeholder Participation
ECN	Energy Research Center of the Netherlands
NIST	National Institute of Standards and Technology
NQA	Nuclear Quality Assurance [standard]
NRC	Nuclear Regulatory Commission
PI	Principal Investigator
PTS	Project Task Statement
QA	quality assurance
R&D	research and development
SRNL	Savannah River National Laboratory
SRNS	Savannah River Nuclear Solutions
WSRC	Washington Savannah River Company

Cementitious Barriers Partnership Quality Assururance Program

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INTRODUCTION

The goals of the Cementitious Barrier Partnership (CBP) Project Quality Assurance Program (QAP) are to ensure that all work performed under the CBP Cooperative Research and Development Agreement (CRADA) 1) will achieve the intended R&D objectives and 2) can be understood, and, if necessary, reproduced successfully by others. Application of this document should be focused on these goals.

This CBP QAP represents an integration of common elements of partners' existing quality assurance plans as well as agreed-upon elements new to this purpose. This document is a general statement of good R&D practices that will be used on all CBP tasks. SRNS endorses the content and intent of this document as a means of ensuring a base level of quality for the work performed under CBP. The designated Principal Investigator (PI) has first-line responsibility. The PI is responsible to ensure that this document is applied and followed during the performance of each applicable task. Additional requirements may be identified and implemented. Any conflicts between the basic quality requirements in this document and specific QA requirements imposed on the various implementing tasks should be identified by the PI and referred to SRNS for resolution.

Although the PI has primary responsibility, it is the responsibility of all persons, technical and non technical, associated with the task to ensure the quality of the work they perform for the task. The PI shall ensure that all personnel actively supporting the conduct of a CBP task should have an understanding of the requirements that are stated in this document and how the quality of their work affects the products developed under each task.

This document will help to ensure that appropriate steps have been taken to protect the accuracy and reproducibility of technical

1.0 ORGANIZATION

The Quality Assurance Program for the CBP provides the appropriate basic quality requirements for all research and development to be performed for CBP tasks. SRNS may impose additional quality requirements if task activities warrant. A PI is designated for each task. The PI is responsible for the conduct of the task and for ensuring that the quality of the task meets CBP QA requirements. Further it is the responsibility of the PI to identify in organization charts and/or other descriptive documents appropriate resources, technical and administrative, that are needed to meet the requirements. Responsibilities and interfaces shall be addressed.

2.0 PROGRAM AND PLANNING

The PI, in conjunction with the SRNS, shall determine the scope and quality assurance requirements of the proposed task. Topics that should be considered include: task objective(s) and goal(s), applicable codes and standards, end use of item or data, schedule, and deliverables.

The PI shall maintain file copies of all revisions and supporting documentation concerning task authorization, planning, and execution.

When planning the task quality controls, the PI should consider the experimental design and the analysis required; test planning, pre-test reviews; limitations of approach and probability of success; parameters to be investigated; test apparatus required; acceptable measurement uncertainty; whether formal inspection is required; test procedures required; data acquisition and reduction methods required; data evaluation methods required; reports required; and any other deliverables.

All work performed under the CBP is assigned in a Project Task Statement (PTS) that identifies scope, budget and schedule for the planned work. Each PTS is agreed to and signed by the CBP partners prior to issuance. The PTSs also identify the quality assurance expectations from this QA plan applicable to the work scope. It is the responsibility of the PI to ensure that the assigned work conducted under each PTS is planned in advance to meet the scope objectives and quality assurance expectations.

3.0 DESIGN CONTROL

3.1 Peer Reviews

Peer reviews may be required for products or services deliverable for CBP tasks. Identification of the need for peer

reviews shall be the responsibility of the cognizant PI. When a formal peer review is held, a formal peer review report that denotes the review objectives and conclusions shall be signed by all the peer review participants.

Use of periodic critiques and peer reviews to help manage tasks is encouraged. Opinions of participants disagreeing with the recommendations of the report shall be attached.

3.2 Calculations

Calculations requiring documentation are those required to substantiate the design of a test article and those made during test data reduction and analysis. Calculations shall be documented in laboratory notebooks, or other SRNS approved means. Documentation on computer output sheets or magnetic media is acceptable provided data are retrievable for as long as other task records. Calculations shall be legible and sufficiently detailed such that a person qualified in the subject can understand the calculations without contacting the originator.

Calculation detail should typically include identification of the objective or purpose of the calculation; design inputs and their sources; methods used and assumptions made - including identification of those assumptions requiring verification; parameters to be investigated; any references used; units; results of the analysis and conclusions, if any.

3.3 Independent Peer Review of Calculations

The PI shall determine if calculations require an independent peer review. This decision shall be based upon the risk inherent in the use of the calculations. Calculations that may require review include designer's calculations for test article fabrication, calculation used for analysis of test data, and calculations required to complete the final report.

When the peer reviewer has completed his review, he shall sign and date the calculations to indicate the review was done. The peer reviewer shall document the results of the review and note any discrepancies in a final report.

3.4 Notebooks/Logbooks

Notebooks/logbooks shall be used to supplement test and experimental data as described under Test Data. Notebooks/logbooks, if used properly, provide a road map for the overall project and form a complete historical record. Notebooks/logbooks become a part of the original records of the research and development work and shall receive special consideration to assure usefulness.

All notebooks/logbooks are to be kept as a part of the CBP task files. One or more notebooks/logbooks may be used to record the data for a single task or one notebook/logbook may serve to record the information from several tasks. A notebook/logbook may also be kept with a piece of test equipment or apparatus for the recording of instrument calibration or data. Information kept in multiple task notebooks/logbooks and instrument logbooks should be transferred to the PI for inclusion in his task records when the data are pertinent to his task. This transfer of data may be accomplished by copying the applicable sections of the notebook/logbook or by including the information in a memo to the PI.

The following guidelines should be followed for notebooks/logbooks: Notebooks/logbooks shall be bound and have numbered pages. A bound notebook assures that vital records are not missing because they were not completed or were misplaced. Entries shall be legible and in indelible ink with no erasures. Any changes or corrections to entries shall be made by drawing a single line through the erroneous entry and having the corrections entered adjacent to the error, dated and initialed. If the reason for the change is significant and not obvious, record reason next to the change as well. Pages of the notebook/logbook shall be filled consecutively. Spaces and pages left blank shall be crossed out so that there is no doubt about whether data should have been recorded or are missing. Supporting documentation (e.g., data sheets, drawings, computer printouts) can be inserted by pasting or gluing into the notebook/logbook when practicable or simply referenced. (The reference, however, must be in enough detail to allow retrieval of the information easily.) Notebook/logbook entries shall be signed and dated by the person making the entry. If only one person is making entries into a notebook, that person need only sign and date the logbook at the end of the operation. If however, more than one person is making entries into the same logbook during inspection or task, each person shall sign and date his entries upon completing the activity.

3.5 Software Quality Assurance

The PI is responsible for all data and other information produced with computers. Prior to using existing software, whether it is purchased or developed internally, the PI shall review the software in sufficient detail to ensure that the methods used by the software and the results obtained from the software are correct for the intended application. A software development program should be planned carefully, reviewed, and tested to ensure that the program accurately implements the required method and that the results are correct. Testing may be by developer or by an independent party. Independent review shall be considered as the risk level increases.

Documentation shall be developed during each phase of a software development program. As a minimum, documentation shall include the program identification, a brief description of significant limitations, capabilities, intended use, and a permanent record of the source code listing. Documentation should increase as risk level of the software and required effort to produce the software increases. A minimum level of document control includes the assignment of software identification, and revision level or date to be included on all software output. Additional controls should be performed as risk level of the software and required effort increases.

NOTE: For detailed information reference ANSI/ASME NQA-2, part 2.7 "Quality Assurance Requirements of Computer Software for Nuclear Facility Application."

3.6 Drawing Control

3.6.1 Requirements

Drawings are defined as representations of mechanical or electrical equipment, test facilities, etc., that are produced on drawing media with formatted borders and title blocks. Sketches are defined as representations of equipment, test facilities, etc., that are used to communicate temporary, preliminary, or intermediate information pertaining to a task. Sketches are usually not to scale and may be prepared without drafting equipment.

Drawings are required for:

- Documentation or long-term retention of design and/or construction of test articles, as defined by the PI, to be able to reproduce the experiment.
- All applications such as construction of equipment, test facilities, etc., requiring code conformance.

3.6.2. Checking and Approval

All drawings shall be checked by an individual other than the drafter and approved by the PI prior to release for fabrication.

4.0 CONTROL OF PURCHASED ITEMS AND SERVICES

Principal Investigators should identify those procurements that could affect the quality or validity of data and any safety considerations. Quality assurance requirements should be included in the purchase requisition package.

4.1 Documentation

Purchase requisitions shall contain a clear statement of what is required, date required, and technical/quality or code requirements.

4.2 Vendor Evaluation

CBP should conduct its purchasing practice to reflect experience with supplier performance in selection of vendors. In specifying equipment for purchase the PI should consider the experience record and the importance of the equipment in specifying the extent of supplier certification and qualification.

4.3 Methods of Acceptance

Acceptability of a purchased item or service shall be determined through source verification, receiving inspection, post installation testing, or certificate of conformance. Results shall be documented; logbook entries are acceptable. Immediate corrective action should be taken if the material is discrepant. Appropriate tags should be used at the PI's option to identify material that is being held for inspection, that which has been inspected and accepted, and that which is discrepant.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be prescribed by documented instructions, procedures or drawings and shall be performed in accordance with those instructions, procedures and drawings.

6.0 CONTROL OF TASK DOCUMENTS

Task plans, results of peer reviews, test procedures, technical reports, calculations, scope of work, etc. should be uniquely identified, documented, and assigned revision numbers to control changes. Whenever changes are made to one document, other affected task documents should be reviewed and changed as necessary.

NOTE: Results such as preliminary plots and data shall be subject to the same traceability requirements as calculations. To make sure that the history of plots can be traced at some future date, the date the graph was generated (or updated), initials of the person generating the graph, and the origin of the data shall be identified on each graph. Original plots shall be maintained as part of the task records.

7.0 IDENTIFICATION AND CONTROL OF MATERIALS AND ITEMS

The PI shall be responsible for ensuring that all task materials and items affecting test results are identified and controlled.

8.0 INSPECTION

Inspections are usually performed for those physical characteristics identified by the PI as critical to the test results. The PI shall be responsible for all inspections performed on his task. Inspections shall be planned and the results documented.

Discrepant conditions discovered during inspection shall be documented and appropriate corrective action shall be taken. The PI shall be responsible for implementing the necessary corrective action.

9.0 TEST CONTROL

9.1 Test Plans/Test Procedures

Tests required to collect data shall be planned, executed, documented, and the results shall be evaluated.

9.2 Test Data

Test data shall be recorded on formal data sheets or logbooks including computer output sheets that show the task title, time, and date, data taker and facility/apparatus used. This data shall reference, if not included elsewhere, other documentation that describes how the test was performed, a description of the test facility, and test article, including sketches or drawings utilized, a list of the instrumentation used, the test procedure and revision or method used (an actual copy may be included), actual parameters used, and deviations to the test procedure. Calculations or logbooks shall cross-reference the data as a source of information.

9.3 Sampling

Design of the sampling process shall be defined controlled, verified and documented, and shall be based on the intended use of the data to be generated.

10. CONTROL OF INSTRUMENTATION

Provision shall be made for identifying instruments taking data. This is necessary should there be a need for the test to be repeated for any reason. Instruments used for taking data critical to the test shall be calibrated and the calibration traceable to a nationally recognized standard or accepted method. All instrumentation used shall be within calibration during the time of the test. It is the equipment user's responsibility to ensure that the equipment has the proper calibration status and that the equipment is calibrated when needed. Calibration status documentation on all calibrated instruments shall be maintained.

11.0 HANDLING, STORING, PACKAGING AND SHIPPING

Handling, storing, packaging and shipping, cleaning and preservation of items critical to the test shall be controlled to prevent damage or loss and to minimize deterioration.

12.0 RECORD MANAGEMENT

Complete documentation of the work performed by CBP is quite important. Any information, memos, meeting minutes or special references that have a bearing on the direction the task has taken, the data acquired, or the interpretation of results shall all be included in the task records. Other examples include:

- Task authorizations and revisions
- Instrumentation records
- Test data
- Inspections performed
- Test articles or test facility configurations
- Audit reports and surveillance reports
- Test procedures
- Drawings and sketches
- Personnel qualification records of key individuals
- Equipment logs
- Task Technical Plan and revisions
- Sampling logs
- Computer software used
- Customer communications
- Procedures used
- Documentation of purchased or customer-furnished materials
- Peer reviews
- Calculations and reviews
- Basic data
- Technical reports
- Laboratory notebooks
- Discrepancy reports
- Certificates of conformance
- Task QA Plan and revisions
- Field logs

The PI shall be responsible for maintaining all task records. Upon task completion, a copy of appropriate task records shall be made available to CBP partners upon request. Original records shall be maintained by the CBP performing entity based upon the entity's data retention policy.

All task records shall be identified in enough detail that they can be easily reproduced, filed and retrieved at a later date. The PI shall be accountable for maintaining a system by which task records are retrievable.

13.0 AUDITS/SURVEILLANCES

SRNS can perform general audit/surveillance activities over CBP tasks upon request by the CBP partners. Deficiencies involving violation of administrative or task requirements shall be identified and resolved in a timely manner. Corrective action is the responsibility of the PI.

Signatures

J. P. Vaughan
SRNL QA Engineer

J. A. Powell
SRNL Quality Engineering Manager

F. J. Leach
SRNL Quality Assurance Manager

P. E. Filpus-Luyckx
Program Manager

GLOSSARY

Audit A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Certificate of Conformance A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specific requirements.

Corrective Action Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Discrepant Condition A deficiency, discrepancy, or noncompliance in characteristics, documentation, or procedures that render the quality of an item or activity unacceptable or indeterminate.

Guidelines Suggested practices. Often used to define a practice that is not mandatory in a program intended to comply with a standard. The word "should" denotes a guideline; the word "shall" denotes a requirement.

Inspection Examination or measurement to verify whether any item or activity conforms to specified requirements.

Instrumentation Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire date with which to verify conformance to specified requirements.

Peer Review The critical documented scrutiny of a report or technical work by technical or scientific experts to determine the accuracy of technical or scientific data, the validity of technical or scientific interpretation of the decision.

Procedure A formal methodology or protocol that specifies or describes how an activity is to be performed. This may be a stand alone document, part of a planning document, or an item recorded in a project logbook.

Procurement Document Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Principal Investigator The person accountable for the task's results. This may be the project manager; lead scientist; principal engineer; researcher; or other responsible staff person, or group leader, or organization head.

Qualification (Personnel) The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

Quality Assurance The planned and systematic actions required to provide adequate confidence that the planning, conduct and results of a project will provide products and results that are reliable and repeatable.

Surveillance The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

Task Record A completed document that furnishes evidence of the quality of items and/or activities affecting quality.

Task Document Scientific or technical documents created for conducting research, regardless of form or characteristic (e.g., logbooks, sketches, data, and software).

Task Technical Plan A written plan setting forth details as to how the PI plans to address the Statement of Work technical and administrative requirements.

Task QA Plan A written plan setting forth controls established or planned to ensure that task activities meet technical and administrative requirements detailed in the Task Technical Plan. Task QA Plans are reviewed and approved by the WSRC Technical Representative and the QA Engineer.

Test An examination, evaluation, observation, or characterization of an item or theory or both.

Traceability The ability to trace the history, application, or location of an item and of like items or activities through recorded identification.

Verification The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.


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